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**42 CFR Parts 403, 412, et al.
Medicare Program; Changes to the
Hospital Inpatient Prospective Payment
Systems and Fiscal Year 2005 Rates; Final
Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

42 CFR Parts 403, 412, 413, 418, 460, 480, 482, 483, 485, and 489

[CMS-1428-F]

RIN 0938-AM80

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**AGENCY:** Centers for Medicare and Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems; and to implement a number of changes made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that was enacted on December 8, 2003. In addition, in the Addendum to this final rule, we describe the changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes are applicable to discharges occurring on or after October 1, 2004. We also are setting forth rate-of-increase limits as well as policy changes for hospitals and hospital units excluded from the IPPS that are paid in full or in part on a reasonable cost basis subject to these limits.

Among the policy changes that we are making are: Changes to the classification of cases to the diagnosis-related groups (DRGs); changes to the long-term care (LTC)-DRGs and relative weights; changes in the wage data, labor-related share of the wage index, and the geographic area designations used to compute the wage index; changes in the qualifying threshold criteria for and the approval of new technologies and medical services for add-on payments; changes to the policies governing postacute care transfers; changes to payments to hospitals for the direct and indirect costs of graduate medical education; changes to the payment adjustment for disproportionate share rural hospitals; changes in requirements and payments to critical access hospitals (CAHs); changes to the disclosure of information requirements for Quality Improvement Organization (QIOs); and changes in the hospital

conditions of participation for discharge planning and fire safety requirements for certain health care facilities.

DATES: The provisions of this final rule are effective on October 1, 2004.

FOR FURTHER INFORMATION CONTACT:

Jim Hart, (410) 786-9520, Operating Prospective Payment, Diagnosis-Related Groups (DRGs), Wage Index, New Medical Services and Technology, Standardized Amounts, Hospital Geographic Reclassifications, Postacute Care Transfers, and Disproportionate Share Hospital Issues; Tzvi Hefter, (410) 786-4487, Capital Prospective Payment, Excluded Hospitals, Graduate Medical Education, Critical Access Hospitals, and Long-Term Care (LTC)-DRGs Issues;

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Acronyms

ACGME—Accreditation Council on Graduate Medical Education
 AHIMA—American Health Information Management Association
 AHA—American Hospital Association
 AOA—American Osteopathic Association
 ASC—Ambulatory Surgical Center
 BBA—Balanced Budget Act of 1997, Pub. L. 105-33
 BIPA—Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Pub. L. 106-554
 BLS—Bureau of Labor Statistics
 CAH—Critical access hospital
 CART CMS—Abstraction & Reporting Tool
 CBSAs—Core-Based Statistical Areas
 CC—Complication or comorbidity
 CMS—Centers for Medicare & Medicaid Services
 CMSA—Consolidated Metropolitan Statistical Area
 COBRA—Consolidated Omnibus Reconciliation Act of 1985, Pub. L. 99-272
 CoP—Condition of Participation
 CPI—Consumer Price Index
 CRNA—Certified registered nurse anesthetist
 DRG—Diagnosis-related group
 DSH—Disproportionate share hospital
 ESRD—End-stage renal disease
 FDA—Food and Drug Administration
 FQHC—Federally qualified health center
 FSES—Fire Safety Evaluation System
 FTE—Full-time equivalent
 FY—Federal fiscal year
 GME—Graduate medical education
 HCRIS—Hospital Cost Report Information System
 HIPC—Health Information Policy Council
 HIPAA—Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191
 HHA—Home health agency
 HPSA—Health Professions Shortage Area
 ICD-9-CM—International Classification of Diseases, Ninth Revision, Clinical Modification
 ICD-10-PCS—International Classification of Diseases, Tenth Edition, Procedure Coding System
 ICF/MRs—Intermediate care facilities for the mentally retarded
 IME—Indirect medical education
 IPPS—Acute care hospital inpatient prospective payment system
 IPF—Inpatient psychiatric facility
 IRF—Inpatient rehabilitation facility
 JCAHO—Joint Commission on the Accreditation of Healthcare Organizations
 LAMA—Left Against Medical Advice
 LTC-DRG—Long-term care diagnosis-related group

LTCH—Long-term care hospital
 LSC—Life Safety Code
 MCE—Medicare Code Editor
 MCO—Managed care organization
 MDC—Major diagnostic category
 MDH—Medicare-dependent small rural hospital
 MedPAC—Medicare Payment Advisory Commission
 MedPAR—Medicare Provider Analysis and Review File
 MEI—Medicare Economic Index
 MGCRB—Medicare Geographic Classification Review Board
 MMA—Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173
 MPFS—Medicare Physician Fee Schedule
 MSA—Metropolitan Statistical Area
 NECMA—New England County Metropolitan Areas
 NCHS—National Center for Health Statistics
 NCVHS—National Committee on Vital and Health Statistics
 NFPA—National Fire Protection Association
 NPR—Notice of Program Reimbursement
 NQF—National Quality Forum
 NVHRI—National Voluntary Hospital Reporting Initiative
 OES—Occupational Employment Statistics
 OIG—Office of the Inspector General
 OMB—Executive Office of Management and Budget
 O.R.—Operating room
 OSCAR—Online Survey Certification and Reporting (System)
 OSHA—Occupational Safety and Health Act
 PACE—Programs of All-Inclusive Care for the Elderly
 PIP—Periodic interim payment
 PMS—Performance Measurement System
 PMSAs—Primary Metropolitan Statistical Areas
 PPS—Prospective payment system
 PRA—Per resident amount
 ProPAC—Prospective Payment Assessment Commission
 PRRB—Provider Reimbursement Review Board
 PS&R—Provider Statistical and Reimbursement System
 QIO—Utilization and Quality Control Quality Improvement Organization
 RHC—Rural health clinic
 RHQDAPU—Reporting Hospital Quality Data for Annual Payment Update
 RRC—Rural referral center
 SCH—Sole community hospital
 SNF—Skilled nursing facility
 SOCs—Standard occupational classifications
 SOM—State Operations Manual
 SSA—Social Security Administration
 SSI—Supplemental Security Income
 TEFRA—Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248
 UHDDS—Uniform Hospital Discharge Data Set

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I. Background

A. Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of hospital inpatient stays under a prospective payment system (PPS). Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each

hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located; and if the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment may vary based on the outcome of the statutory calculations.

If the hospital is an approved teaching hospital, it receives a percentage add-on payment for each case paid under the IPPS (known as the indirect medical education (IME) adjustment). This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any outlier payment due is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid the higher of a hospital-specific rate based on their costs in a base year (the higher of FY 1982, FY 1987, or FY 1996) or the IPPS rate based on the standardized amount. For example, sole community

hospitals (SCHs) are the sole source of care in their areas, and Medicare-dependent, small rural hospitals (MDHs) are a major source of care for Medicare beneficiaries in their areas. Both of these categories of hospitals are afforded this special payment protection in order to maintain access to services for beneficiaries (although MDHs receive only 50 percent of the difference between the IPPS rate and their hospital-specific rates if the hospital-specific rate is higher than the IPPS rate).

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services “in accordance with a prospective payment system established by the Secretary.” The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital PPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Similar adjustments are also made for IME and DSH as under the operating IPPS. In addition, hospitals may receive an outlier payment for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain specialty hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Psychiatric hospitals and units; rehabilitation hospitals and units; long-term care hospitals (LTCHs); children’s hospitals; and cancer hospitals. Various sections of the Balanced Budget Act of 1997 (Pub. L. 105–33), the Medicare, Medicaid and SCHIP (State Children’s Health Insurance Program) Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) provide for the implementation of PPSs for rehabilitation hospitals and units (referred to as inpatient rehabilitation facilities (IRFs)), psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)), and LTCHs, as discussed below. Children’s hospitals and cancer hospitals continue to be paid under reasonable cost-based reimbursement.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

a. IRFs

Under section 1886(j) of the Act, as amended, rehabilitation hospitals and units (IRFs) have been transitioned from payment based on a blend of reasonable cost reimbursement subject to a hospital-specific annual limit under section 1886(b) of the Act and prospective payments for cost reporting periods beginning January 1, 2002, through September 30, 2002, to payment at 100 percent of the Federal rate effective for cost reporting periods beginning on or after October 1, 2002 (66 FR 41316, August 7, 2001; 67 FR 49982, August 1, 2002; and 68 FR 45674, August 1, 2003). The existing regulations governing payments under the IRF PPS are located in 42 CFR part 412, subpart P.

b. LTCHs

Under the authority of sections 123(a) and (c) of Public Law 106–113 and section 307(b)(1) of Public Law 106–554, LTCHs are being transitioned from being paid for inpatient hospital services based on a blend of reasonable cost-based reimbursement under section 1886(b) of the Act to 100 percent of the Federal rate during a 5-year period, beginning with cost reporting periods that start on or after October 1, 2002. For cost reporting periods beginning on or after October 1, 2006, LTCHs will be paid 100 percent of the Federal rate (May 7, 2004 LTCH PPS final rule (69 FR 25674)). LTCHs may elect to be paid based on 100 percent of the Federal rate instead of a blended payment in any year during the 5-year transition period. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O.

c. IPFs

Sections 124(a) and (c) of Public Law 106–113 provide for the development of a per diem PPS for payment for inpatient hospital services furnished in IPFs under the Medicare program, effective for cost reporting periods beginning on or after October 1, 2002. This system must include an adequate patient classification system that reflects the differences in patient resource use and costs among these hospitals and maintains budget neutrality. We published a proposed rule to implement the PPS for IPFs on November 28, 2003 (68 FR 66920). The November 28, 2003, proposed rule proposed an April 1, 2004, effective date for purposes of ratesetting and calculating impacts. However, the proposed rule was unusually complex because it proposed a completely new payment system for inpatient hospital services furnished by

psychiatric hospitals and units and the public requested additional time to comment. As a result, we extended the comment period for the proposed rule. Thus, we are still in the process of analyzing public comments and developing a final rule for publication. Consequently, an April 1, 2004, effective date for the IPF PPS is no longer possible.

3. Critical Access Hospitals (CAHs)

Under sections 1814, 1820, and 1834(g) of the Act, payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services on a reasonable cost basis. Reasonable cost is determined under the provisions of section 1861(v)(1)(A) of the Act and existing regulations under 42 CFR parts 413 and 415.

4. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act; the amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

On August 1, 2003, we published a final rule in the **Federal Register** (68 FR 45346) that implemented changes to the Medicare hospital inpatient prospective payment systems for both operating cost and capital-related costs, as well as changes addressing payments for excluded hospitals and payments for GME costs. Generally these changes were effective for discharges occurring on or after October 1, 2003. On October 6, 2003, we published a document in the **Federal Register** (68 FR 57731) that corrected technical errors made in the August 1, 2003, final rule.

B. Provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, was enacted. Public Law 108–173 made a number of changes to the Act relating to prospective payments to hospitals for inpatient services, payments to

excluded hospitals and units, and payments to CAHs. This final rule implements amendments made by the following sections of Pub. L. 108–173:

- Section 401, which provides that, for discharges occurring in a fiscal year beginning with FY 2004 under the IPPS, Medicare will pay hospitals in rural and small urban areas in the 50 States using the standardized amount (computed for the previous fiscal year) that would be used to pay hospitals in large urban areas (or beginning with FY 2005, for all hospitals in the previous fiscal year), increased by the appropriate market basket percentage increase. One standardized amount for hospitals in Puerto Rico would be established that would equal the amount for hospitals in large urban areas in Puerto Rico.

- Section 402, which provides that for discharges occurring on or after April 1, 2004, the DSH payment adjustment for a hospital that is not a large urban or large rural hospital will be calculated using the current DSH adjustment formula for large urban hospitals, subject to a limit of 12 percent for any of these hospitals that are not rural referral centers. (There is no limit on the DSH payment percentage for rural referral centers.)

- Section 403, which provides that, for discharges occurring on or after October 1, 2004, a hospital's labor-related share to which the wage index is applied will be decreased to 62 percent of the standardized amount when such a change will result in higher total payments to the hospital. This provision also applies to the labor-related share of the standardized amount for hospitals in Puerto Rico.

- Section 405(a), which provides that inpatient, outpatient, and covered SNF services provided by a CAH will be reimbursed at 101 percent of reasonable costs for services furnished to Medicare beneficiaries. This provision is applicable to payments for services furnished during cost reporting periods beginning on or after January 1, 2004.

- Section 405(b), which expands coverage of the costs associated with covered Medicare services furnished by on-call emergency room providers in CAHs to include services furnished by physician assistants, nurse practitioners, and clinical nurse specialists, effective for costs incurred for services furnished on or after January 1, 2005.

- Section 405(c), which provides that eligible CAHs may receive payments for their inpatient services on a periodic interim payment (PIP) basis, effective with payments made on or after July 1, 2004.

- Section 405(d), which allows CAHs to elect to receive payments under the

optional payment method (a payment encompassing both inpatient CAH services and physician and practitioner services to outpatients) even if some practitioners do not reassign to the CAH their rights to bill for professional services to CAH outpatients. This provision applies to cost reporting periods occurring on or after July 1, 2004, except that in the case of a CAH that made an election of the optional payment method before November 1, 2003, the provision applies to cost reporting periods beginning on or after July 1, 2001.

- Section 405(e), which increases the limit on the number of beds that a CAH may have for acute care from 15 to 25 beds. This provision applies to CAH designations made before, on, or after January 1, 2004. Any election made in accordance with the regulations promulgated to implement this provision will only apply prospectively.

- Section 405(g), which provides that a CAH may establish psychiatric and rehabilitation distinct part units and limits the number of beds in each unit to no more than 10. Services in these distinct part units will be paid under the respective payment methodology applicable to these distinct-part units. This provision applies to cost reporting periods beginning on or after October 1, 2004.

- Section 405(h), which terminates a State's authority to waive the location requirement for a CAH by designating the CAH as the necessary provider, effective January 1, 2006. A grandfathering provision is included for CAHs that are certified as necessary providers prior to January 1, 2006, which allows any CAH that is designated as a necessary provider in its State's rural health plan prior to January 1, 2006, to maintain its necessary provider designation.

- Section 406, which provides for a graduated adjustment to the inpatient prospective payment rates to account for the higher costs associated with hospitals described under section 1886(d) of the Act that are located more than 25 road miles from another subsection (d) hospital and that have less than 800 discharges during a fiscal year, effective for discharges occurring on or after October 1, 2004. The increase in these payments must be based on the empirical relationship between the standardized cost per case for such hospitals and the total number of discharges of these hospitals and the amount of the additional incremental costs (if any) associated with that number of discharges, may not be greater than 25 percent, and the determination of the percentage

payment increase is not subject to administrative or judicial review.

- Section 410A, which authorizes the Secretary to establish a demonstration program to test the feasibility and advisability of the establishment of rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The Secretary must select no more than 15 rural community hospitals to participate in the demonstration. The Secretary must implement the demonstration program not later than January 1, 2005, but may not implement the program before October 1, 2004.

- Section 422(a), which provides that a hospital's GME FTE resident cap will be reduced, and the reduction will be redistributed among other hospitals if the hospital's resident count is less than its resident cap (rural hospitals with less than 250 acute care inpatient beds will be exempt) in a particular reference period. This provision is effective for cost reporting periods beginning on or after July 1, 2005.

- Section 422(b), which specifies that the formula multiplier for the IME adjustment is 0.66 for FTE residents attributable to redistributed resident positions, effective for discharges occurring on or after July 1, 2005.

- Section 501, which provides the update factor for payments for hospital inpatient operating costs for FY 2005 and subsequent fiscal years is the market basket percentage increase. For FYs 2005 through 2007, the update factor will be the market basket percentage increase minus 0.4 percentage points for any "subsection (d) hospital" that does not submit hospital quality data on 10 measures as specified by the Secretary.

- Section 502, which modifies the IME formula multiplier to be used in the calculation of the IME adjustment for midway through FY 2004 and provides a new schedule of formula multipliers for FYs 2005 and thereafter.

- Section 503(a), which includes a requirement for updating the ICD-9-CM diagnosis and procedure codes in April 1 of each year, in addition to the current process of annual updates on October 1 of each year. This change will not affect Medicare payments or DRG classifications until the fiscal year that begins after that date.

- Section 503(b), which provides for changes to the threshold amount for determining eligibility of new technologies or medical services for add-on payments; provides for public input on applications for new technology or medical service add-on payments prior to the publication of a proposed rule; provides for

reconsideration of applications received for FY 2004 that were denied; provides for preference in the use of DRG adjustments; and provides that new technology or medical service payments shall not be budget neutral. This provision is effective for fiscal years beginning in FY 2005.

- Section 504, which increases the national portion of the operating PPS payment rate for hospitals in Puerto Rico from 50 percent of the Federal rate to 75 percent of the Federal rate and decreases the Puerto Rico portion of the operating PPS payment from 50 percent to 25 percent, effective for discharges occurring on or after October 1, 2004. For the period of April 1, 2004, through September 30, 2004, payments for hospitals in Puerto Rico will be based on 62.5 percent Federal rate and 37.5 percent of the Puerto Rico rate.

- Section 505, which provides for an increase in a hospital's wage index value to take into consideration a commuter wage adjustment for hospital employees who reside in a county and work in a different area with a higher wage index.

- Section 508, which provides for the establishment of a one-time process for a hospital to appeal its geographic classification for wage index purposes. By law, any reclassification resulting from this one-time appeal applies for a 3-year period to discharges occurring on or after April 1, 2004.

- Section 711, which freezes the annual CPI-U updates to hospital-specific per resident amount (PRAs) for GME payments for those PRAs that exceed the ceiling, effective for cost reporting periods beginning FY 2004, through FY 2013.

- Section 712, which provides for an exception to the initial residency period for purposes of direct GME payments for geriatric residency or fellowship programs that allows the 2 years spent in an approved geriatric program to be counted as part of the resident's initial training period, but not to count against any limitation on the initial residency period. This provision is effective for cost reporting periods beginning on or after October 1, 2003.

- Section 713, which, during a 1-year moratorium period of January 1, 2004 through December 31, 2004, allows hospitals to count allopathic or osteopathic family practice residents training in nonhospital settings for IME and direct GME purposes, without regard to the financial arrangement between the hospital and the teaching physician practicing in the nonhospital setting to which the resident is assigned.

- Section 733, which provides for Medicare payment of routine costs, as

well as costs relating to the transplantation and appropriate related items and services, for Medicare beneficiaries participating in a clinical trial involving pancreatic islet cell transplantation, beginning no earlier than October 1, 2004.

- Section 926, which requires the Secretary to make information publicly available that enables hospital discharge planners, Medicare beneficiaries, and the public to identify skilled nursing facilities (SNFs) that are participating in the Medicare program, and requires a hospital, as part of its discharge planning, to evaluate a patient's need for SNF care.

- Section 947, which requires that, by July 1, 2004, hospitals not otherwise subject to the Occupational Safety and Health Act (OSHA) (or a State occupational safety and health plan that is approved under section 18(b) of that Act) must comply with the OSHA bloodborne pathogens (BBP) standard as part of their Medicare provider agreements.

C. Summary of the Provisions of the May 18, 2004 Proposed Rule

On May 18, 2004, we published a proposed rule in the **Federal Register** (69 FR 28196) that set forth proposed changes to the Medicare IPPS for operating costs and for capital-related costs in FY 2005 and to implement the provisions of Pub. L. 108-173 specified in section I.B. of this preamble. We also set forth proposed changes relating to payments for GME costs, payments to certain hospitals and units that continue to be excluded from the IPPS and paid on a reasonable cost basis, payments for DSH, requirements and payments for CAHs, conditions of participation for hospitals relating to discharge planning and fire safety requirements, requirements for Medicare provider agreements relating to bloodborne pathogen standards, and QIO disclosure of information requirements. These changes were proposed to be effective for discharges occurring on or after October 1, 2004, unless otherwise noted.

The following is a summary of the major changes that we proposed to make:

1. Changes to the DRG Reclassifications and Recalibrations of Relative Weights

As required by section 1886(d)(4)(C) of the Act, we proposed annual adjustments to the DRG classifications and relative weights. Based on analyses of Medicare claims data, we proposed to establish a number of new DRGs and make changes to the designation of diagnosis and procedure codes under other existing DRGs.

Among the proposed changes discussed were:

- Restructuring and retitling of several DRGs to reflect expanded coverage of heart assist systems such as ventricular assist devices (VAD) or left ventricular assist devices (LVAD) as destination (or permanent) therapy for end-stage heart failure patients who are not candidates for heart transplantation: DRG 103 (Heart Transplant or Implant of Heart Assist System) (proposed title change), DRG 104 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization) and DRG 105 (Cardiac Valve and Other Major Cardiothoracic Procedures Without Cardiac Catheterization), and DRG 525 (Other Heart Assist System Implant) (proposed title change).

- Addition of pacemaker device and lead procedure code combinations that could lead to the assignment of DRG 115 (Permanent Cardiac Pacemaker Implant with Acute Myocardial Infarction, Heart Failure, or Shock or ACID Lead or Generator Procedures) and DRG 116 (Other Permanent Cardiac Pacemaker Implant).

- Movement of the procedure code for 360 spinal fusion from DRG 496 (Combined Anterior/Posterior Spinal Fusion) to DRG 497 (Spinal Fusion Except Cervical With CC) and DRG 498 (Spinal Fusion Except Cervical Without CC).

- Addition of combination codes, which also include heart failure, to the list of major problems under DRG 387 (Prematurity With Major Problems) and DRG 389 (Full-Term Neonate With Major Problems).

- Modification of DRGs 504 through 509 under MDC 22 (Burns) to recognize the impact of long-term mechanical ventilation on burn cases and renaming DRG 504 as proposed title "Extensive Burns or Full Thickness Burns With Mechanical Ventilation 96+ Hours With Skin Graft" and DRG 505 as proposed title "Extensive Burns or Full Thickness Burns With Mechanical Ventilation 96+ Hours Without Skin Graft."

- Deletion of DRG 483 (Tracheostomy for Face, Mouth, and Neck Diagnoses) and splitting the assignment of cases to two proposed new DRGs on the basis of the performance of a major operating room procedure: proposed new DRGs 541 and 542 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnosis With and Without Major Operating Room Procedure, respectively).

We also presented our reevaluation of FY 2004 applicants for add-on payments for high-cost new medical services and technologies, and our analysis of FY

2005 applicants (including public input, as directed by Public Law 108-173, obtained in a town hall meeting).

We proposed the annual update of the long-term care diagnosis-related group (LTC-DRG) classifications and relative weights for use under the LTCH PPS for FY 2005.

2. Changes to the Hospital Wage Index

We proposed revisions to the wage index and the annual update of the wage data. Specific issues addressed included the following:

- The FY 2005 wage index update, using wage data from cost reporting periods that began during FY 2001.

- Revision of the labor market areas as a result of OMB revised definitions of geographical statistical areas.

- A discussion of the collection of occupational mix data and the occupational mix adjustment to the wage index that we proposed to apply beginning October 1, 2004.

- Revisions to the wage index based on hospital redesignations and reclassifications, including changes that reflect the new OMB standards for assignment of hospitals to geographic areas.

- The adjustment to the wage index based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index, to implement section 505 of Public Law 108-173.

- A discussion of eligible hospitals reclassified under the one-time appeals process under section 508 of Public Law 108-173.

- Changes to the labor-related share to which the wage index is applied in determining the PPS rate for hospitals located in specific geographic areas, to implement section 403 of Public Law 108-173.

- The revised timetable for reviewing and verifying the wage data that will be in effect for the FY 2005 wage index.

3. Other Decisions and Changes to the PPS for Inpatient Operating and GME Costs

In the proposed rule, we discussed a number of provisions of the regulations in 42 CFR parts 412 and 413 and set forth proposed changes concerning the following:

- Expansion of the current postacute care transfer policy.

- Payments for inpatient care in providers that change classification status during a patient stay.

- Changes in the definitions of urban and rural areas for geographic reclassification purposes.

- Equalization of the standardized amount for urban and rural hospitals.

- The reporting of hospital quality data as a condition for receiving the full annual payment update increase.

- Revision of the regulations to reflect the revision of the labor share of the wage index.

- Revision of the regulations to reflect the wage index adjustment for commuting patterns of hospital employees who live in one county and commute to work in other areas with higher level wages.

- Changes in the threshold amount for eligibility for new medical services and technology add-on payments.

- Revision to our policy on additional payments to hospitals with high percentages of ESRD discharges.

- Changes to the IME adjustment formula multipliers, and the formula multiplier applicable to redistribution of unused numbers of FTE resident slots.

- Changes in DSH adjustment payments to rural and small urban hospitals.

- Payment adjustments for low-volume hospitals.

- Changes in policy affecting hospitals that apply as a group for reclassification and a discussion of possible reclassifications for dominant hospitals and hospitals in single-hospital MSAs.

- Changes in policies governing payments for direct GME, including the redistribution of unused FTE resident slots; changes in the GME initial residency period; extension of the update limitation on hospital-specific per resident amounts; and changes in the policies on residents training in nonhospital settings, including written agreements for teaching physician compensation.

- An announcement of the rural community hospital demonstration to be established under section 410A of Public Law 108–173 and the opportunity for eligible hospitals to apply for participation in the demonstration program.

- A solicitation of public comments on the effect of increases in malpractice insurance premiums on hospitals participating in the Medicare program and beneficiary access of services.

4. Changes to the PPS for Capital-Related Costs

In the proposed rule, we discussed the payment requirements for capital-related costs and proposed changes relating to capital payments to hospitals located in Puerto Rico, changes in the policies on exception payments for extraordinary circumstances, treatment of hospitals previously reclassified for the operating standardized amounts, and capital payment adjustments based

on the proposed changes in geographic classifications.

5. Changes for Hospitals and Hospital Units Excluded From the IPPS

In the proposed rule, we discussed the following proposed revisions and clarifications concerning excluded hospitals and hospital units and CAHs:

- Changes in the payment rate for new excluded hospitals.

- Changes to the criteria for determining payments to hospitals-within-hospitals.

- Changes to the policies governing payment to CAHs, including a change in the payment percentage for services furnished by CAHs; changes in the rules governing the election by a CAH of the optional method of payment; expansion of the payment to emergency room on-call providers to include physician assistants, nurse practitioners, and clinical nurse specialists; authorization for the making of periodic interim payments (PIPs) for CAHs for inpatient services furnished; revision of the bed count limit for CAHs from 15 to 25 acute care beds; proposed requirements for establishing psychiatric and rehabilitation distinct part units in CAHs; and termination of the location requirement for a CAH by designating the CAH as a necessary provider.

6. Changes to QIO Disclosure of Information Requirements

In the proposed rule, we discussed our proposed clarification of the requirements for disclosure by QIOs of information on institutions and practitioners collected in the course of the QIO's quality improvement activities.

7. Changes Relating to Medicare Provider Agreements, Hospital Conditions of Participation, and Fire Safety Requirements for Certain Health Care Facilities

We proposed to—

- Require hospitals, as part of the discharge planning standard under the Medicare hospital conditions of participation, to furnish a list of Medicare-participating home health agencies to patients who are expected to receive home health services after discharge and to provide information on Medicare-certified SNFs to patients who are likely to need posthospital extended care services.

- Require that Medicare provider agreements include provisions that would ensure that all hospital employees who may come into contact with human blood in the course of their duties are provided proper protection from bloodborne pathogens.

- Correct a technical error relating to the application of the 2000 edition of the Life Safety Code as the fire safety requirements for certain health care facilities; and clarify the effective date for the prohibition on the use of roller latches in these facilities.

8. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits

In the Addendum to the May 18, 2004, proposed rule, we set forth proposed changes to the amounts and factors for determining the FY 2005 prospective payment rates for operating costs and capital-related costs. We also established the proposed threshold amounts for outlier cases. In addition, we addressed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2005 for hospitals and hospital units excluded from the PPS.

9. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected hospitals.

10. Recommendation of Update Factor for Hospital Inpatient Operating Costs

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provided our recommendations of the appropriate percentage changes for FY 2005 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs (and hospital-specific rates applicable to SCHs and MDHs).

- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by hospitals and hospital units excluded from the IPPS.

11. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, the Medicare Payment Advisory Commission (MedPAC) is required to submit a report to Congress, no later than March 1 of each year, that reviews and makes recommendations on Medicare payment policies. MedPAC's March 2004 recommendation concerning hospital inpatient payment policies addressed only the update factor for inpatient hospital operating costs and capital-related costs under the IPPS and for hospitals and distinct part hospital units excluded from the IPPS. This recommendation was addressed in Appendix B of the May 18, 2004,

proposed rule. For further information relating specifically to the MedPAC March 1 report or to obtain a copy of the report, contact MedPAC at (202) 220-3700 or visit MedPAC's Web site at: <http://www.medpac.gov>.

D. Public Comments Received in Response to the May 18, 2004 Proposed Rule

We received over 30,000 timely items of correspondence containing multiple comments on the May 18, 2004 proposed rule. Summaries of the public comments and our responses to those comments are set forth below under the appropriate heading.

Comment Period: One commenter indicated that, under the Administrative Procedures Act (APA), 5 U.S.C. 553(b), the 60-day comment period should have started from the date the proposed rule was published in the **Federal Register**, not the date the rule was placed on the CMS Web site.

Response: We believe publication of the proposed rule is fully consistent with the law. The APA does not prescribe any specific length for the comment period. In addition, the proposed rule was placed on display at the Office of the Federal Register and a copy of the rule also appeared on our Web site. The substance of the rule was fully available on the Web site, as well as on display at the Office of the Federal Register. Finally, we note that, in accordance with section 1886(d) of the Act, the Secretary is required to ensure that the updated IPPS rates are in place

at the beginning of the Federal fiscal year, or by October 1, 2004. Our priority is to ensure that hospitals receive their final updated rates for the new fiscal year.

II. Changes to DRG Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as DRGs) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, we pay for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually. These adjustments are made to reflect changes

in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The changes to the DRG classification system and the recalibration of the DRG weights for discharges occurring on or after October 1, 2004, are discussed below.

B. DRG Reclassifications

1. General

Cases are classified into DRGs for payment under the IPPS based on the principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the stay. In a small number of DRGs, classification is also based on the age, sex, and discharge status of the patient. The diagnosis and procedure information is reported by the hospital using codes from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM).

For FY 2004, cases are assigned to one of 518 DRGs in 25 major diagnostic categories (MDCs). Most MDCs are based on a particular organ system of the body. For example, MDC 6 is Diseases and Disorders of the Digestive System. This approach is used because clinical care is generally organized in accordance with the organ system affected. However, some MDCs are not constructed on this basis because they involve multiple organ systems (for example, MDC 22 (Burns)). The table below lists the 25 MDCs.

Major Diagnostic Categories (MDCs)	
1	Diseases and Disorders of the Nervous System
2	Diseases and Disorders of the Eye
3	Diseases and Disorders of the Ear, Nose, Mouth, and Throat
4	Diseases and Disorders of the Respiratory System
5	Diseases and Disorders of the Circulatory System
6	Diseases and Disorders of the Digestive System
7	Diseases and Disorders of the Hepatobiliary System and Pancreas
8	Diseases and Disorders of the Musculoskeletal System and Connective Tissue
9	Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast
10	Endocrine, Nutritional and Metabolic Diseases and Disorders
11	Diseases and Disorders of the Kidney and Urinary Tract
12	Diseases and Disorders of the Male Reproductive System
13	Diseases and Disorders of the Female Reproductive System
14	Pregnancy, Childbirth, and the Puerperium
15	Newborns and Other Neonates with Conditions Originating in the Perinatal Period
16	Diseases and Disorders of the Blood and Blood Forming Organs and Immunological Disorders
17	Myeloproliferative Diseases and Disorders and Poorly Differentiated Neoplasms
18	Infectious and Parasitic Diseases (Systemic or Unspecified Sites)
19	Mental Diseases and Disorders
20	Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders
21	Injuries, Poisonings, and Toxic Effects of Drugs
22	Burns
23	Factors Influencing Health Status and Other Contacts with Health Services
24	Multiple Significant Trauma
25	Human Immunodeficiency Virus Infections

In general, cases are assigned to an MDC based on the patient's principal diagnosis before assignment to a DRG. However, for FY 2004, there are eight DRGs to which cases are directly

assigned on the basis of ICD-9-CM procedure codes. These DRGs are for heart, liver, bone marrow, lung, simultaneous pancreas/kidney, and pancreas transplants and for

tracheostomies. Cases are assigned to these DRGs before they are classified to an MDC. The table below lists the current eight pre-MDCs.

Pre-Major Diagnostic Categories (Pre-MDCs)	
DRG 103	Heart Transplant
DRG 480	Liver Transplant
DRG 481	Bone Marrow Transplant
DRG 482	Tracheostomy for Face, Mouth, and Neck Diagnoses
DRG 483	Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except for Face, Mouth, and Neck Diagnoses
DRG 495	Lung Transplant
DRG 512	Simultaneous Pancreas/Kidney Transplant
DRG 513	Pancreas Transplant

Within most MDCs, cases are then divided into surgical DRGs and medical

DRGs. Surgical DRGs are based on a hierarchy that orders operating room

(O.R.) procedures or groups of O.R. procedures by resource intensity.

Medical DRGs generally are differentiated on the basis of diagnosis and age (less than or greater than 17 years of age). Some surgical and medical DRGs are further differentiated based on the presence or absence of a complication or a comorbidity (CC).

Generally, nonsurgical procedures and minor surgical procedures that are not usually performed in an operating room are not treated as O.R. procedures. However, there are a few non-O.R. procedures that do affect DRG assignment for certain principal diagnoses, for example, extracorporeal shock wave lithotripsy for patients with a principal diagnosis of urinary stones.

Patient's diagnosis, procedure, discharge status, and demographic information is fed into the Medicare claims processing systems and subjected to a series of automated screens called the Medicare Code Editor (MCE). The MCE screens are designed to identify cases that require further review before classification into a DRG.

After patient information is screened through the MCE and any further development of the claim is conducted, the cases are classified into the appropriate DRG by the Medicare GROUPER software program. The GROUPER program was developed as a means of classifying each case into a DRG on the basis of the diagnosis and procedure codes and, for a limited number of DRGs, demographic information (that is, sex, age, and discharge status).

After cases are screened through the MCE and assigned to a DRG by the GROUPER, the PRICER software calculates a base DRG payment. The PRICER calculates the payments for each case covered by the IPPS based on the DRG relative weight and additional factors associated with each hospital, such as IME and DSH adjustments. These additional factors increase the payment amount to hospitals above the base DRG payment.

The records for all Medicare hospital inpatient discharges are maintained in the Medicare Provider Analysis and Review (MedPAR) file. The data in this file are used to evaluate possible DRG classification changes and to recalibrate the DRG weights. However, in the July 30, 1999, IPPS final rule (64 FR 41500), we discussed a process for considering non-MedPAR data in the recalibration process. In order for us to consider using particular non-MedPAR data, we must have sufficient time to evaluate and test the data. The time necessary to do so depends upon the nature and quality of the non-MedPAR data submitted. Generally, however, a significant sample of the non-MedPAR

data should be submitted by mid-October for consideration in conjunction with the next year's proposed rule. This allows us time to test the data and make a preliminary assessment as to the feasibility of using the data. Subsequently, a complete database should be submitted by early December for consideration in conjunction with the next year's proposed rule.

Many of the changes to the DRG classifications are the result of specific issues brought to our attention by interested parties. We encourage individuals with concerns about DRG classifications to bring those concerns to our attention in a timely manner so they can be carefully considered for possible inclusion in the next proposed rule and so any proposed changes may be subjected to public review and comment. Therefore, similar to the timetable for interested parties to submit non-MedPAR data for consideration in the DRG recalibration process, concerns about DRG classification issues should be brought to our attention no later than early December in order to be considered and possibly included in the next annual proposed rule updating the IPPS.

In the May 18, 2004, proposed rule, we proposed numerous changes to the DRG classification system for FY 2005. The changes we proposed to the DRG classification system for FY 2005, the public comments we received concerning the proposed changes, the final DRG changes, and the methodology used to recalibrate the DRG weights are set forth below. The changes we are implementing in this final rule will be reflected in the revised FY 2005 GROUPER version 22.0 and effective for discharges occurring on or after October 1, 2003. Generally, our DRG analysis in the May 18, 2004, proposed rule was based on data from the December 2003 update of the FY 2003 MedPAR file.

Unless otherwise noted in this final rule, our DRG analysis is based on data from the March 2004 update of the FY 2003 MedPAR file, which contains hospital bills received through March 31, 2004, for discharges in FY 2003.

2. MDC 1 (Diseases and Disorders of the Nervous System): Intracranial Hemorrhage and Stroke With Infarction

In the May 18, 2004, proposed rule, we noted that it had come to our attention that the title of DRG 14 (Intracranial Hemorrhage and Stroke With Infarction) may be misleading because it implies that a combination of conditions exists when the DRG is assigned. When we developed this title,

we did not intend to imply that a combination of conditions exists. Therefore, we proposed to change the title of DRG 14 to read "Intracranial Hemorrhage or Cerebral Infarction".

We received one comment on this proposal in support of the DRG title change. Therefore, we are adopting as final the proposed change of the title of DRG 14 to "Intracranial Hemorrhage or Cerebral Infarction".

3. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Heart Assist System Implant

Circulatory support devices, also known as heart assist systems, ventricular assist devices (VADs) or left ventricular assist devices (LVADs), offer a surgical alternative for end-stage heart failure patients. This type of device is often implanted near a patient's native heart and assumes the pumping function of the weakened heart's left ventricle. In many cases, heart transplantation would be the treatment of choice for this type of patient. However, the low number of donor hearts limits this treatment option.

We have reviewed the payment and DRG assignment for this type of device many times in the past. The reader is referred to the August 1, 2002 IPPS final rule (67 FR 49989) for a complete listing of those discussions.

In the August 1, 2002, final rule (67 FR 49990), we attempted to clinically and financially align VAD procedures by creating new DRG 525 (Heart Assist System Implant). We also noted that cases in which a heart transplant also occurred during the same hospitalization episode would continue to be assigned to DRG 103 (Heart Transplant). At that time, we announced that DRG 525 would consist of any principal diagnosis in MDC 5, plus one of the following surgical procedure codes:

- 37.62, Insertion of nonimplantable heart assist system.
- 37.63, Repair of heart assist system.
- 37.65, Implant of external heart assist system.
- 37.66, Insertion of implantable heart assist system.

(To avoid confusion, we note that the titles of codes 37.62, 37.63, 37.65, and 37.66 have been revised for FY 2005 through the ICD-9-CM Coordination and Maintenance Committee process as reflected in Table 6F, Revised Procedure Code Titles in the Addendum to this final rule.)

Commenters on the May 19, 2003, proposed rule that preceded the August 1, 2003, IPPS (FY 2004) final rule notified us that procedure code 37.66

was neither a clinical nor a financial match to the rest of the procedure codes now assigned to DRG 525. We did not modify DRG 525 for FY 2004. We agreed that we would continue to evaluate whether to make further changes to DRG 525. After publication of the August 1, 2003, final rule, we again reviewed the MedPAR data concerning DRG 525, and came to the conclusion that procedure code 37.62 is different in terms of clinical procedures and resource utilization from the other procedure codes assigned to DRG 525. Therefore, in a correction to the August 1, 2003, IPPS (FY 2004) final rule, published on October 6, 2003 (68 FR 57733), we revised the composition of DRG 525 by correcting the assignment of procedures to DRG 525 in light of the lower charges associated with procedure code 37.62. We moved code 37.62 into DRG 104 (Cardiac Valve and Other Major Cardiothoracic Procedures With Cardiac Catheterization) and DRG 105 (Cardiac Valve and Other Major Cardiothoracic Procedures Without Cardiac Catheterization), and left procedure codes 37.63, 37.65, and 37.66 into DRG 525.

In addition, we have evaluated a request for expanded coverage for VADs and LVADs as destination (or permanent) therapy for end-stage heart failure patients who are not candidates for heart transplantation. VADs and LVADs had been approved for support of blood circulation post-cardiotomy (effective for services performed on or after October 18, 1993) and as a bridge to heart transplant (effective for services performed on or after January 22, 1996) to assist a damaged or weakened heart in pumping blood. The criteria that must be fulfilled in order for Medicare coverage to be provided for these purposes have been previously discussed in the August 1, 2000, final rule (65 FR 47058), and can also be accessed online at: http://www.cms.gov/manuals/pm_trans/r2ncd1.pdf.

As a result of that review, effective for services performed on or after October 1, 2003, VADs have been approved as destination therapy for patients requiring permanent mechanical cardiac support. Briefly, VADs used for destination therapy are covered only if they have received approval from the FDA for that purpose, and the device is

used according to the FDA-approved labeling instructions. VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of less than 2 years). Implanting facilities as well as patients must also meet all of the additional conditions that are listed in the national coverage determination for artificial hearts and related devices, which is posted on the above CMS website.

In the May 18, 2004, proposed rule, we again reviewed the FY 2003 MedPAR data for all cases in which a VAD had been implanted, using the criterion of any case containing a procedure code of 37.66. We found a total of 65 cases in 3 DRGs: DRG 103 (Heart Transplant); DRG 483 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses); and DRG 525 (Heart Assist System Implant). The following table displays our findings:

DRG With Code 37.66 Reported	Count	Average Length of Stay	Average Charges
103	14	77.36	\$ 836,011
483	6	100.50	\$1,400,706
525	45	38.93	\$ 308,725

The remaining 354 cases in DRG 103 that did not report code 37.66 had average charges of \$282,578. The remaining 171 cases in DRG 525 that did not contain code 37.66 had an average length of stay of 12.39 days and average charges of \$168,388. The 45 cases in DRG 525 with code 37.66 accounted for 26 percent of the cases. However, the average charges for these cases are approximately \$140,340 higher than the average charges for cases in DRG 525 that did not report code 37.66.

Commenters on the FY 2004 final rule suggested adding code 37.66 to DRG 103. We were concerned with the timing of that comment, as it was received after publication of the proposed rule. We noted that the commenters' suggestions on the structure of the DRGs involved were significant, and that change of that magnitude should be subject to public review and comment. We also noted that we would evaluate the suggestion further (68 FR 45370). However, as one of the indications for this device has

become destination therapy, and as this new indication is more clinically aligned with DRG 103, in the May 18, 2004 proposed rule, we proposed to remove procedure code 37.66 from DRG 525 and assign it to DRG 103. We also proposed to change the title of DRG 103 to "Heart Transplant or Implant of Heart Assist System". The proposed restructured DRG 103 included any principal diagnosis in MDC 5, plus one of the following surgical procedure codes:

- 33.6, Combined heart-lung transplantation.
- 37.51, Heart transplantation.
- 37.66, Insertion of implantable heart assist system.

In addition to the proposed changes to DRG 103, we proposed to change the title of DRG 525 to "Other Heart Assist System Implant."

Comment: A number of commenters recommended that we continue to examine the MedPAR data for code 37.66 and heart transplants to confirm

that the weight is accurate. Some of these commenters noted that the weight might need to be increased in either the short term or next year. One commenter who, we believe, did not have access to the proposed rule, suggested the same proposed changes that were included in the proposed rule.

Response: We will continue to evaluate the assignment of these codes annually for clinical and resource coherence. We point out that the relative weights are determined based on a formula and the formula is based on historic hospital charges. To increase one weight in a manner not consistent with the formula would skew other weights, in addition to distorting our mandated budget neutrality provision.

Comment: Two commenters requested clarification concerning patients who receive the implantable heart assist system as a bridge to transplant and are discharged and subsequently return for a heart transplant. The commenters

wanted to know if DRG 103 would be assigned in both cases.

Response: DRG 103 would be assigned to the case when a VAD is implanted. It would also be assigned when the patient returns to the hospital for a heart transplant. However, we take this opportunity to clarify that only one DRG 103 payment will be made per admission. If a patient has both the VAD and a heart transplant during the same hospital admission, DRG 103 would be paid only once. Depending on the circumstances, the case may qualify for cost outlier status, which is designed to defray some of the additional expenses of the case.

Comment: One commenter suggested that the term "Insertion" in the code title for 37.66 be changed to "Implant" to more accurately reflect the resource intense nature of the VAD implant.

Response: We regret that we cannot accommodate this request. The cardiac device code titles have been discussed

at the two previous ICD-9-CM Coordination and Maintenance Committee meetings (December 2003 and April 2004). At those meetings, we asked for comments about the code titles, and in response to public comment, we removed the term "Implant" and substituted "Insertion" in the title. As noted elsewhere in this preamble, the codes in Table 6 of the Addendum are not subject to comment. The codes themselves are final at the time the proposed rule is published, which gives our industry partners the opportunity to put them into their printed and electronic programs without the concern that they may be changed later in the rulemaking process.

Comment: One commenter urged CMS to retain a common DRG assignment for procedure codes 37.65 and 37.66. The commenter believed that assigning these two procedure codes to different DRGs would not ensure that payment is adequate to allow hospitals

to provide mechanical circulatory support therapies, as clinically indicated, and in a cost-efficient manner. The commenter further believed that payment for implantable VADs (code 37.66) at a higher level than external VADs (code 37.65) would create financial incentives unrelated to, and potentially at odds with, clinical considerations, which would skew device choice and increase Medicare program costs. The commenter stated that the initial use of the least expensive device that can provide the necessary therapeutic benefit leads to the best clinical outcomes and the lowest total system costs. The commenter encouraged CMS to adopt a prudent payment policy and an adequate test of whether a patient's heart will recover before an implantable VAD procedure is undertaken.

Response: We reviewed data on DRG 525 in the FY 2003 MedPAR file and are summarizing the findings below:

Code	Number of Cases	Average Length of Stay	Average Charges
37.62, Insertion of nonimplantable heart assist system	1	66	\$273,361
37.63, Repair of heart assist system	62	13.37	\$139,758
37.65, Implant of external heart assist system	108	11.32	\$183,852
37.66, Insertion of implantable heart assist system	45	38.93	\$308,725

We believe that the data on the length of stay and average charges demonstrate considerable differences in the two VAD devices. The implantable VAD (code 37.66) had a length of stay more than three times longer than that of the external VAD (code 37.65), and charges that average over \$100,000 per case greater than those of the external VAD. To comply with this commenter's suggestion and leave both codes in the same DRG would result in overpayment of external VAD procedures and underpayment of the implantable VADs. We do not find either alternative acceptable.

We will continue to closely monitor DRGs 103 and 525 on an annual basis, and will review our data using the specific procedure codes that comprise these two DRGs.

Comment: One commenter stated that the MedPAR data on charges for FY 2003 VAD cases used to develop and defend the proposal to assign procedure codes 37.65 and 37.66 to different DRGs are an inadequate basis for the proposal. The commenter stated that the FY 2003 data on code 37.66 used in support of the proposal (to move these cases to DRG 103) must be comprised primarily of bridge-to-transplant cases, as the use of VADs for destination therapy was only recently approved. Therefore, the commenter believes, any destination therapy patients in the data must have been clinical trial patients. The commenter asserted that these clinical trial patients were a sicker group of patients than would normally be found, and that they received more ancillary services during the course of the trial than would be likely in normal clinical

practice. As a result, the data for these patients would be skewed to higher average charges and longer lengths of stay.

Response: The data associated with code 37.66 reflect the insertion of an implantable VAD. We do not have a method of capturing the intent of the physician upon insertion of this device. When the chest is opened and the device is inserted, we have no way of determining if this patient requires the device as a bridge-to-transplant as the patient awaits a donor organ, or if this VAD is to be considered destination therapy. Code 37.66 captures only the procedure performed and the device inserted.

The following table represents FY 2002 data in DRG 525.

Code	Number of Cases	Average Length of Stay	Average Charges
37.62, Insertion of non-implantable heart assist system*	182	13.1	\$112,747
37.63, Repair of heart assist system*	78	16.7	\$190,627
37.65, Implant of external heart assist system*	102	10.9	\$162,863
37.66, Insertion of implantable heart assist system*	50	40.1	\$342,725

*For ease in comparison of FY 2002 and FY 2003 data, we have kept the same (new) code titles for both years.

When we compare the above table containing FY 2002 data to the previous table containing FY 2003 data, we find similar results in length of stay and average charges for codes 37.63, 37.65, and 37.66. The FY 2003 data show only one case with code 37.62: it is difficult to draw any meaningful conclusions based on one case. These data represent cases before bridge-to-transplant was a covered indication for VAD. As the data in the 2 years are so similar, we believe that we have correctly reassigned code 37.66 to DRG 103.

Comment: One commenter stated that DRG 525, as amended on October 1, 2003, to include every type of mechanical circulatory support device requiring a sternotomy and multiple-day support, constituted a clinically coherent group of surgeries encompassing a range of device types and costs. The commenter stated that, as the device types in that DRG grouping are available in the same hospital mechanical circulatory support programs, blended reimbursement did not constitute a financial impediment to proper clinical choice. The commenter stated that the FY 2003 iteration of DRG 525 should be preserved, which would allow the dynamics of the clinical setting and the market to determine the choice among available VADs.

Response: We are aware that reimbursement dynamics may have an influence on the practice of medicine. However, we are also aware that the placement of cases reporting code 37.66 in DRG 525 may cause a financial hardship for hospitals. The movement of code 37.66 to DRG 103 is appropriate from the perspective of resource utilization, and will also alleviate some of the disincentive to offer this procedure to patients who meet the medical criteria for implantation.

Comment: One commenter noted that coverage of VAD procedures should be limited to Medicare-certified transplant

centers. The commenter also noted that VAD implants assigned to DRG 103 are limited to those [hospitals] using devices that are approved by the FDA for use outside the inpatient hospital setting.

Response: Section 60—Durable Medical Equipment in the Medicare Coverage Manual sets forth our requirements concerning the use of VADs. The manual states:

- The VAD must be used in accordance with the FDA approved labeling instructions;
- The patient is approved and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center; and
- The implanting site, if different than the Medicare-approved transplant center, must receive the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD.

In conjunction with the data review of DRGs 103 and 525, we also evaluated DRGs 104 and 105. DRGs 104 and 105 were restructured in FY 2003 by moving code 37.62 into them. We examined the MedPAR data and found that the average charges for DRGs 104 and 105 were \$113,667 and \$82,899, respectively, for cases not reporting code 37.62, while cases containing code 37.62 had average charges of \$124,559 and \$166,129, respectively.

The removal of code 37.66 from DRG 525 would have the effect of clinically realigning that DRG to be more coherent. As a result of the proposal to remove code 37.66 from DRG 525 and assign it to DRG 103, we also proposed to remove code 37.62 from DRGs 104 and 105 and assign it back into DRG 525. The average charges for code 37.62 in DRGs 104 and 105 (\$124,559 and \$166,129) more closely matched the average charges reported for the 171 cases in DRG 525, absent code 37.66 (\$168,388).

We indicated that the proposed new DRG 525 would consist of any principal diagnosis in MDC 5, plus the following surgical procedure codes:

- 37.52, Implantation of total replacement heart system*
- 37.53, Replacement or repair of thoracic unit of total replacement heart system*
- 37.54, Replacement or repair of other implantable component of total replacement heart system*
- 37.62, Insertion of nonimplantable heart assist system
- 37.63, Repair of heart assist system
- 37.65, Implant of external heart assist system

We received one comment in support of this portion of our proposal. Based on the rationale described above, we are adopting the proposed changes to DRGs 103, 104, and 105 as final without modification.

b. Cardiac Resynchronization Therapy and Heart Failure

In the May 18, 2004 proposed rule, we addressed a request we had received from a manufacturer of a Cardiac Resynchronization Therapy Defibrillator (CRT-D) device for a modification to DRG 535 (Cardiac Defibrillator Implant With Cardiac Catheterization With Acute Myocardial Infarction/Heart Failure/Shock) and DRG 536 (Cardiac Defibrillator Implant With Cardiac Catheterization Without Acute Myocardial Infarction/Heart Failure/Shock). The commenter pointed out that defibrillator device implantations, including the CRT-D type of defibrillator, are assigned to DRG 535 when the patient also has a cardiac catheterization and has either an acute myocardial infarction, heart failure, or shock as a principal diagnosis. If the

* These codes represent noncovered services for Medicare beneficiaries. However, it is our longstanding practice to assign every code in the ICD-9-CM classification to a DRG. Therefore, they have been assigned to DRG 525.

patient receiving the defibrillator implant and cardiac catheterization does not have a principal diagnosis of acute myocardial infarction, heart failure, or shock, the cases are assigned to DRG 536.

The commenter requested that cases be assigned to DRG 535 when the patient has heart failure as either a principal diagnosis or a secondary diagnosis. The commenter stated that patients receive a CRT-D (as opposed to other types of defibrillators) when they have both heart failure and arrhythmia. The commenter was concerned that some coders may sequence the heart failure as a secondary diagnosis, which would result in the patient being assigned to DRG 536.

As stated earlier, DRGs 535 and 536 are split based on the principal diagnosis of acute myocardial infarction, heart failure, or shock. Cases are not assigned to DRG 535 when heart failure is a secondary diagnosis.

The commenter described a scenario where a patient was admitted with heart failure for an evaluation of the need for a CRT-D implant. The hospitalization studies indicated that the patient had a ventricular tachycardia. The commenter indicated that coders would be confused as to which code should be listed as the principal diagnosis.

CMS' determination based on review of this scenario as described was that the heart failure led to the admission and would be the principal diagnosis. This case would properly be assigned to DRG 535. Furthermore, when two conditions are considered to be equally responsible for the admission, either one of the two conditions may be selected as the principal diagnosis.

The commenter also stated that its own study shows CRT-D patients have significantly higher charges than do other patients in DRGs 535 and 536 who receive an implantable defibrillator. This was the case whether heart failure

was used as a principal or secondary diagnosis.

A cardiac catheterization is a diagnostic procedure generally performed to establish the nature of the patient's cardiac problem and determine if implantation of a cardiac defibrillator is appropriate. Generally, the cardiac catheterization can be done on an outpatient basis. Patients who are admitted with acute myocardial infarction, heart failure, or shock and have a cardiac catheterization are generally acute patients who require emergency implantation of the defibrillator. Thus, there are very high costs associated with these patients.

For the analysis in the proposed rule, we examined the MedPAR file for all cases in DRGs 535 and 536 and only cases in DRG 536 in which acute myocardial infarction or heart failure was listed as a secondary diagnosis. The following chart illustrates the results of our findings:

DRGs	Count	Average Length of Stay	Average Charges
535	6,801	9.50	\$110,663.57
536 - All cases	17,454	5.47	89,493.85
536 - Cases With Secondary Diagnosis of Cardiac Defibrillator Implant With Cardiac Catheterization Without Acute Myocardial Infarction/Heart Failure/Shock	8,562	6.5	94,832.14

The data show that cases with a secondary diagnosis of acute myocardial infarction or heart failure have average charges (\$94,832.14) closer to the overall average charges for DRG 536 (\$89,493.85) where they are currently assigned. Overall charges for DRG 535 were \$110,663.57. We do not believe these data support modifying DRG 535 and DRG 536 as requested. Many of the CRT-D patients who are admitted for heart failure would be assigned into DRG 535. Furthermore, modifying the DRG logic for one specific type of defibrillator (CRT-D) is not consistent with our overall policy of grouping similar types of patients together in the same DRG. In addition, to modify the DRG logic for the small percentage of cases where there might be confusion concerning the selection of the principal diagnosis does not seem prudent. Therefore, we did not propose a modification to DRG 535 or 536 for CRT-Ds.

Comment: Several commenters supported our proposal not to change

the current DRG structure of DRG 535 and DRG 536 for CRT-D devices. Our proposal was in response to a manufacturer that had requested that CRT-D cases be assigned to DRG 535 when the patient has heart failure as either a principal diagnosis or a secondary diagnosis.

Response: After publication of the May 18, 2004 proposed rule, we discussed the issue of coding cases implanted with a CRT-D at the June 2004 meeting of the American Hospital Association's Editorial Advisory Board for Coding Clinical for ICD-9-CM. Discussions between coding representatives from the American Hospital Association, the American Health Information Management Association, the National Centers for Health Statistics, and CMS did not identify diagnosis sequencing problems for patients receiving a CRT-D, as was suggested by the manufacturer. A number of problems in coding the implantation of these devices using the procedure codes were discussed. In

addition, we learned that physicians are not clearly and consistently documenting the types of devices being implanted. This is leading to a number of questions from hospitals on how to assign the correct codes for an implantable cardiac defibrillator (ICD) versus the newer CRT-D. As a result of these further discussions, the Editorial Advisory Board for Coding Clinical for ICD-9-CM is developing a series of questions and answers to clearly illustrate to hospitals how the various devices, leads, and generators are to be correctly coded.

We appreciate the support of the commenters for maintaining the current DRG structure for DRGs 535 and 536 and not modifying them in this final rule for one specific type of defibrillator.

Comment: One commenter, a national hospital organization, opposed our recommendation not to alter the logic of DRG 535. The commenter believed that resynchronization is not performed during an acute exacerbation of congestive heart failure. Rather, the

commenter indicated, the patient returns at a later date once the congestive heart failure becomes more stabilized. The commenter added that, at that time, the patient often manifests associated arrhythmias that require the resynchronization. The commenter believed that, as a result, under the current proposal, this case would possibly not group to DRG 535 if the congestive heart failure were not sequenced as the principal diagnosis.

Response: The commenter stated that the hospital might not list congestive heart failure as the principal diagnosis in the case described. However, if this were a planned second admission for the implantation of a CRT-D for congestive heart failure, the hospital would assign congestive heart failure as the principal diagnosis. The associated arrhythmias would be listed as a secondary diagnosis. This case would be assigned to DRG 535. If the admission were equally due to both the congestive heart failure and the arrhythmias, the hospital could choose either one as the principal diagnosis. Once again, the hospital could select congestive heart failure as the principal diagnosis and DRG 535 would be assigned. It would not be appropriate to change the DRG logic for DRG 535 to capture congestive heart failure as either the principal diagnosis or secondary diagnosis for CRT-D patients when appropriate coding would lead to the correct DRG assignment. Therefore, it would not be appropriate to modify the logic for DRGs 535 and 536 for congestive heart failure at this time.

Comment: Commenters who supported our proposal of maintaining the current DRG structure for DRGs 535 and 536 suggested that coders should follow the ICD-9-CM Official Guidelines for Coding and Reporting (available on the following Web site: <http://www.cdc.gov/nchs/icd9.htm>) when sequencing the principal diagnosis for admissions involving cardiac resynchronization. The commenters indicated that, if the reason for the admission is heart failure, that condition would be sequenced as the principal diagnosis. The commenter added that when two conditions are equally responsible for the admission, the ICD-9-CM Official Guidelines for Coding and Reporting allow either condition to be sequenced as the principal diagnosis. The commenters further stated that, in that case, the condition resulting in the higher-weighted DRG adjustment would likely be sequenced as the principal diagnosis. The commenter recommended that CMS continue to analyze the data in DRGs 535 and 536 and seek additional clinical

input regarding the typical principal diagnosis for patients being admitted to evaluate the need for a CRT-D device. The commenters added that further revisions to these DRGs may be warranted in the future.

Response: We agree with the commenters that coders should follow the ICD-9-CM Official Guidelines for Coding and Reporting. We also agree that although we are currently maintaining the structure of DRGs 535 and 536, we will continue to examine data for these procedures in future years to ensure that assignment of cases to these DRGs remains appropriate.

Comment. One commenter indicated that its hospital was assigning the following codes for heart failure cases where the existing automatic cardioverter/defibrillator pulse generator is replaced and the pocket in which the device is implanted is revised:

- 37.98 Replacement of automatic cardioverter/defibrillator pulse generator only.
- 37.99 Other operations of heart and pericardium.

The commenter stated that when the hospital submits a claim with the code for the replacement of the generator (code 37.98), the case is assigned to DRG 115 (Permanent Cardiac Pacemaker Implant With Acute Myocardial Infarction, Heart Failure, or Shock or ACID Lead or Generator Procedures). When the hospital submits a claim with codes for both the generator replacement (code 37.98) and the pocket revision (code 37.99), the case is assigned to DRG 111 (Major Cardiovascular Procedures Without CC). The commenter was concerned because DRG 111 has a lower relative weight than DRG 115. The commenter believed that DRG 111 does not adequately reimburse the hospital for the replacement of the pulse generator device.

The commenter requested that we consider modifying the DRG logic when both codes are submitted, modify the surgical hierarchy, or develop separate codes for revisions and relocations of defibrillator generators.

Response: We are addressing the issue of the surgical hierarchy surfaced by the commenter in section II.B.11. of this final rule. We have carefully evaluated the other issues raised by the commenter, and we concur that assigning procedures such as the revision or relocation of defibrillator pockets to a vague code such as code 37.99 does not allow these procedures to be clearly identified. We believe that grouping disparate procedures such as repositioning of leads, removal without

replacement of pulse generator, and revision or relocation of pockets within one code makes the DRG refinements difficult. We will discuss this topic at the October 7-8, 2004 meeting of the ICD-9-CM Coordination and Maintenance Committee. We will give consideration to creating one or more new codes to more clearly identify these procedures. With these more precise codes, we should be able to modify the DRG logic to resolve this issue.

Comment: Several commenters requested that we restructure DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheterization) by splitting it into two DRGs based on the presence of acute myocardial infarction (AMI), heart failure, or shock. One commenter pointed out that we previously split DRG 514 (Cardiac Defibrillator with Cardiac Catheterization) into two DRGs based on these conditions. In FY 2004, we created DRGs 535 and 536 (Cardiac Defibrillator Implant with Cardiac Catheterization With and Without AMI/Heart Failure/Shock, respectively). The commenter commended us for splitting DRG 514 into these two new DRGs and asked that we now split DRG 515 in a similar manner.

The commenter stated that there was significant difference in hospital charges associated with cases in DRG 515 with and without these principal diagnoses. The commenter stated that it was important to ensure more appropriate payment for all defibrillator cases and better align the DRG payment logic across all pacemaker and defibrillator cases based on important differences in hospital resource requirements.

The commenter pointed out that, in the FY 2004 IPPS rule, we indicated that we did not believe the number of cases within DRG 515, or the differences in charges for cases with and without a principal diagnosis of acute myocardial infarction, heart failure, or shock, were sufficient to merit the creation of two separate DRGs. The commenter stated there was an increase in defibrillator implants assigned to DRG 515 in FY 2003 based on changes in medical science and practice patterns, and speculated that a large number of cases now assigned to DRG 515 are for patients with a principal diagnosis of acute myocardial infarction, heart failure, or shock. The commenter believed that these patients will have significant differences in hospital charges and lengths of stay as compared to those cases in DRG 515 without these principal diagnoses. In addition, the commenter mentioned that other DRGs within MDC 5 are split based on the principal diagnosis or the presence of complications or comorbidities. In

summation, the commenter requested that we split DRG 515 into two separate new DRGs based on the principal diagnoses of acute myocardial infarction, heart failure, or shock. The commenter believed the split is justified based on the large number of cases in DRG 515, the large percentage of cases that include a principal diagnosis of acute myocardial infarction, heart failure, or shock, and the significantly higher charges and length of patient stays associated with these cases.

Another commenter made a similar request to split DRG 515 into two separate new DRGs based on the principal diagnosis of acute myocardial infarction, heart failure, or shock. The commenter stated that we had split DRG 514 into two DRGs (DRGs 535 and 536), and this split has worked well in the facility environment to accurately capture charges and assign appropriate DRGs to cases.

Response: We have performed additional analysis of our FY 2003 MedPAR claims data for DRG 515 using the March 2004 update of the files. We found that 32 percent (4,191) of cases reported for DRG 515 contained a principal diagnosis of acute myocardial infarction, heart failure, or shock. These cases had average charges of \$84,688, as compared to average charges of \$77,554 for all cases in DRG 515. Therefore, DRG 515 cases with a principal diagnosis of acute myocardial infarction, heart failure, or shock had average charges that were \$7,134 (9 percent) higher than those for all cases in DRG 515. The data also show that patients with a principal diagnosis of acute myocardial infarction, heart failure, or shock have average lengths of stay of 6.056 days compared to 4.73 days for all cases in DRG 515. Therefore, cases in DRG 515 with a principal diagnosis of acute myocardial infarction, heart failure, or shock have an average length of stay that is only 1.326 days longer than that for all cases in DRG 515.

The data that we included in the May 18, 2004, proposed rule (69 FR 28208) showed significantly larger differences between DRGs 535 and 536 in average lengths of stay and charges. DRG 535 had an average length of stay of 9.5 days and average charges of \$110,663.57. DRG 536 had an average length of stay of 5.47 days and average charges of \$89,493.85. The difference in average charges was \$21,169.72.

As a result of this analysis, we find that the requested split of DRG 515 would not result in cases with as significantly different lengths of stay or charges as compared to the difference between DRGs 535 and 536. In addition, our current data show only 4,191 cases

that would be assigned to a new DRG for Cardiac Defibrillator Implant without Cardiac Catheterization with a principal diagnosis of acute myocardial infarction, heart failure, or shock. Given the limited number of cases in DRG 515 and the relatively small differences between average charges and length of stay for the two DRGs suggested by the commenter, we have decided that a modification of DRG 515 is not warranted at this time. However, we will examine the data in the future to determine if changes are warranted.

In summary, we are not making changes to DRG 535 or DRG 536 for CRT-D cases at this time. In addition, DRG 515 will remain unchanged for FY 2005. However, we will continue to study data on these DRGs to consider whether future DRG refinements are warranted.

c. Combination Cardiac Pacemaker Devices and Lead Codes

In the May 18, 2004, proposed rule, we discussed a comment we had received that recommended that we include additional combination procedure codes representing cardiac pacemaker device and lead codes under DRG 115 (Permanent Cardiac Pacemaker Implant With Acute Myocardial Infarction, Heart Failure, or Shock or ACID Lead or Generator Procedures) and DRG 116 (Other Permanent Cardiac Pacemaker Implant). DRGs 115 and 116 are assigned when a complete pacemaker unit with leads is implanted. Combinations of pacemaker devices and lead codes that would lead to the DRG assignment are listed under DRGs 115 and 116. The commenter recommended that the following pacemaker device and lead procedure code combinations be added to these two DRGs:

- 00.53 & 37.70
- 00.53 & 37.71
- 00.53 & 37.72
- 00.53 & 37.73
- 00.53 & 37.74
- 00.53 & 37.76

These codes are defined as follows:

- 00.53, Implantation or replacement of cardiac resynchronization pacemaker, pulse generator only [CRT-P]
 - 37.70, Initial insertion of pacemaker lead [electrode], not otherwise specified
 - 37.71, Initial insertion of transvenous lead [electrode] into ventricle
 - 37.72, Initial insertion of transvenous lead [electrode] into atrium and ventricle
 - 37.73, Initial insertion of transvenous lead [electrode] into atrium
 - 37.74, Initial insertion or replacement of epicardial lead [electrode] into epicardium

- 37.76, Replacement of transvenous atrial and/or ventricular lead(s) [electrode]

We consulted our medical advisors and they agreed that these recommended procedure code combinations also describe pacemaker device and lead implantations and should be included under DRGs 115 and 116. Therefore, we proposed to add the recommended procedure code combinations to the list of procedure code combinations under DRGs 115 and 116.

Comment: Several commenters, including those from organizations representing hospitals and coders, supported our proposal to add the pacemaker device and lead procedure code combinations to DRGs 115 and 116 as specified above. The commenters agreed that these combinations indicate that a complete pacemaker unit, including a pacemaker unit and leads, is implanted.

Response: We appreciate the commenters' support for our proposal.

In summary, we are adopting, as final without modification, our proposal to add the procedure code combinations of pacemaker devices and lead procedure codes included above and specified in the proposed rule to the list of procedure code combinations under DRGs 115 and 116.

d. Treatment of Venous Bypass Graft [Conduit] with Pharmaceutical Substance

In the May 18, 2004, proposed rule, we included in Table 6B of the Addendum a new ICD-9-CM procedure code 00.16 (Pressurized treatment of venous bypass graft [conduit] with pharmaceutical substance) that was approved, effective on October 1, 2004. We received a number of comments on this new code.

Comment: A number of comments from physicians applauded our decision to create new procedure code 00.16. The commenters stated that, upon approval by the Food and Drug Administration (FDA) of this procedure, the code will be used to recognize the E2F Decoy (edifoligide) procedure. This procedure will be performed on patients undergoing bypass vein graft procedures if the FDA finds the procedure to be safe and effective. The commenters stated that they are currently performing this procedure on a number of their patients, and asked that Medicare payments that are in addition to that for the cardiac bypass procedure be made to offset resource utilization and costs incurred by hospitals.

Response: We appreciate the commenters' support for the creation of

this procedure code. We proposed to classify this procedure as a non-O.R. procedure in Table 6B of the Addendum to the proposed rule. The “N” under the O.R. column in Table 6B means that the code will not be considered an O.R. procedure and therefore, will not affect the DRG assignment. While the commenters suggested that extra payment be made for this procedure in addition to that for the cardiac bypass procedure, they did not suggest a means to do so. Furthermore, because procedure code 00.16 will not begin to be used until October 1, 2004, we have no data for this new procedure. Accordingly, in this final rule, we are retaining as final the proposed classification of procedure code 00.16 as a non-O.R., ICD-9-CM procedure code. Code 00.16 will not affect the DRG assignment.

4. MDC 6 (Diseases and Disorders of the Digestive System): Artificial Anal Sphincter

In the FY 2003 IPPS final rule (67 FR 50242), we created two new codes for procedures involving an artificial anal sphincter, effective for discharges occurring on or after October 1, 2002: code 49.75 (Implantation or revision of artificial anal sphincter) that is used to identify cases involving implantation or revision of an artificial anal sphincter and code 49.76 (Removal of artificial anal sphincter) that is used to identify cases involving the removal of the device. In Table 6B of that final rule, we assigned both codes to one of four MDCs, based on principal diagnosis, and one of six DRGs within those MDCs. In the August 1, 2003, IPPS final rule (68 FR 45372), we discussed the assignment of these codes in response to a request we had received to consider reassignment of these two codes to different MDCs and DRGs. The requester believed that the average charges (\$44,000) for these codes warranted reassignment. In the August 1, 2003, IPPS final rule, we stated that we did not have sufficient MedPAR data available on the reporting of codes 49.75 and 49.76 to make a determination on DRG reassignment of these codes. We agreed that, if warranted, we would give further consideration to the DRG assignments of these codes because it is our customary practice to review DRG assignment(s) for newly created codes to determine clinical coherence and similar resource consumption after we have had the opportunity to collect MedPAR data on utilization, average length of stay charges, and distribution throughout the system.

Therefore, we reviewed the FY 2003 MedPAR data for the presence of codes

49.75 and 49.76. We then arrayed the results by DRG, count, average length of stay, charges, and the presence or absence of a secondary diagnosis that could be classified as a CC. We found that there were a total of 13 cases in 5 total DRGs with CCs, and 9 cases in 4 total DRGs without CCs, for a total of 22 cases that reported these procedure codes. We had anticipated that the majority of cases would have been found in DRGs 157 (Anal and Stomal Procedures With CC) and 158 (Anal and Stomal Procedures Without CC), but found only 2 cases grouped to DRG 157 and 4 cases grouped to DRG 158. Our data showed average charges of \$22,374 for the cases with CC, and average charges of \$20,831 for the cases without CC. Average charges for DRG 157 were \$18,196, while average charges for DRG 158 were \$9,348.

Our medical advisors also reviewed the contents of DRGs 157 and 158. The consensus was that codes 49.75 and 49.76 are not a clinical match to the other procedure codes found in these two DRGs. The other procedure codes in DRGs 157 and 158 are for simpler and less invasive procedures. In some circumstances, these procedures could potentially be performed in an outpatient setting or in a physician's office. Our medical advisors determined that clinical coherence was not demonstrated and recommended that we move these codes to DRGs 146 (Rectal Resection With CC) and 147 (Rectal Resection Without CC), as these anal sphincter procedures more closely resemble the procedures in these DRGs. In addition, the average charges for paired DRG 146 (\$33,853) and DRG 147 (\$21,747) more closely resemble the actual average charges found in the MedPAR data for these cases.

Even though there were few reports of codes 49.75 and 49.76 in the MedPAR data and we did not anticipate a significant increase in utilization of these procedures, we proposed that these two codes would only be removed from paired DRGs 157 and 158 and reassigned to paired DRGs 146 and 147 under MDC 6 (Diseases and Disorders of the Digestive System). We also proposed that all other MDC and DRG assignments for codes 49.75 and 49.76 would remain the same.

Comment: Two commenters agreed with our proposal and suggested that the recommendation be adopted as a final change. One commenter recommended that CMS continue to monitor the cost of these cases for future consideration of the creation of a new DRG. This commenter stated that CMS has limited reassignment of codes 49.75 and 49.76 to only one pair of DRGs.

Specifically, these procedures were assigned to DRGs 157 and 158 and will be reassigned to DRGs 146 and 147. The commenter took issue with this limited correction and urged CMS to create a new DRG for “Complex Anal/Rectal Procedure with Implant”.

Response: As noted above, codes 49.75 and 49.76 are arrayed in four MDCs and six DRGs within those MDCs. To clarify the proposed rule, we proposed to move these codes within MDC 6, but we did not propose to change any other DRG assignment. With an appropriate principal diagnosis, and absent any other surgical procedure that would reconfigure the case, these codes will continue to be assigned to the other four DRGs in the other three MDCs.

We point out that this reassignment of cases in MDC 6 will double the payment for cases now classified to DRG 146, and will more than double the payment for cases now classified to DRG 147 based on the increases in the relative weights.

With regard to the suggestion to create a specific DRG for this procedure, we remind the commenter that the DRG structure is a system of averages, and is based on groups of patients with similar characteristics. It has not been our past practice to create a DRG based on one device from one manufacturer. We will continue to monitor these two procedure codes and the DRGs to which they are assigned for the annual IPPS updates. However, for FY 2005, we are adopting the proposal to reassign cases reporting codes 49.75 and 49.76 in MDC 6 to DRGs 146 and 147 as final, without further modification.

5. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. 360 Degree Spinal Fusions

In the May 18, 2004 proposed rule, we discussed a comment we had received that suggested procedure code 81.61 (360 Spinal fusion) should not be included in DRG 496 (Combined Anterior/Posterior Spinal Fusion). The commenter stated that code 81.61 does not represent the same types of cases as other codes included in DRG 496. The commenter indicated that cases reported with code 81.61 involve making only one incision, and then fusing both the anterior and posterior portion of the spine. All other cases in DRG 496 involve two separate surgical approaches used to reach the site of the spinal fusion. For these other patients, an incision is made into the patient, and a fusion is made in part of the spine. The patient is then turned over and a separate incision is made so that a fusion can be made in another part of

the spine. The commenter added that these two separate incisions and fusions are more time consuming than the single incision used for code 81.61. The

commenter also stated that patients receiving the two surgical approaches have a longer recovery period and use more hospital resources.

We examined data in the MedPAR file for cases assigned to DRG 496 and found the following:

DRG	Count	Average Length of Stay	Average Charges
496 - All Cases	2,706	8.0	\$74,967.33
496 - Cases with code 81.61	829	4.7	50,659.69
496 - Cases with code 81.61 with CC	451	5.4	55,639.50
496 - Cases with code 81.61 without CC	378	3.8	44,718.16
496 - Cases without 81.61	1877	9.4	85,703.09

We also examined cases in related DRG 497 (Spinal Fusion Except Cervical With CC) and DRG 498 (Spinal Fusion

Except Cervical Without CC) in which code 81.61 was not reported. The results

of our examination are summarized in the following table.

DRG	Count	Average Length of Stay	Average Charges
497	16,965	6.19	\$49,315.27
498	11,598	3.95	\$37,450.68

These data clearly showed that cases with code 81.61 have significantly lower average charges than other cases in DRG 496 that have two surgical approaches. Cases with code 81.61 are more closely aligned with cases in DRG 497 and DRG 498. Furthermore, including code 81.61 will have the effect of lowering the relative weights for DRG 496 in future years. Therefore, we proposed to remove code 81.61 from DRG 496 and reassign it to DRGs 497 and 498.

Comment: Several commenters supported our proposal to remove code 81.61 from DRG 496 and reassign it to DRGs 497 and 498. One commenter representing a major hospital organization stated that patients receiving two surgical approaches have a longer recovery period and use more hospital resources. The commenter believed that there is confusion regarding the use of code 81.61 that stems from physicians who do not use the term "360 degree spinal fusion" in the medical record, and hospital coders who need to review the operative report to determine which surgeries, in fact, qualify for code 81.61. The commenter agreed that code 81.61 should be moved from DRG 496 to DRGs 497 and 498. However, the commenter recommended that data for code 81.61 be reviewed in the future once coding practices have improved. Another commenter

representing a national organization of health information managers also supported our proposal to remove code 81.61 from DRG 496 and reassign it to DRGs 497 and 498. The commenter stated that MedPAR data indicate that this procedure is less expensive than other procedures classified to DRG 496.

Response: We agree with the commenters that code 81.61 should be removed from DRG 496 and reassigned to DRGs 497 and 498. We also agree that the data for code 81.61 should be reviewed in the future to determine if additional DRG revisions are warranted.

Comment: Several commenters opposed our proposal to remove procedure code 81.61 from DRG 496 and to reassign it to DRGs 497 and 498. The commenters believed that CMS' reasoning was flawed in three areas: clinical coherence, accurate coding, and the incentive for more efficient care.

First, the commenters believed that CMS did not fully address the clinical coherence of the cases, electing instead to make its proposal largely on the basis of charge coherence, alone. The commenters further believed that the combination of anterior and posterior fusions in a single surgery is the most appropriate for defining clinical characteristic of all cases currently included in DRG 496. The commenters stated that except for the number of

incisions, a 360-degree (anterior and posterior) fusion is clinically comparable to all other anterior and posterior fusions because of the patient and the surgical characteristics.

Second, the commenters expressed concerns that a significant number of 360-degree single-incision spinal fusion cases were inaccurately coded. The commenters pointed out that the data we used to examine the reporting of code 81.61 (which was created on October 1, 2002) represented only the first year of the use of the code. The commenters suggested that a significant number of 360-degree single-incision spinal fusion cases were incorrectly coded as involving a two-incision approach. Thus, these cases should have been correctly assigned to DRG 496, but were mislabeled as involving a two-incision approach. One commenter stated that, as a manufacturer, it provides a coding hotline for hospitals with questions related to spinal cases. For the period January 2003 through April 2004, 20 percent (113 out of 563) of the total calls related to accurate coding of this procedure.

One commenter stated that a high rate of coding errors is not surprising in the first year of use, given that code 81.61 just became effective for FY 2003, that 360-degree spinal fusion is a complex topic, and that misinformation may

have been given. The commenter recommended that consideration of a reclassification be held for at least another year or two to ensure that a sufficient volume of more accurate data can be collected and analyzed.

Third, with regard to the issue of DRGs serving as an incentive for more efficient care, the commenters believed that CMS proposed the reassignment of code 81.61 to avoid lowering the relative weight for DRG 496 in the future. They stated that, by contrast, CMS has often maintained in the past that the DRG weighting process allows changes in the resource intensity of specific types of cases (whether upward or downward) to be reflected over time, as technology evolves. The commenters indicated that the single-incision method may be less time-consuming, use fewer hospital resources, and allow patients to enjoy a shorter recovery period. The commenters stated that collection and analysis of additional and more accurate data may well show this. However, the commenters recommended that we leave code 81.61 in DRG 496 as a financial incentive for providers to perform the lower-resource procedure. The commenters believed this would lead to the reduction of the relative weight for DRG 496 as more providers performed the less expensive procedure (single-incision anterior/posterior fusion). The commenters stated that the weighting process in DRG 496 is ideally designed to accomplish the goal of having hospitals perform a procedure that requires less resources.

Response: We do not agree with the commenters' suggestions that our analysis did not fully address the clinical coherence of the cases or that our analysis was based largely on charge coherence alone. As we stated in the proposed rule, anterior and posterior fusions of the spine using one incision are quite different from those fusions involving two incisions of the spine. The patient endures a more extensive surgery when incisions to the spine are made using approaches from both the front and back of the patient. The surgery and recovery time are longer when two incisions are made into the patient. While we agree that the charge data support our proposal, we disagree that we ignored clinical differences in these two approaches.

We acknowledge that there have been a number of questions concerning the use of code 81.61. This code has been discussed at the Editorial Advisory Board on Coding Clinic for ICD-9-CM. Based on some of the records sent to the Board, it would appear that some hospitals are incorrectly applying this code. The Board is attempting to

develop additional educational material to include in future issues of *Coding Clinic for ICD-9-CM*.

However, as we discussed in the proposed rule, cases reported with code 81.61 had average charges that are significantly lower than spinal fusions using two approaches. Approximately 30 percent (829) of the 2,706 DRG 496 cases reported code 81.61. The 360-degree spinal fusion cases had average charges that were only 68 percent of those for all cases in DRG 496. The average charge for all cases in DRG 496 was \$74,967.33, while the average charge for DRG 496 cases with code 81.61 was only \$50,659.69. There were also significant differences in the length of stay. The average length of stay for all cases in DRG 496 was 8.0 days, while it was only 4.7 days for cases with code 81.61.

While there may be some confusion in the correct coding of 360 degree spinal fusions with a single incision, there are significant differences in the charges of those reported cases with 360 degree spinal fusion, single incision approach. If we were to keep code 81.61 in DRG 496, the result would be a lowering of the weight for DRG 496 in future years. We discussed this issue with our medical advisors who agreed that the data and clinical similarities support our proposal to remove code 81.61 from DRG 496 and reassign it to DRGs 497 and 498. The nature of the surgery and the charges are similar to other cases in DRGs 497 and 498.

We believe that the commenters' argument that leaving code 81.61 in DRG 496 would subsequently lead to a lowering of the relative weight for DRG 496 because it would increasingly consist of cases involving a single incision approach that would have lower charges seems to confirm CMS' suggestion that the single incision approaches are significantly less resource intensive as well as less surgically invasive than the two-incision approaches. Therefore, we do not believe these cases belong in DRG 496 along with the more extensive surgeries.

Comment: One commenter opposed moving code 81.61 from DRG 496 and into DRGs 497 and 498. The commenter stated that the amount of time it takes to perform a single incision 360-degree spinal fusion is similar to that of performing an anterior and posterior spinal fusion with two approaches. The commenter stated that any extra time in completing the surgery involves turning the patient over so that the separate approach (incision) can be made. The commenter stated that, in his hospital, the length of stay for one incision versus

two incision approaches to spinal fusion does not vary significantly.

Response: While the commenter's hospital may have similar length of stays for patients who have single versus two incision approaches to spinal fusion, our national data show a significant difference. As stated earlier, the average length of stay for DRG 496 was 8.0 days, while that for cases with code 81.61 was 4.7 days. We believe the data support this DRG change.

Therefore, we are adopting as final our proposal to remove code 81.61 from DRG 496 and reassign it to DRGs 497 and 498. We will examine data for cases reporting 81.61 in future years to determine if additional DRG modifications are needed.

b. Multiple Level Spinal Fusion

On October 1, 2003 (68 FR 45596), the following new ICD-9-CM procedure codes were created to identify the number of levels of vertebra fused during a spinal fusion procedure:

- 81.62, Fusion or refusion of 2-3 vertebrae.
- 81.63, Fusion or refusion of 4-8 vertebrae.
- 81.64, Fusion or refusion of 9 or more vertebrae.

Prior to the creation of these new codes, we received a comment recommending the establishment of new DRGs that would differentiate between the number of levels of vertebrae involved in a spinal fusion procedure. In the August 1, 2003, final rule, we discussed the creation of these new codes and the lack of sufficient MedPAR data with the new multiple level spinal fusion codes (68 FR 45369). The commenter had conducted an analysis and submitted data to support redefining the spinal fusion DRGs. The analysis found that increasing the levels fused from 1 to 2 levels to 3 levels or more levels increased the mean standardized charges by 38 percent for lumbar/thoracic fusions, and by 47 percent for cervical fusions.

The following current spinal fusion DRGs separate cases based on whether or not a CC is present: DRG 497 (Spinal Fusion Except Cervical With CC) and DRG 498 (Spinal Fusion Except Cervical Without CC); DRG 519 (Cervical Spinal Fusion With CC) and DRG 520 (Cervical Spinal Fusion Without CC). However, the difference in charges associated with the current CC split was only slightly greater than the difference attributable to the number of levels fused as found by the commenter's analysis. In addition, adopting the commenter's recommendation would have necessitated adjusting the DRG relative weights using non-MedPAR data

because Medicare claims data with the new ICD-9-CM codes would not have been available until the FY 2003 MedPAR file. Therefore, at that time, we did not redefine the spinal fusion DRGs to differentiate on the basis of the number of levels of vertebrae involved in a spinal fusion procedure.

We did not yet have any reported cases utilizing the new multilevel spinal fusion codes in our data. We stated that we would wait until sufficient data with the new multilevel spinal fusion codes were available before making a final determination on whether multilevel spinal fusions should be incorporated into the spinal fusion DRG structure. The codes went into effect on October 1, 2003, and we have not received any data using these codes. Spinal surgery is an area of rapid changes. In addition, we have created a series of new procedure codes that describe a new type of spinal surgery, spinal disc replacement. (See codes 84.60 through 84.69 in Table 6B in the Addendum to this final rule that will go into effect on October 1, 2004.) Our medical advisors describe this new surgical procedure as a more conservative approach for back pain than the spinal fusion surgical procedure. With only limited data concerning multiple level spinal fusion and the rapid changes in spinal surgery, we believed it was more prudent not to propose the establishment of new DRGs based on the number of levels of vertebrae involved in a spinal fusion procedure in the May 18, 2004, proposed rule.

In addition, no other surgical DRG is split based on the number of procedures performed. For instance, the same DRG is assigned whether one or more angioplasties are performed on a patient's arteries. The insertion of multiple stents within an artery does not result in a different DRG assignment. Similarly, the excision of neoplasms from multiple sites does not lead to a different DRG assignment. To begin splitting DRGs based on the number of procedures performed or devices inserted could set a new and significant precedent for DRG policy. Therefore, in the May 18, 2004, proposed rule, we indicated that while we would continue to study this area, we did not propose to redefine the spinal fusion DRGs based on the number of levels of vertebrae fused.

Comment: Several commenters supported our proposal not to modify the spinal fusion DRGs to differentiate between the number of levels of vertebrae involved in a spinal fusion procedure. The commenters agreed that we should wait until we received sufficient data with the new multilevel

spinal fusion codes to propose any new DRG revisions for using these codes.

Response: We agree with the commenters that it would be premature to propose DRG revisions to the spinal fusion DRGs based on the new multiple level spinal fusion codes. Furthermore, as stated in the proposed rule, no other surgical DRG is split based on the number of procedures performed. To do so would have the potential of dramatically increasing the number of DRGs. Therefore, it would be prudent to wait for claims data prior to considering such a departure from the current DRG structure.

Comment: One commenter who supported our recommendation expressed concern that our decision was grounded in part on the expectation that a "more conservative" surgical approach for back pain (that is spinal disc replacement) will be available soon. (In the proposed rule, we noted that new codes for spinal disc prosthesis procedures, codes 84.60 through 84.69, will go into effect on October 1, 2004.) The commenter stated that FDA has not approved some of the spinal disc prostheses. The commenter believed that this new technology may not become a medically accepted procedure in the clinical community. The commenter believed that we were implying that we would defer a decision on modification of the spinal fusion DRGs until such time as the FDA formally approves spinal disc prosthesis procedures. The commenter recommended that the spinal fusion DRGs should not be modified at this point; that CMS should wait for data using the multiple level spinal fusion codes prior to proposing modifications of the spinal fusion DRGs; and that CMS not wait to make any modifications to these DRGs based upon FDA approval of spinal disc prostheses.

Response: We agree with the commenter that we should wait to evaluate claims data with the new multilevel spinal fusion codes before using these codes to revise the DRG structure. While we mentioned that new codes were created for FY 2005 for other types of spinal procedures, such as spinal disc prostheses, we did not mean to imply that we would defer analysis on multilevel spinal fusion until such time as the FDA reviews and approves other specific types of procedures and devices. We acknowledge that different types of procedures should be considered independently.

In this final rule, we are maintaining the current DRG structure for the spinal fusion DRGs. We will wait for claims data on the new codes to become available before we consider proposing

future revisions to the spinal fusion DRGs.

c. Insertion of Spinal Disc Prostheses and Other Spinal Devices

In the May 18, 2004, proposed rule, we included in Table 6B of the Addendum new codes that were created to capture the insertion of spinal disc prostheses and other spinal devices (codes 84.59 through 84.69). We proposed to assign these new codes to DRGs 499 and 500 (Back and Neck Procedures Except Spinal Fusion with and without CC, respectively) within MDC 8. Shortly after publication of the proposed rule, we discovered errors of omission in the assignment of these codes within the MDCs in Table 6B. These codes should have also included DRG assignments within MDC 1, MDC 21, and MDC 24, in addition to the specified assignment to MDC 8. We corrected these errors of omission in a correction notice published on June 25, 2004 (69 FR 35716). The correction notice showed the following additional DRG assignments for these codes:

MDC 1, DRGs 531 and 532 (Spinal Procedures With and Without CC, respectively).

MDC 21, DRGs 442 and 443 (Other Procedure for Injuries With and Without CC, respectively).

MDC 24, DRG 486 (Other Procedures for Multiple Significant Trauma).

The official ICD-9-CM code conversion table showed code 80.51 (Excision of intervertebral disc) as the predecessor code for codes 84.60 through 84.69. There was no predecessor code listed for code 84.59. Code 80.51 was assigned to DRGs 499 and 500 in MDC 8. It was also assigned to DRGs 531 and 532 in MDC 1, DRGs 442 and 443 in MDC 21, and DRG 486 in MDC 24.

By correcting the proposed DRG assignment information for codes 84.59 and 84.60 through 84.69, we clearly indicated our proposal of assigning these codes 84.59 and 84.60 through 84.69 to DRGs 531 and 532 in MDC 1; DRGs 499 and 500 in MDC 8; DRGs 442 and 443 within MDC 21; and DRG 486 in MDC 24.

Comment: Several commenters that are developing spinal disc prosthesis devices described these spinal disc prostheses devices as minimally invasive alternatives to spinal fusion. The commenters indicated that there is controversy among spine surgeons as to the cause, or causes, of back pain. However, they stated that many surgeons believe degeneration of the nucleus and annular destruction is a major source of pain. The commenters stated that if patients fail conservative

treatment, spinal fusion is currently the primary treatment option. The commenters further stated that fusing one or more levels in the spine results in increased stress and strain and the potential breakdown at adjacent disc levels. In addition, the commenters stated that partial and total spinal disc replacement prosthesis devices were designed to replace the degenerated nucleus or disc and restore the normal disc function and anatomy. They believed these devices have the potential of decreasing stress, which is redistributed to adjacent levels of the spine when spinal fusions are performed. The commenters indicated that fusion surgery patients have poor return to work results, that recovery periods are extended, and that the spinal disc prosthesis devices reduce this recovery period.

The commenters objected to the proposed assignment of the new spinal disc prosthesis codes (84.60 through 84.69) to DRGs 499 and 500 in MDC 8. The commenters stated that since total and partial spinal disc prostheses will be used for patients who would very likely be candidates for spinal fusion, the procedures should be assigned to DRGs 497 and 498 for those in the lumbar spine and to DRGs 519 and 520 for those implanted in the cervical spine. One commenter compared the implantation of a total spinal disc prosthesis device in the lumbar spine to that of fusion of the lumbar spine with the use of a BAK cage. The commenter stated that both use an anterior approach to the surgery, and both involve implanting devices in the anterior part of the spine. One procedure involves implanting the spinal disc prosthesis; the other involves implanting a BAK cage while fusing the spine.

The commenters stated that the costs of treating these types of patients with spinal disc prosthesis devices are also similar to the costs for those patients in the spinal fusion DRGs. One commenter stated that the operating room time would be similar, with the total lumbar disc prosthesis devices taking about 111 minutes and the lumbar fusion with a BAK cage taking 114 minutes. The commenter presented information to show a patient stay of 3.7 days for the total lumbar disc prosthesis procedures versus 4.3 days for the lumbar fusion with BAK cages. One commenter stated that the cost of the total disc prosthesis is approximately \$10,585, compared to \$4,800 for a BAK cage used in a lumbar fusion.

Response: Based on advice from our medical advisors, we disagree with the suggestion that patients having partial

and total spinal disc prosthesis procedures are clinically similar to patients assigned to the spinal fusion DRGs. To mix these two distinctly different approaches to the treatment of back pain would violate the principal of clinical cohesiveness of DRGs. DRGs 497, 498, 519, and 520 include only procedures that involve fusion of the spine. DRGs 499 and 500 include a number of other procedures performed on the spine and explicitly exclude spinal fusion procedures. Currently, spinal disc prosthesis procedures are assigned to code 80.51 (Excision of intervertebral disc). The new, more specific codes (84.60 through 84.69) will go into effect on October 1, 2004. As stated earlier, code 80.51 is assigned to DRGs 499 and 500 within MDC 8. Our proposal of assigning the new spinal disc prosthesis codes to DRGs 499 and 500 would maintain current practice based on the assignment of the predecessor code 80.51. Our medical advisors also stated that it would be inappropriate to move the partial and total spinal disc procedures to the spinal fusion DRGs because the implantation of these disc devices do not involve fusion of the spine. We do not yet have any charge data on these new types of spinal procedures because the codes are being implemented on October 1, 2004. Thus, it would also be premature to assign these new procedures to the fusion DRGs.

In this final rule, we are assigning the total and partial spinal disc procedures and other spinal devices (codes 84.59 and codes 84.60 through 84.69) to DRGs 499 and 500 within MDC 8 as proposed. We will continue to monitor data on these procedures as their use increases to determine if future DRG modifications are needed.

d. Kyphoplasty

In the May 18, 2004, proposed rule, in Table 6B of the Addendum, we included new ICD-9-CM codes that go into effect October 1, 2004. Among these new codes are codes 81.65 (Vertebroplasty) and 81.66 (Kyphoplasty). We added these new codes to better differentiate between the surgical procedures of vertebroplasty and kyphoplasty. Both procedures are currently assigned to code 78.49 (Other repair or plastic operation on bone) and are assigned to the DRGs 223 and 234 in MDC 8, DRGs 442 and 443 in MDC 21, and DRG 486 in MDC 24.

In the May 18, 2004, proposed rule, we proposed to assign both new codes 81.65 and 81.66 to the same DRGs to which code 78.49 is assigned.

Comment: Several commenters supported the creation of the new

procedure codes for kyphoplasty and vertebroplasty. However, some of the commenters opposed the assignment of code 81.66 to DRGs 233 and 234 in MDC 8. The commenters stated that kyphoplasty is a significantly more resource intensive procedure than vertebroplasty and requires special inflatable bone tamps and bone cement. The commenters further stated that while kyphoplasty involves internal fixation of the spinal fracture and restoration of vertebral height, vertebroplasty involves only fixation. The commenters indicated that kyphoplasty procedures are more akin to spinal fusion and should be assigned to DRGs 497 and 498 (Spinal Fusion Except Cervical With and without CC, respectively) in MDC 8. The commenters did not object to the DRG assignments for MDC 21 or MDC 24 for kyphoplasty, or to the proposed DRG assignments for 81.65.

Response: Commenters supported the creation of the new procedure codes for kyphoplasty and vertebroplasty. The commenters indicated that kyphoplasty is more resource intensive than vertebroplasty and is more similar to resources used in a spinal fusion. However, we do not have data to support this claim because the new codes will not be implemented until October 1, 2004. We believe that it would be premature to consider DRG refinements using these new ICD-9-CM procedure codes at this time.

Therefore, we are adopting, as final, our proposed assignment of new codes 81.65 and 81.66 to DRGs 223 and 234 in MDC 8, DRGs 442 and 443 in MDC 21, and DRG 486 in MDC 24, as indicated in Table 6B of the Addendum to this final rule. We will take the commenters' recommendation into consideration when we conduct our annual reviews of MedPAR data.

6. MDC 15 (Newborns and Other Neonates With Conditions Originating in the Perinatal Period)

In the May 18, 2004, proposed rule, we indicated that we continue to receive comments that MDC 15 (Newborn and Other Neonates With Conditions Originating in the Perinatal Period) does not adequately capture care provided for newborns and neonates by hospitals. The commenters pointed out that we have not updated the DRGs within MDC 15 as we have for other parts of the DRG system.

Our primary focus of updates to the Medicare DRG classification system is on changes relating to the Medicare patient population, not the pediatric or neonatal patient populations. However, we acknowledge the Medicare DRGs are

sometimes used to classify other patient populations. Over the years, we have received comments about aspects of the Medicare newborn DRGs that appear problematic, and we have responded to these on an individual basis. In the May 9, 2002, IPPS proposed rule (67 FR 31413), we proposed extensive changes to multiple DRGs within MDC 15. Because of our limited data and experience with newborn cases under Medicare, we contacted the National Association of Children's Hospitals and Related Institutions (NACHRI) to obtain proposals for possible revisions of the DRG categories within MDC 15. We received extensive comments opposing these revisions. Therefore, we did not implement the proposals.

We advise those non-Medicare systems that need a more up-to-date system to choose from other systems that are currently in use in this country, or to develop their own modifications. As previously stated, we do not have the data or the expertise to develop more extensive newborn and pediatric DRGs. Our mission in maintaining the Medicare DRGs is to serve the Medicare population. Therefore, we will make only minor corrections of obvious errors to the DRGs within MDC 15. In the May 18, 2004, IPPS proposed rule, we indicated that we did not plan to conduct a more extensive analysis involving major revisions to these DRGs.

Comment: Commenters, including several national hospital associations, supported our proposal not to undertake a major revision to MDC 15 at this time, but instead to address specific errors brought to our attention by providers and other commenters. One commenter, a national organization representing health information managers and coders, agreed with our approach to updating MDC 15 without undertaking a major revision. The commenter stated it believed a comprehensive revision of MDC 15 should not be undertaken without broad input from all types of hospitals that provide care for neonates to ensure the appropriateness of these DRG revisions across all institutions treating newborns. The commenter indicated that, given CMS' limited data and experience with newborn cases, it supported CMS' decision not to conduct a major overhaul of the newborn DRGs. However, the commenter agreed that CMS should address specific, individual requests for modifications to the newborn DRGs on a case-by-case basis.

One commenter who supported our proposal indicated that there are challenges to developing DRG classifications systems and applications appropriate to children. The commenter acknowledged the practical difficulties

of CMS assuming a larger role in this area, given the difference between the Medicare population and that of newborns and children. The commenter stated that there are evolving alternative DRG classification systems for children. The commenter agreed that a broad-based fundamental restructuring of the neonatal DRGs would be a huge and complex undertaking and indicated that there are other DRG classification systems that are attempting at varying levels of sophistication to do this restructuring for the neonatal and pediatric patient populations. The commenter supported our approach of responding to specific requests for updating MDC 15 on a case-by-case basis.

Response: We appreciate the commenters' support for our decision to perform only limited updates to MDC 15 based on specific requests for modification. We will continue to address specific requests for modification of the newborn DRGs on an individual basis.

In the IPPS final rule for FY 2004 (68 FR 45360), we added heart failure diagnosis codes 428.20 through 428.43 to the list of secondary diagnosis of major problem under DRG 387 (Prematurity With Major Problems) and DRG 389 (Full-Term Neonate With Major Problems). We received a comment after the August 1, 2003 final rule stating that we should add the following list of combination codes, which also include heart failure, to the list of major problems under DRGs 387 and 389:

- 398.91, Rheumatic heart failure (congestive).
- 402.01, Malignant hypertensive heart disease, with heart failure.
- 402.11, Benign hypertensive heart disease, with heart failure.
- 402.91, Unspecified hypertensive heart disease, with heart failure.
- 404.01, Malignant hypertensive heart and renal disease, with heart failure.
- 404.03, Malignant hypertensive heart and renal disease, with heart failure and renal failure.
- 404.11, Benign hypertensive heart and renal disease, with heart failure.
- 404.13, Benign hypertensive heart and renal disease, with heart failure and renal failure.
- 404.91, Unspecified hypertensive heart and renal disease, with heart failure.
- 404.93, Unspecified hypertensive heart and renal disease, with heart failure and renal failure.
- 428.9, Heart failure, unspecified.

We agree that the codes listed above also include heart failure and should

also be added to DRGs 387 and 389 as major problems. Therefore, in the May 18, 2004, proposed rule, we proposed to add the heart failure codes listed above to DRGs 387 and 389 as major problems.

Comment: Several commenters supported the addition of the combination codes, including heart failure, to the list of major problems under DRGs 387 and 389 because there are a number of other heart failure codes already listed as major problems under DRGs 387 and 389.

Response: We appreciate the support of the commenters for our proposal.

In this final rule, we are adopting, as final without modification, the proposed revisions to add the specified combination codes to the list of major problems under DRGs 387 and 389.

7. MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders): Drug-Induced Dementia

In the May 18, 2004, proposed rule, we discussed a request that we had received from a commenter that we remove the principal diagnosis code 292.82 (Drug-induced dementia) from MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders) and the following DRGs under MDC 20:

- DRG 521 (Alcohol/Drug Abuse or Dependence With CC).
- DRG 522 (Alcohol/Drug Abuse or Dependence With Rehabilitation Therapy Without CC).
- DRG 523 (Alcohol/Drug Abuse or Dependence Without Rehabilitation Therapy Without CC).

The commenter indicated that a patient who has a drug-induced dementia should not be classified to an alcohol/drug DRG. However, the commenter did not propose a new DRG assignment for code 292.82.

Our medical advisors evaluated the request and determined that the most appropriate DRG classification for a patient with drug-induced dementia would be within MDC 20. The medical advisors indicated that because this mental condition is drug induced, it is appropriately classified to DRGs 521 through 523 in MDC 20. Therefore, we did not propose a new DRG classification for the principal diagnosis code 292.82.

Comment: Several commenters supported our proposal not to modify DRGs 521 through 523 by removing code 292.82. One commenter representing hospital coders disagreed with our proposal to retain code 292.82 in DRGs 521 through 523. The commenter stated that DRGs 521 through 523 are described as alcohol/drug abuse and dependence DRGs. The

commenter further indicated that drug-induced dementia could be caused by an adverse effect of a prescribed medication or a poisoning. The commenter did not believe that assignment of drug-induced dementia to DRGs 521 through 523 was appropriate if the drug-induced dementia is related to an adverse effect or poisoning due to a prescribed drug. The commenter recommended that admissions for drug-induced dementia be classified to DRGs 521 through 523 only if there is a secondary diagnosis indicating alcohol/drug abuse or dependence.

The commenter further recommended that drug-induced dementia that is due to the adverse effect of drugs be classified to the same DRGs as other types of dementia, such as DRG 429 (Organic Disturbances and Mental Retardation). The commenter stated that when drug-induced dementia is caused by a poisoning, either accidental or intentional, the appropriate poisoning code would be sequenced as the principal diagnosis and, therefore, these cases would likely already be assigned to DRGs 449 and 450 (Poisoning and Toxic Effects of Drugs, Age Greater Than 17, With and Without CC, respectively) and DRG 451 (Poisoning and Toxic Effects of Drugs, Age 0–17). The commenter suggested that these DRG assignments would be the appropriate DRG assignments for drug-induced dementia due to a poisoning.

Response: We have considered the issues raised by the commenters relating to the DRG assignment for code 292.82 and the suggested alternatives for DRG assignment based on sequencing of the principal diagnosis and reporting of additional secondary diagnoses. We acknowledge that patients do develop drug-induced dementia from drugs that are prescribed as well as from drugs that are not prescribed. However, we still believe that dementia developed as a result of use of a drug is appropriately assigned to DRGs 521 through 523, as mentioned by the commenters who supported the current assignment. We also agree that if the drug-induced dementia is caused by a poisoning, either accidental or intentional, the appropriate poisoning code should be sequenced as the principal diagnosis. As the commenter stated, these cases would be assigned to DRGs 449 through 451.

We will continue to evaluate the DRG assignment for this code during the next year and further consider the alternative

DRG structures suggested by the commenters, if warranted. We will also further examine the use of secondary diagnoses as a means of better classifying patients with drug-induced dementia and consider alternative DRG assignments such as those mentioned by the commenters. We also encourage hospitals to examine the coding for these types of cases to determine if there are any coding or sequencing errors.

We are adopting as final our proposal to maintain the current structure of DRGs 521 through 523. However, we will continue to examine the issue to determine whether any changes to the structure of these DRGs are warranted.

8. MDC 22 (Burns): Burn Patients on Mechanical Ventilation

In the May 18, 2004, proposed rule (69 FR 28211), we discussed concerns that had been raised by hospitals treating burn patients that the current DRG payment for burn patients on mechanical ventilation is not adequate. The DRG assignment for these cases depends on whether the hospital performed the tracheostomy or the tracheostomy was performed prior to transfer to the hospital. If the hospital does not actually perform the tracheostomy, the case is assigned to one of the burn DRGs in MDC 22 (Burns). If the hospital performs a tracheostomy, the case is assigned to Pre-MDC DRG 482 (Tracheostomy for Face, Mouth, and Neck Diagnoses) or DRG 483 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses).

In the August 1, 2002, final rule, we modified DRGs 482 and 483 to recognize code 96.72 (Continuous mechanical ventilation for 96+ hours) for the first time in the DRG assignment (67 FR 49996). The modification was partially in response to concerns that hospitals could omit diagnosis codes indicating face, mouth, or neck diagnoses in order to have cases assigned to DRG 483 rather than the much lower paying DRG 482 (the payment for DRG 483 is more than four times greater than the DRG 482 payment weight). In addition, we noted that many patients assigned to DRG 483 did not have code 96.72 recorded. We believed this was due, in part, to the limited number of procedure codes (six) that can be submitted on the current billing form and the fact that code 96.72 did not affect the DRG assignment prior

to FY 2003. The modification was the first attempt to refine DRGs 482 and 483 so that patients who receive long-term mechanical ventilation for more than 96 hours are differentiated from those who receive mechanical ventilation for less than 96 hours. The modification was intended to ensure that patients who have a tracheostomy and continuous mechanical ventilation greater than 96 hours (code 96.72) would be assigned to DRG 483. By making the GROUPER recognize long-term mechanical ventilation and assigning those patients to the higher weighted DRG 483, we encouraged hospitals to be more aware of the importance of reporting code 96.72 and to increase reporting of code 96.72 when, in fact, patients had been on the mechanical ventilator for greater than 96 hours. We stated in the August 1, 2002 final rule that, once we received more accurate data, we would give consideration to further modifying DRGs 482 and 483 based on the presence of code 96.72.

As we indicated in the May 18, 2004, proposed rule, to assess the DRG payments for burn patients on mechanical ventilation, we analyzed FY 2003 MedPAR data for burn cases in the following DRGs to determine the frequency for which these burn cases were treated with continuous mechanical ventilation for 96 or more consecutive hours (code 96.72):

- DRG 483 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses).
- DRG 504 (Extensive 3rd Degree Burns With Skin Graft).
- DRG 505 (Extensive 3rd Degree Burns Without Skin Graft).
- DRG 506 (Full Thickness Burn With Skin Graft or Inhalation Injury With CC or Significant Trauma)
- DRG 507 (Full Thickness Burn With Skin Graft or Inhalation Injury Without CC or Significant Trauma)
- DRG 508 (Full Thickness Burn Without Skin Graft or Inhalation Injury With CC or Significant Trauma)
- DRG 509 (Full Thickness Burn Without Skin Graft or Inhalation Injury Without CC or Significant Trauma)
- DRG 510 (Nonextensive Burns With CC or Significant Trauma)
- DRG 511 (Nonextensive Burns Without CC or Significant Trauma)

The following chart summarizes those findings:

DRG	Count	Average Length of Stay	Average Charges
483 All cases	31,754	37.68	\$210,631.94
483 Cases with code 96.72 reported	19,669	36.54	\$195,171.66
483 Cases without code 96.72 reported	12,085	39.52	\$235,794.39
504 All cases	98	30.54	\$191,645.49
504 Cases with code 97.62 reported	19	25.79	\$264,095.16
504 Cases without code 96.72 reported	79	31.68	\$174,220.89
505 All cases	119	2.96	\$18,619.78
505 Cases with code 96.72 reported	20	7.70	\$42,613.00
505 Cases without code 96.72 reported	99	2.00	\$13,772.67
506 All cases	754	16.15	\$61,370.63
506 Cases with code 96.72 reported	54	20.13	\$138,272.46
506 Cases without code 96.72 reported	700	15.85	\$55,438.20
507 All cases	236	8.78	\$25,891.89
507 Cases with code 96.72 reported	1	38.00	\$137,132.00
507 Cases without code 96.72 reported	235	8.66	\$25,418.53
508 All cases	448	7.02	\$18,332.46
508 Cases with code 96.72 reported	5	10.40	\$83,171.80
508 Cases without code 96.72 reported	443	6.98	\$17,600.64
509 All cases	117	4.32	\$8,994.71
509 Cases with code 96.72 reported	0	0	0
509 Cases without code 96.72 reported	117	4.32	\$8,994.71
510 All cases	1,209	6.90	\$18,457.21
510 Cases with code 96.72 reported	21	20.52	\$93,925.62
510 Cases without code 96.72 reported	1,188	6.66	\$17,123.18
511 All cases	413	4.18	\$10,046.89
511 Cases with code 96.72 reported	0	0	0
511 Cases without code 96.72 reported	413	4.18	\$10,046.89

We found 120 cases that reported code 96.72 within the 3,394 burn DRG cases (DRGs 504 through 511). Cases reporting code 96.72 have significantly longer average lengths of stay and average charges. The majority (54) of these cases that reported code 96.72 were in DRG 506. The cases with code 96.72 reported had average charges approximately 1.5 times higher than other cases in DRG 506 without code 96.72.

We noted that there were 21 cases that reported code 96.72 within DRG 510. Since the 21 patients were on continuous mechanical ventilation for 96 consecutive hours or more, it seems surprising that the principal diagnosis was listed as one of the nonextensive burn codes included in DRG 510. A closer review of these cases shows some questionable coding and reporting of

information. It would appear that hospitals did not always correctly select the principal diagnosis (the reason after study that led to the hospital admission). For instance, one admission was for a second-degree burn of the ear. This patient was on a ventilator for over 96 hours. It would appear that the reason for the admission was a diagnosis other than the burn of the ear. Other cases where the patient received long-term mechanical ventilation included those with a principal diagnosis of first degree burn of the face, second degree burn of the nose, second degree burn of the lip, and an unspecified burn of the foot. These four cases reported average charges ranging from \$48,551 to \$186,824 and had lengths of stay ranging from 8 to 36 days.

The impact of long-term mechanical ventilation is quite clear on burn cases as was shown by the data above. Therefore, in the May 18, 2004, proposed rule, we proposed to modify the burn DRGs 504 through 509 under MDC 22 to recognize this impact. We also proposed to modify DRG 504 and DRG 505 so that code 96.72 will be assigned to these DRGs when there is a principal or secondary diagnosis of extensive third degree burns or full thickness burns (those cases currently assigned to DRGs 504 through 509). In other words, when cases currently in DRGs 506 through 509 also have code 96.72 reported, they would now be assigned to DRGs 504 or 505. We also proposed to modify the titles of DRGs 504 and 505 to reflect the proposed changes in reporting code 96.72 as follows:

- Proposed DRG 504, (Extensive Burns or Full Thickness Burns With Mechanical Ventilation 96+ Hours With Skin Graft)

- Proposed DRG 505, (Extensive Burns or Full Thickness Burns With Mechanical Ventilation 96+ Hours Without Skin Graft)

Cases currently assigned to DRGs 504 and 505 that do not entail 96+ hours of mechanical ventilation will continue to be assigned to DRGs 504 and 505 because they would have extensive burns, as required by the DRG logic.

We did not propose to include DRG 510 and DRG 511 within this revised DRG logic. Cases currently assigned to DRG 510 or DRG 511 that also report code 96.72 would not be reassigned to DRGs 504 and 505. We recommended that hospitals examine cases that are assigned to DRG 510 or DRG 511 and that have code 96.72 to determine if there are possible coding problems or other issues. As stated earlier, in examining reported cases within DRG 510, we noted several cases with code 96.72 that appear to have an incorrect principal diagnosis. It would appear that the principal diagnosis may more appropriately be related to an inhalation injury, if the injury was present at the time of admission.

We solicited comments on our proposal to move cases reporting code 96.72 from DRGs 506 through 509 and assign them to DRGs 504 and 505. We also solicited comments on our proposal not to include DRGs 510 and 511 in this proposed revision.

Comment: Several commenters supported our recommended changes for the burn DRGs 504 through 509 under MDC 22. The commenters agreed that utilizing long-term mechanical ventilation of 96 or more hours (code 96.72) would assist in identifying the more expensive burn patients. One commenter stated that the proposed DRG changes would be greatly beneficial to burn center hospitals and to patients who have suffered burn injuries. The commenters supported the proposal to move cases reporting code 96.72 that are currently assigned to DRGs 506 through 509 into DRGs 504 and 505. The commenter also agreed with our proposal that cases assigned to DRGs 510 and 511 that also report code 96.72 should not be reassigned to DRGs 504 and 505, because the data cited appeared to indicate incorrect principal diagnoses were reported in these cases. The commenters also recommended that consideration be given to further refinements of DRGs 504 and 505. The commenters recommended that in the future CMS consider further DRG splits for cases in DRGs 504 and 505 that have

extensive third degree burns with an inhalation injury and 96+ hours of mechanical ventilation or perhaps creating a new DRG specifically for these patients.

Response: We appreciate the commenters' support of our proposal. As we indicated in the May 18, 2004, proposed rule and in our discussion of the reporting of code 96.72 in the August 1, 2002, IPPS final rule (67 FR 49996), we did not have data on cases of reported burns among patients who receive mechanical ventilation until the FY 2003 MedPAR data became available. In the FY 2003 IPPS final rule, we had asked hospitals to examine their coding and reporting practices and to begin reporting code 96.72 when burn patients were on long-term mechanical ventilation. Hospitals have now increased their reporting of code 96.72 among burn cases when patients were on long-term mechanical ventilation. With these improved data, in the proposed rule, we were able to identify the impact that mechanical ventilation had on the treatment of burn patients.

In the proposed rule, we discussed our concern that hospitals may have a sequencing problem for some reported cases of minor burns in which the patient was on long-term mechanical ventilation. We suggested that some of these patients may have been admitted to the hospital for an inhalation injury as opposed to a minor burn. The American Hospital Association (AHA) has reviewed our data and shares our concern. The AHA has informed us that it is drafting instructional material that will appear in *Coding Clinic for ICD-9-CM* to assist hospitals in sequencing the principal diagnosis for burn cases in which the patients have an inhalation injury and a minor skin burn.

We will continue to analyze cases assigned to the burn DRGs to determine if additional DRG refinements, such as the alternative suggestions mentioned by the commenters, are necessary.

Comment: Another commenter representing hospital coders expressed its support of the proposed restructuring of the burn DRGs to account for the use of mechanical ventilation. The commenter shared our concern about possible errors in the sequencing of diagnoses on claims resulting in a nonextensive burn being reported as the principal diagnosis instead of the more serious inhalation or respiratory condition that was the actual reason for the inpatient admission. The commenter asked that we encourage hospitals to review admissions assigned to DRG 510 or 511 that have a code for mechanical ventilation (codes 96.70 through 96.72) assigned in order to identify any coding

errors. The commenter recommended that hospitals identify cases in which poor medical record documentation resulted in miscoding of the reason for the inpatient admission or mechanical ventilation for burn patients. The commenter further recommended that hospitals use these cases as the basis for physician education to improve documentation practices.

Response: We appreciate the commenter's support of the proposed DRG changes for burn patients on mechanical ventilation. As we indicated in the proposed rule, we agree with the commenters' suggestion that hospitals should review their medical records for cases assigned to DRG 510 or 511 that had a code for mechanical ventilation to determine if there are coding errors. We agree that it is important for hospitals to have good medical record documentation in order to code accurately.

After analysis of the public comments received, we are adopting, as final, our proposed changes to the burn DRGs. In summary, we are modifying DRGs 504 and 505 so that cases in which there is a principal diagnosis of extensive third degree burns or full thickness burns with code 96.72 reported are assigned to these two DRGs, rather than to DRGs 506 through 509. We are also changing the title of DRG 504 to "Extensive Burns or Full Thickness Burns With Mechanical Ventilation 96+ Hours With Skin Graft" and the title of DRG 505 to "Extensive Burns or Full Thickness Burns With Mechanical Ventilation 96+ Hours Without Skin Graft". We will continue to follow these DRGs to determine if additional changes are needed.

9. Pre-MDC: Tracheostomy

In the August 1, 2002, IPPS final rule (67 FR 49996), for FY 2003, we modified DRG 482 (Tracheostomy for Face, Mouth, and Neck Diagnoses) and DRG 483 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses) to recognize procedure code 96.72 (Continuous mechanical ventilation 96+ hours) in the DRG 483 assignment. As discussed above and in the proposed rule, we were concerned about an underreporting of code 96.72 and wanted to encourage increased reporting of this code.

In the May 18, 2004, proposed rule, we indicated that we had examined cases in the MedPAR file in which code 96.72 was reported within DRGs 482 and 483. The following chart illustrates the average charges and lengths of stays for cases within DRGs 482 and 483 with and without code 96.72 reported:

DRG	Count	Average Length of Stay	Average Charges
482 - All cases	3,557	11.77	\$ 45,419.10
482 - Cases with code 96.72	22	31.64	137,880.41
482 - Cases without code 96.72	3,535	11.64	44,843.67
483 - All cases	31,754	37.68	210,631.94
483 - Cases with code 96.72	19,669	36.54	195,171.66
483 - Cases without code 96.72	12,085	39.52	235,794.39

Of the 3,557 cases reported in DRG 482, only 22 cases reported code 96.72. These 22 cases did not have a tracheostomy performed. All 22 cases reported code 30.4 (Laryngectomy), which also leads to an assignment of DRG 482. It would appear that the long-term mechanical ventilation was performed through an endotracheal tube instead of through a tracheostomy. While the average charges for DRG 482 cases with code 96.72 reported were significantly higher than the average charges for other cases in the DRG, we did not believe that the very limited number of cases (22) warranted a proposed DRG modification. Therefore, we did not propose any modification for DRG 482. In the May 18, 2004, IPPS proposed rule, we indicated that we will continue to monitor cases assigned to this DRG.

We did not receive any comments on our proposal not to modify DRG 482 and, therefore, are not making any changes to the DRG in this final rule.

In the proposed rule we stated that in DRG 483, 19,669 cases were reported with code 96.72. However, we noted that the data were counter-intuitive. While one would expect to find higher average charges for cases reported with code 96.72, the opposite is the case. Cases in DRG 483 reported with code 96.72 had average charges that were \$40,623 lower than those not reported with code 96.72. Clearly, the presence or absence of code 96.72 does not explain differences in charges for patients within DRG 483.

As stated earlier, we are concerned that hospitals may not always report code 96.72 because of space limitations. The electronic billing system limits the

number of procedure codes that can be reported to six codes. We then looked at whether or not another major O.R. procedure was performed in addition to a tracheostomy. The DRG 483 logic requires that all patients assigned to DRG 483 have a tracheostomy. We examined cases in DRG 483 in the MedPAR file and discovered that those patients in DRG 483 who had a major procedure performed in addition to the tracheostomy had higher charges. A major procedure is a procedure whose code is included on the list that would be assigned to DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), except for tracheostomy codes 31.21 and 31.29. Currently, this additional O.R. procedure does not affect the DRG assignment for cases assigned to DRG 483. The following chart reflects our findings.

DRG	Count	Average Length of Stay	Average Charges
483 - All Cases	31,754	37.68	\$210,631.94
483 - Cases with major O.R. procedure	15,664	42.70	\$255,914.00
483 - Cases without major O.R. procedure	12,867	32.7	\$168,890.20

We found that cases of patients assigned to DRG 483 who had a major procedure (in addition to the required tracheostomy) had average charges that were \$87,023 higher than the average charges for cases without a major O.R. procedure and had an average length of stay of 5 days more than those without a major O.R. procedure. We found that the performance of an additional major O.R. procedure helps to identify the more expensive patients within DRG 483.

Therefore, as a result of our findings, in the May 18, 2004, proposed rule, we proposed to modify DRG 483 by dividing these cases into two new DRGs depending on whether or not there is a major O.R. procedure reported (in

addition to the tracheostomy). We proposed to delete DRG 483 and create two new DRGs as follows:

- Proposed new DRG 541 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses With Major O.R. Procedure)
- Proposed new DRG 542 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses Without Major O.R. Procedure)

We solicited comments on our proposal to delete DRG 483 and replace it with two proposed new DRGs by splitting the assignment of cases on the

basis of the performance of a major O.R. procedure (in addition to the tracheostomy).

Comment: Some commenters supported our proposed changes to DRG 483. One commenter stated that, based on the data presented by CMS, the proposal appears to be a reasonable approach to distinguish the more expensive cases in DRG 483. The commenter also stated that hospitals are not always reporting code 96.72 due to space limitations (that is, the electronic billing system limits the number of procedures that can be reported to six procedure codes). The commenter stated that patients in this patient population (undergoing procedures with procedure code 96.72) may have several significant

O.R. procedures that may be sequenced before code 96.72, resulting in code 96.72 not appearing on the claim.

Response: We appreciate the commenters' support of our proposed DRG revision as a reasonable approach to distinguish the more expensive cases from the less expensive cases in DRG 483. We continue to encourage hospitals to report code 96.72 for patients on mechanical ventilation for 96+ hours.

Comment: Some commenters opposed our DRG change because of issues surrounding our proposed inclusion of DRG 483 as a DRG that would qualify for payment as a post-acute care transfer case.

Response: We are responding to the specific comments received regarding the proposed inclusion of DRG 483 under the postacute care transfer discussion in section IV.A. of the preamble of this final rule. The commenters did not provide other specific objections to the proposed deletion of DRG 483 and the proposed creation of new DRGs 541 and 542.

Comment: Several commenters requested clarification of what procedures would be classified as major O.R. procedures in relationship to our proposed changes to DRG 483.

Response: As we stated in the May 18, 2004 proposed rule, a major O.R. procedure is a procedure whose code is included on the list that would be assigned to DRG 468, except for tracheostomy codes 31.21 and 31.29. These are the procedure codes listed as O.R. procedures in Appendix E of the Diagnosis Related Groups Definitions Manual. The reporting of a major procedure with a procedure code from Appendix E, along with an unrelated principal diagnosis, results in a case being assigned to DRG 468. Major O.R. procedures do not include prostatic or nonextensive procedures, or both, which are assigned to DRGs 476 and 477.

Currently, the reporting of an additional major O.R. procedure code does not affect the DRG assignment for cases assigned to DRG 483. In the proposed rule, we proposed to modify this logic by deleting DRG 483 and creating two new DRGs 541 and 452 that are split on the basis of the performance of a major O.R. procedure (in addition to tracheostomy codes 31.21 and 31.29).

Comment: Several commenters agreed that the CMS data support the subdivision of DRG 483 based on the presence of an additional major O.R. procedure. They agreed that this approach helps to identify the more expensive patients within DRG 483. One commenter stated that the proposed modifications were valuable. Another

commenter stated that the proposed DRG revisions will better reflect the costs of furnishing care to these two categories of patients.

Response: We agree with the commenters that subdividing the cases assigned to DRG 483 based on the presence of an additional major O.R. procedure helps to identify the more expensive patients. We also agree that the proposed new DRGs should lead to more equitable payment for the more expensive tracheostomy cases. Therefore, we are proceeding with finalizing our proposal of deleting DRG 483 and replacing it with DRGs 541 and 542.

Comment: One commenter expressed concern regarding the proposed creation of a new DRG for mechanical ventilation as a pre-MDC for all patients undergoing more than 96 hours of mechanical ventilation. The commenter suggested that we delete DRG 475 (Respiratory System Diagnoses with Ventilator Support) from MDC 4 and move all of these cases reporting code 96.72 to a new DRG for mechanical ventilation in the pre-MDC section.

Response: Patients undergoing more than 96 hours of mechanical ventilation are captured through code 96.72.

Currently, patients with a respiratory system diagnosis listed in MDC 4 who receive mechanical ventilation are assigned to DRG 475. Cases are assigned to DRG 475 if one of the following procedure codes is reported:

- 96.70, Continuous mechanical ventilation of unspecified duration.
- 96.71, Continuous mechanical ventilation for less than 96 consecutive hours.
- 96.72, Continuous mechanical ventilation for 96 consecutive hours or more.

In the August 1, 2002, final rule (67 FR 49996), we discussed the reporting of code 96.72. We pointed out the importance of hospitals accurately reporting the use of long-term mechanical ventilation (code 96.72). We stated in the August 1, 2002, final rule that, once we received more accurate data, we would give consideration to further modifying DRGs 482 and 483 based on the presence of code 96.72. As discussed previously, in this final rule, we are modifying DRG 483 to differentiate between patients with and without other major O.R. procedures (in addition to the tracheostomy). We are also modifying the burn DRGs to better classify those patients on long-term mechanical ventilation.

As stated in the May 4, 2001, proposed rule (66 FR 22646): "Central to the success of the Medicare inpatient hospital prospective payment system is

that DRGs have remained a clinical description of why the patient required hospitalization." Thus, the central classification criteria for DRG assignment has been the reason the patient was admitted (that is, the principal diagnosis for medical patients and the procedures performed for surgical patients). For a medical patient admitted for respiratory disease, the use of mechanical ventilation was used as a classification criteria because the mechanical ventilation was directly associated with the reason for hospital admission. The one exception to this rule is for patients who received a tracheostomy for long-term mechanical ventilation. These are catastrophic patients who, in general, have serious disease in multiple organ systems. Tracheostomies are performed on patients when it is anticipated that the patients will remain on mechanical ventilation for an extended period. The tracheostomy patients with long-term mechanical ventilation were all assigned to the same DRG regardless of their reason for admission. As we discussed previously, we are subdividing the patients assigned to DRG 483 into two new DRG 541 and 542 based on the presence of an additional major O.R. procedure.

We believe it would not be appropriate to classify mechanical ventilation patients who do not receive a tracheostomy in the same manner as long-term mechanical ventilation patients who receive a tracheostomy. The patients who do not receive a tracheostomy tend to require mechanical ventilation for shorter periods and do not use the level of resources required by tracheostomy patients.

The reason for admission for patients with short-term mechanical ventilation can vary greatly and include degenerative nervous system diseases, short-term acute disease, trauma, and terminal care. Further, the resource requirements for patients on short-term mechanical ventilation vary greatly, depending on the patient's reason for admission. We believe it is more appropriate to classify patients with short-term mechanical ventilation based on their reason for admission and to provide additional payments for patients with extreme resource use through outlier payments. Therefore, we are not accepting the commenter's request that we delete DRG 475 and create a new DRG in the Pre-MDC section for mechanical ventilation. We will maintain DRG 475 as it is currently configured.

In summary, in this final rule, we are deleting DRG 483 and establishing the

following new DRGs 541 and 542 as replacements:

- DRG 541 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses With Major O.R. Procedure)

- DRG 542 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses Without Major O.R. Procedure)

10. Medicare Code Editor (MCE) Changes

As explained under section II.B.1. of this preamble, the Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. In the May 18, 2004, IPPS proposed rule (69 FR 28213), we proposed to make changes to three of the edits in the MCE.

a. Edit 11 (Noncovered Procedures) in the MCE contains codes that describe procedures for which Medicare does not provide reimbursement. In the proposed rule, we stated that we had received a request to remove procedure codes relating to stem cell transplants from Edit 11 to conform the MCE edit to our published coverage decisions in the Medicare Coverage Issues Manual. Chapter 13.5 of the Program Integrity Manual (PIM) states that contractor discretion exists to cover diagnoses for which coverage is not explicitly precluded by a national coverage decision. Specifically this section states: that “a local medical review policy (LMRP)” must be clear, concise, properly formatted and not restrict or conflict with NCDs or coverage provisions in interpretive manuals. If an NCD or coverage provision in an interpretive manual states that a given item is ‘covered for diagnoses/ conditions A, B, and C,’ contractors may not use that as a basis to develop LMRP to cover only “diagnosis/conditions A, B, C”. When an NCD or coverage provision in an interpretive manual does not exclude coverage for other diagnoses/conditions, contractors must allow for individual consideration unless the LMRP supports automatic denial for some or all of those other diagnoses/conditions.”

The national coverage decision on stem cell transplantation provides for coverage of certain diagnoses and excludes coverage for other diagnoses. However, the vast majority of diagnoses are not mentioned as either covered or noncovered. In accordance with the above-cited provision of the PIM, contractors must allow for individual consideration of these diagnoses. Thus,

they are not appropriate for inclusion in the edit for noncovered procedures.

In the proposed rule, we indicated that we agreed that we need to make conforming changes relating to stem cell transplants. Therefore, we proposed the following restructure of Edit 11:

This list contains ICD–9–CM procedure codes identified as “Noncovered Procedures” that are always considered noncovered procedures:

- 11.71, Keratomileusis
- 11.72, Keratophakia
- 11.75, Radial keratotomy
- 11.76, Epikeratophakia
- 36.32, Other transmymocardial revascularization
- 37.35, Partial ventriculectomy
- 37.52, Implantation of total replacement heart system
- 37.53, Replacement or repair of thoracic unit of total replacement heart system
- 37.54, Replacement or repair of other implantable component of total replacement heart system
- 39.28, Extracranial-intracranial (EC–IC) vascular bypass
- 44.93, Insertion of gastric bubble (balloon)
- 50.51, Auxiliary liver transplant
- 52.83, Heterotransplant of pancreas
- 57.96, Implantation of electronic bladder stimulator
- 57.97, Replacement of electronic bladder stimulator
- 63.70, Male sterilization procedure, not otherwise specified
- 63.71, Ligation of vas deferens
- 63.72, Ligation of spermatic cord
- 63.73, Vasectomy
- 64.5, Operations for sex transformation, not elsewhere classified
- 66.21, Bilateral endoscopic ligation and crushing of fallopian tubes
- 66.22, Bilateral endoscopic ligation and division of fallopian tubes
- 66.29, Other bilateral endoscopic destruction or occlusion of fallopian tubes
- 66.31, Other bilateral ligation and crushing of fallopian tubes
- 66.32, Other bilateral ligation and division of fallopian tubes
- 66.39, Other bilateral destruction or occlusion of fallopian tubes
- 98.52, Extracorporeal shockwave lithotripsy [ESWL] of the gallbladder and/or bile duct
- 98.59, Extracorporeal shockwave lithotripsy of other sites

The following list contains ICD–9–CM procedure codes identified as “Noncovered Procedures” only when any of the following diagnoses are present as either a principal or secondary diagnosis.

Procedure List

- 41.01, Autologous bone marrow transplant without purging
- 41.04, Autologous hematopoietic stem cell transplant without purging
- 41.07, Autologous hematopoietic stem cell transplant with purging
- 41.09, Autologous bone marrow transplant with purging

Principal or Secondary Diagnosis List

- 204.00, Acute lymphoid leukemia, without mention of remission
- 205.00, Acute myeloid leukemia, without mention of remission
- 206.00, Acute monocytic leukemia, without mention of remission
- 207.00, Acute erythremia and erythroleukemia, without mention of remission
- 208.00, Acute leukemia of unspecified cell type, without mention of remission
- 205.10, Acute myeloid leukemia, in remission
- 205.11, Chronic myeloid leukemia, in remission

The following list contains ICD–9–CM procedure codes identified as “Noncovered Procedures” only when any of the following diagnoses are present as either a principal or secondary diagnosis.

Procedure List

- 41.02, Allogeneic bone marrow transplant with purging
- 41.03, Allogeneic bone marrow transplant without purging
- 41.05, Allogeneic hematopoietic stem cell transplant without purging
- 41.08, Allogeneic hematopoietic stem cell transplant with purging

Principal or Secondary Diagnosis List

- 203.00, Multiple myeloma, without mention of remission
 - 203.01, Multiple myeloma, in remission
- The following list contains ICD–9–CM procedure codes identified as “Non-Covered Procedures” except when there is at least one principal or secondary diagnosis code present from both list 1 and list 2.

Procedure List

- 52.80, Pancreatic transplant, not otherwise specified
- 52.82, Homotransplant of pancreas

Diagnosis List 1:

- 250.00, Diabetes mellitus without mention of complication, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
- 250.01, Diabetes mellitus without mention of complication, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled

- 250.02, Diabetes mellitus without mention of complication, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
 - 250.03, Diabetes mellitus without mention of complication, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
 - 250.10, Diabetes with ketoacidosis, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
 - 250.11, Diabetes with ketoacidosis, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
 - 250.12, Diabetes with ketoacidosis, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
 - 250.13, Diabetes with ketoacidosis, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
 - 250.20, Diabetes with hyperosmolarity, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
 - 250.21, Diabetes with hyperosmolarity, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
 - 250.22, Diabetes with hyperosmolarity, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
 - 250.23, Diabetes with hyperosmolarity, type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
 - 250.30, Diabetes with other coma, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
 - 250.31, Diabetes with other coma, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
 - 250.32, Diabetes with other coma, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
 - 250.33, Diabetes with other coma, type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
 - 250.40, Diabetes with renal manifestation, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
 - 250.41, Diabetes with renal manifestation, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
 - 250.42, Diabetes with renal manifestation, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
 - 250.43, Diabetes with renal manifestation, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
 - 250.50, Diabetes with ophthalmic manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
 - 250.51, Diabetes with ophthalmic manifestations, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
 - 250.52, Diabetes with ophthalmic manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
 - 250.53, Diabetes with ophthalmic manifestations, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
 - 250.60, Diabetes with neurological manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
 - 250.61, Diabetes with neurological manifestations, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
 - 250.62, Diabetes with neurological manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
 - 250.63, Diabetes with neurological manifestations, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
 - 250.70, Diabetes with peripheral circulatory disorders, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
 - 250.71, Diabetes with peripheral circulatory disorders type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
 - 250.72, Diabetes with peripheral circulatory disorders, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
 - 250.73, Diabetes with peripheral circulatory disorders, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
 - 250.80, Diabetes with other specified manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
 - 250.81, Diabetes with other specified manifestations, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
 - 250.82, Diabetes with other specified manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
 - 250.83, Diabetes with other specified manifestations, type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
 - 250.90, Diabetes with unspecified complication, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
 - 250.91, Diabetes with unspecified complication, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
 - 250.92, Diabetes with unspecified complication, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
 - 250.93, Diabetes with unspecified complication, type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
- Note:** The proposed rule contained inadvertent typographical errors in the above list on four diabetes codes at 250.50 through 250.53. These errors have been corrected in this list in the final rule.
- Diagnosis List 2
- 403.01, Malignant hypertensive renal disease, with renal failure
 - 403.11, Benign hypertensive renal disease, with renal failure
 - 403.91, Unspecified hypertensive renal disease, with renal failure
 - 404.02, Malignant hypertensive heart and renal disease, with renal failure
 - 404.03, Malignant hypertensive heart and renal disease, with heart failure and renal failure
 - 404.12, Benign hypertensive heart and renal disease, with renal failure
 - 404.13, Benign hypertensive heart and renal disease, with heart failure and renal failure
 - 404.92, Unspecified hypertensive heart and renal disease, with renal failure
 - 404.93, Unspecified hypertensive heart and renal disease, with heart failure and renal failure
 - 585, Chronic renal failure
 - V42.0, Organ or tissue replaced by transplant, kidney
 - V43.89, Organ or tissue replaced by other means, other

We received one comment in support of our proposal to restructure Edit 11 in the MCE. Therefore, we are adopting the proposal as final.

In addition, it has come to our attention that two of the new codes created for use for discharges effective October 1, 2004, should also be included on Edit 11 in order to conform to current coverage policy. These changes were not included in the proposed rule. However, the addition of these codes is not a change in CMS policy. Rather, it is simply a procedural change that is necessary to effectuate CMS' existing coverage policy and to facilitate the appropriate payment (or non-payment) of claims reporting these codes. Therefore, we are making the following additional changes to the MCE:

- In the "Non-Covered Procedures" section of Edit 11, we are adding code 00.62 (Percutaneous angioplasty or atherectomy of intracranial vessel(s)) to the list of procedure codes that are always considered noncovered procedures.

- ICD-9-CM O.R. procedure code 00.61 (Percutaneous angioplasty or atherectomy of precerebral (extracranial vessel(s)) is identified as a "Non-Covered Procedure" except when the following non-O.R. procedure and secondary diagnosis are also present:

Non-O.R. Procedure: 00.63 (Percutaneous insertion of carotid artery stent(s); and

Secondary Diagnosis: V70.7 (Examination of participant in clinical trial).

We are making these changes in Version 22.0 of the MCE software program.

b. Edit 6 (Manifestations Not Allowed As Principal Diagnosis) in the MCE contains codes that describe the manifestation of an underlying disease, not the disease itself, and therefore, should not be used as a principal diagnosis. The following codes describe manifestations of an underlying disease; they should not be used as a principal diagnosis according to ICD-9-CM coding convention. Therefore, in the May 18, 2004, proposed rule, we proposed to add the following diagnosis codes to Edit 6:

- 289.52, Splenic sequestration
- 517.3, Acute chest syndrome (inadvertently erroneously cited as 571.3 in the May 18, 2004 proposed rule)

- 785.52, Septic shock

Coding conventions in the ICD-9-CM Diagnostic Tabular List specify that etiologic conditions be coded first.

We received two comments in support of our proposal to add three

diagnosis codes to Edit 6 of the MCE. However, both commenters pointed out a typographical error in one of the citations of the diagnosis codes. Code 571.3 should have read 517.3.

We are adopting, as final, our proposed additions of the diagnosis codes to Edit 6, with the correction of the one code number cited.

c. Edit 9 (Unacceptable Principal Diagnoses) contains codes "that describe a circumstance which influences an individual's health status but is not a current illness of injury; therefore, these codes are considered unacceptable as a principal diagnosis." (This definition can be found on page 1094 of the DRG Definitions Manual, Version 21.0). Last year, we became aware that two codes should be removed from this list, as they can be legitimate causes for inpatient admission. However, we were made aware of this too late in the process to make a change to this edit prior to FY 2004. In the May 18, 2004, IPSS proposed rule (69 FR 28197), we indicated that we will now be able to make the necessary system changes before the start of FY 2005. Therefore, we proposed to remove the following codes from Edit 9:

- V53.01, Adjustment of cerebral ventricular (communicating) shunt
- V53.02, Adjustment of neuropacemaker (brain) (peripheral nerve) (spinal cord)

We received one comment in support of our proposed removal of codes V53.01 and V53.02 from Edit 9 in the MCE. Therefore, we are adopting, as final, our proposed removal of the two codes from Edit 9.

11. Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different DRG within the MDC to which the principal diagnosis is assigned.

Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the DRG associated with the most resource-intensive surgical class.

Because the relative resource intensity of surgical classes can shift as a function of DRG reclassification and recalibrations, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications and

recalibrations, to determine if the ordering of classes coincides with the intensity of resource utilization.

A surgical class can be composed of one or more DRGs. For example, in MDC 11, the surgical class "kidney transplant" consists of a single DRG (DRG 302) and the class "kidney, ureter and major bladder procedures" consists of three DRGs (DRGs 303, 304, and 305). Consequently, in many cases, the surgical hierarchy has an impact on more than one DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes DRGs 1 and 2 and surgical class B includes DRGs 3, 4, and 5. Assume also that the average charge of DRG 1 is higher than that of DRG 3, but the average charges of DRGs 4 and 5 are higher than the average charge of DRG 2. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weight the average charge of each DRG in the class by frequency (that is, by the number of cases in the DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of "other O.R. procedures" as discussed below.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, this result is unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average charge is ordered above a surgical class with a higher average charge. For example, the "other O.R. procedures" surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average charge for the DRG or DRGs in that surgical class may be higher than that for other surgical classes in the MDC. The "other O.R. procedures" class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients in the MDC with these diagnoses. Therefore, assignment to

these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average charges for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average charges are likely to shift such that the higher-ordered surgical class has a lower average charge than the class ordered below it.

Based on the preliminary recalibration of the DRGs, in the May 18, 2004 proposed rule, we proposed modifications of the surgical hierarchy as set forth below.

We proposed to revise the surgical hierarchy for the pre-MDC DRGs and MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue).

In the pre-MDC DRGs, we proposed to reorder DRG 541 (Tracheostomy With Mechanical Ventilation 96 + Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses With Major O.R. Procedure) and DRG 542 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses Without Major O.R. Procedure) above DRG 480 (Liver Transplant).

In MDC 8, we proposed to—

- Reorder DRG 496 (Combined Anterior/Posterior Spinal Fusion), DRG 497 (Spinal Fusion Except Cervical With CC), and DRG 498 (Spinal Fusion Except Cervical Without CC) above DRG 471 (Bilateral or Multiple Major Joint Procedures of the Lower Extremity).

- Reorder DRG 519 (Cervical Spinal Fusion With CC) and DRG 520 (Cervical Spinal Fusion Without CC) above DRG 216 (Biopsies of the Musculoskeletal System and Connective Tissue).

- Reorder DRG 213 (Amputation for the Musculoskeletal System and Connective Tissue Disorders) above DRG 210 (Hip and Femur Procedures Except Major Joint Age > 17 With CC), DRG 211 (Hip and Femur Procedures Except Major Joint Age > 17 Without CC), and DRG 212 (Hip and Femur Procedures Except Major Joint Age 0–17).

- Reorder DRG 499 (Back and Neck Procedures Except Spinal Fusion With CC) and DRG 500 (Back and Neck Procedures Except Spinal Fusion Without CC) above DRG 218 (Lower Extremity and Humerus Procedures Except Hip, Foot, and Femur Age > 17 With CC), DRG 219 (Lower Extremity and Humerus Procedures Except Hip,

Foot, and Femur Age > 17 Without CC), and DRG 220 (Lower Extremity and Humerus Procedures Except Hip, Foot, and Femur Age 0–17).

In the proposed rule, we were unable to test the effects of the proposed revisions to the surgical hierarchy and to reflect these changes in the proposed relative weights because the revised GROUPER software was unavailable at the time the proposed rule was completed. Rather, we simulated most major classification changes to approximate the placement of cases under the proposed reclassification, and then determined the average charge for each DRG. These average charges served as our best estimate of relative resource used for each surgical class. We have now tested the proposed surgical hierarchy changes after the revised GROUPER was received and are reflecting the final changes in the DRG relative weights in this final rule. Further, as discussed in section II.C. of this preamble, the final recalibrated weights are somewhat different from the proposed weights because they are based on more complete data.

We have tested the proposed revisions using the March 2004 update of the FY 2003 MedPAR file and the revised GROUPER software and have found that the revisions are supported by the data, and no additional changes are indicated except those discussed below pertaining to the implementation of new DRG 543 (Craniotomy with Implantation of Chemotherapeutic Agent or Acute Complex Central Nervous System Principal Diagnosis). (For a complete description of this change see the discussion under “Other Issues” in section II.B.16 of this preamble.) Due to the implementation of DRG 543, we also are reordering the following DRGs in MDC 1 (Disease and Disorders of the Nervous System): DRG 543 above DRGs 1 (Craniotomy Age > 17 With CC) and 2 (Craniotomy Age > 17 Without CC). Therefore, we are adopting these changes as final.

Comment: One commenter requested a change in the surgical hierarchy for a case where procedure code 37.99 (Other operations on heart and pericardium) and code 37.98 (Replacement of an automatic cardioverter/defibrillator pulse generator only) is reported during the same admission. This case is assigned to either DRG 110 (Major Cardiovascular Procedures With CC) or DRG 111 (Major Cardiovascular Procedures Without CC). The commenter requested that this case be reassigned to DRG 115 (Permanent Cardiac Pacemaker Implant with AMI, Heart Failure, or Shock or AICD Lead or Generator Procedure) because it has a

higher DRG weight than DRG 110 or DRG 111.

Response: The surgical hierarchy places a patient with multiple procedures in the most resource intensive class of DRGs, but not necessarily in the most resource intensive DRG. In the scenario described by the commenter, there are two surgical classes, one including DRGs 110 and 111 and the other including DRG 115 and DRG 116 (Other Permanent Cardiac Pacemaker Implant). The average charges for the class containing DRGs 110 and 111 are approximately \$16,604 more than for the class containing DRGs 115 and 116. As a result, the class containing DRGs 110 and 111 is ordered higher in the surgical group than the class containing DRGs 115 and 116. As a result, the case is assigned to either DRG 110 or DRG 111.

12. Refinement of Complications and Comorbidities (CC) List

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. We developed this list of diagnoses, using physician panels, to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity. In previous years, we have made changes to the list of CCs, either by adding new CCs or deleting CCs already on the list. In the May 18, 2004, proposed rule, we did not propose to delete any of the diagnosis codes on the CC list.

Comment: One commenter requested that ICD-9-CM codes 996.64 (Infection due to indwelling urinary catheter) and 599.0 (Urinary tract infection) be removed from the CC List so that hospitals are not rewarded with higher payment when they allow patients to develop urinary tract infections. The commenter pointed out that these conditions are often avoidable complications of hospitalization, and that hospitals allow these infections to occur in order to receive higher payments from Medicare.

Response: We do not agree with the assertion that hospitals allow urinary tract infections to occur in Medicare patients in order to receive higher payment rates. While it is true that some urinary tract infections are preventable through the use of improved sterile technique, reduced indwelling catheter duration, more appropriate use of broad spectrum antibiotics and improved patient mobilization, among others, we do not believe there is a direct causal link between substandard hospital care and the presence of urinary tract infection in general.

Particularly in the elderly Medicare population, urinary tract infections occur in diverse clinical scenarios that lead to colonization and ultimately overt clinical infection within the urinary tract. General debilitation, various acute illnesses, immobility, impaired host defense mechanisms, dehydration and the post-surgical state are but a few of the situations in which urinary tract infections may occur, and which do in fact require higher resource utilization when they occur. Therefore, we are not removing codes 996.64 and 599.0 from the CC List.

In this final rule, as we proposed, we are not deleting any of the diagnosis codes on the CC list for FY 2005.

In the May 19, 1987, proposed notice (52 FR 18877) and the September 1, 1987, final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another.
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another.
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another.
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another.
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC.¹

¹ See the September 30, 1988 final rule (53 FR 38485) for the revision made for the discharges

In the May 18, 2004, proposed rule, we proposed a limited revision of the CC Exclusions List to take into account the proposed changes that will be made in the ICD-9-CM diagnosis coding system effective October 1, 2004. (See section II.B.15. of this preamble for a discussion of ICD-9-CM changes.) We proposed these changes in accordance with the principles established when we created the CC Exclusions List in 1987.

We received no comments on the proposed changes. Therefore, we will adopt the CC Exclusions List as proposed.

Tables 6G and 6H in the Addendum to this final rule contain the revisions to the CC Exclusions List that will be effective for discharges occurring on or after October 1, 2004. Each table shows the principal diagnoses with changes to the excluded CCs. Each of these principal diagnoses is shown with an asterisk, and the additions or deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis.

CCs that are added to the list are in Table 6G—Additions to the CC Exclusions List. Beginning with discharges on or after October 1, 2004, the indented diagnoses will not be recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

CCs that are deleted from the list are in Table 6H—Deletions from the CC Exclusions List. Beginning with discharges on or after October 1, 2004, the indented diagnoses will be recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

Copies of the original CC Exclusions List applicable to FY 1988 can be obtained from the National Technical Information Service (NTIS) of the

occurring in FY 1989; the September 1, 1989 final rule (54 FR 36552) for the FY 1990 revision; the September 4, 1990 final rule (55 FR 36126) for the FY 1991 revision; the August 30, 1991 final rule (56 FR 43209) for the FY 1992 revision; the September 1, 1992 final rule (57 FR 39753) for the FY 1993 revision; the September 1, 1993 final rule (58 FR 46278) for the FY 1994 revisions; the September 1, 1994 final rule (59 FR 45334) for the FY 1995 revisions; the September 1, 1995 final rule (60 FR 45782) for the FY 1996 revisions; the August 30, 1996 final rule (61 FR 46171) for the FY 1997 revisions; the August 29, 1997 final rule (62 FR 45966) for the FY 1998 revisions; the July 31, 1998 final rule (63 FR 40954) for the FY 1999 revisions; the August 1, 2000 final rule (65 FR 47064) for the FY 2001 revisions; the August 1, 2001 final rule (66 FR 39851) for the FY 2002 revisions; the August 1, 2002 final rule (67 FR 49998) for the FY 2003 revisions; and the August 1, 2003 final rule (68 FR 45364) for the FY 2004 revisions.) In the July 30, 1999 final rule (64 FR 41490), we did not modify the CC Exclusions List for FY 2000 because we did not make any changes to the ICD-9-CM codes for FY 2000.

Department of Commerce. It is available in hard copy for \$152.50 plus shipping and handling. A request for the FY 1988 CC Exclusions List (which should include the identification accession number (PB) 88-133970) should be made to the following address: National Technical Information Service, United States Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161; or by calling (800) 553-6847.

Users should be aware of the fact that all revisions to the CC Exclusions List (FYs 1989, 1990, 1991, 1992, 1993, 1994, 1995, 1996, 1997, 1998, 1999, 2001, 2002, 2003, and 2004) and those in Tables 6G and 6H of this final rule for FY 2005 must be incorporated into the list purchased from NTIS in order to obtain the CC Exclusions List applicable for discharges occurring on or after October 1, 2004. (**Note:** There was no CC Exclusions List in FY 2000 because we did not make changes to the ICD-9-CM codes for FY 2000.)

Alternatively, the complete documentation of the GROUPER logic, including the current CC Exclusions List, is available from 3M/Health Information Systems (HIS), which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. The current DRG Definitions Manual, Version 21.0, is available for \$225.00, which includes \$15.00 for shipping and handling. Version 22.0 of this manual, which includes the final FY 2005 DRG changes, is available for \$225.00. These manuals may be obtained by writing 3M/HIS at the following address: 100 Barnes Road, Wallingford, CT 06492; or by calling (203) 949-0303. Please specify the revision or revisions requested.

13. Review of Procedure Codes in DRGs 468, 476, and 477

Each year, we review cases assigned to DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), DRG 476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these DRGs.

DRGs 468, 476, and 477 are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group. DRG 476 is assigned to those discharges in which one or more of the following

prostatic procedures are performed and are unrelated to the principal diagnosis:

- 60.0, Incision of prostate
- 60.12, Open biopsy of prostate
- 60.15, Biopsy of periprostatic tissue
- 60.18, Other diagnostic procedures on prostate and periprostatic tissue
- 60.21, Transurethral prostatectomy
- 60.29, Other transurethral prostatectomy
- 60.61, Local excision of lesion of prostate
- 60.69, Prostatectomy, not elsewhere classified
- 60.81, Incision of periprostatic tissue
- 60.82, Excision of periprostatic tissue
- 60.93, Repair of prostate
- 60.94, Control of (postoperative) hemorrhage of prostate
- 60.95, Transurethral balloon dilation of the prostatic urethra
- 60.96, Transurethral destruction of prostate tissue by microwave thermotherapy
- 60.97, Other transurethral destruction of prostate tissue by other thermotherapy
- 60.99, Other operations on prostate

All remaining O.R. procedures are assigned to DRGs 468 and 477, with DRG 477 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis.²

a. Moving Procedure Codes from DRG 468 or DRG 477 to MDCs

We annually conduct a review of procedures producing assignment to DRG 468 or DRG 477 on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these DRGs into one of the

²In the August 1, 2003 final rule (68 FR 45365) we moved several procedures from DRG 468 to DRGs 476 and 477 because the procedures are nonextensive. The original list of the ICD-9-CM procedure codes for the procedures we consider nonextensive procedures, if performed with an unrelated principal diagnosis, was published in Table 6C in section IV. of the Addendum to the September 30, 1988 final rule (53 FR 38591). As part of the final rules published on September 4, 1990 (55 FR 36135), August 30, 1991 (56 FR 43212), September 1, 1992 (57 FR 23625), September 1, 1993 (58 FR 46279), September 1, 1994 (59 FR 45336), September 1, 1995 (60 FR 45783), August 30, 1996 (61 FR 46173), and August 29, 1997 (62 FR 45981), we moved several other procedures from DRG 468 to DRG 477, and some procedures from DRG 477 to DRG 468. No procedures were moved in FY 1999, as noted in the July 31, 1998 final rule (63 FR 40962); in FY 2000, as noted in the July 30, 1999 final rule (64 FR 41496); in FY 2001, as noted in the August 1, 2000 final rule (65 FR 47064); or in FY 2002, as noted in the August 1, 2001 final rule (66 FR 39852). In the August 1, 2002 final rule (67 FR 49999), we did not move any procedures from DRG 477. However, we did move procedure codes from DRG 468 and placed them in more clinically coherent DRGs.

surgical DRGs for the MDC into which the principal diagnosis falls. The data are arrayed two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical DRGs for the MDC in which the diagnosis falls. Based on this year's review, we did not identify any procedures in DRG 477 that should be removed. Therefore, in the May 18, 2004 proposed rule, we did not propose to move any procedures from DRG 477 to one of the surgical DRGs in this final rule.

We did not receive any comments on our proposal not to move any procedures from DRG 477 to one of the surgical DRGs and, therefore, are adopting our proposal as final.

b. Reassignment of Procedures among DRGs 468, 476, and 477

We also annually review the list of ICD-9-CM procedures that, when in combination with their principal diagnosis code, result in assignment to DRGs 468, 476, and 477, to ascertain if any of those procedures should be reassigned from one of these three DRGs to another of the three DRGs based on average charges and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data. Based on a comment we received in response to last year's proposed rule (68 FR 45366), in the May 18, 2004 proposed rule, we proposed to move procedure code 51.23

(Laparoscopic cholecystectomy) from DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis) into DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis).

The commenter suggested that a laparoscopic procedure was probably not an extensive O.R. procedure; it was more likely a nonextensive O.R. procedure. We indicated that we agreed and, therefore, proposed this change. In addition, we proposed to add several new procedure codes to DRGs 476 and 477. These procedures are also listed on Table 6B—New Procedure Codes in the Addendum to this final rule. However,

DRGs 476 and 477 are not limited to one MDC, so the new codes are also included here for nonextensive cases in which the procedures are unrelated to the principal diagnosis:

- 44.67, Laparoscopic procedures for creation of esophagogastric sphincteric competence
- 44.68, Laparoscopic gastroplasty
- 44.95, Laparoscopic gastric restrictive procedure
- 44.96, Laparoscopic revision of gastric restrictive procedure
- 44.97, Laparoscopic removal of gastric restrictive device(s)
- 44.98, Laparoscopic adjustment of size of adjustable gastric restrictive device

In DRG 476, the above codes are to be added to the section "With or Without Operating Room Procedures" in the GROUPER logic.

We did not propose to move any procedure codes from DRG 476 to DRGs 468 or 477, or from DRG 477 to DRGs 468 or 476.

We did not receive any comments on this proposal and, therefore, are adopting it as final.

c. Adding Diagnosis or Procedure Codes to MDCs

Based on our review this year, we did not propose to add any diagnosis codes to MDCs. We did not receive any comments on this proposal. Therefore, we are adopting our proposal as final and are making no changes to MDCs other than those specified in other portions of this section II. of the preamble of this final rule.

14. Pancreatic Islet Cell Transplantation in Clinical Trials

Section 733(a) of Public Law 108-173 directs the Secretary, acting through the National Institute of Diabetes and Digestive and Kidney Disorders (NIDDKD) to conduct a clinical investigation of pancreatic islet cell transplantation that includes Medicare beneficiaries. Section 733(b) of Public Law 108-173 provides for Medicare payments, beginning no earlier than October 1, 2004, for the routine costs as well as the costs of the transplantation and appropriate related items and services for Medicare beneficiaries who are participating in a clinical trial as if such transplantation were covered under Medicare Part A or Part B. Routine costs are defined as reasonable and necessary routine patient care costs (as defined in the CMS Coverage Issues Manual, Section 30-1) including immunosuppressive drugs and other followup care. Section 733(c)(2) of Public Law 108-173 defines transplantation and appropriate related

items and services as items and services related to the acquisition and delivery of the pancreatic islet cell transplantation, notwithstanding any national noncoverage determination contained in the CMS Coverage Issues Manual.

As we indicated in the May 18, 2004, proposed rule, while the DRG payment will cover the transplant injection and the subsequent hospital stay, we considered establishing an add-on payment to the DRG payment amount to reimburse the acquisition costs associated with islet cell procurement (69 FR 28218). Historically, organ acquisition costs have been reimbursed as a cost pass-through. However, islet cell transplants are not exactly the same as solid organ transplants. While solid pancreata are procured, islet cells are not transplanted in the solid organ state as are other types of organs. Rather, the pancreata are procured by an organ procurement organization (OPO) and are then sent to an islet cell resource center that extracts the islet cells from the pancreata and sends the cells on to the transplant center. Because the procurement and processing system for islet cell transplants is not the same as for solid organ transplants, we proposed not paying for these costs as a pass-through. With the anticipated small number of beneficiaries in the clinical trial and the Medicare program's unfamiliarity with the isolation process, we believed it would be most appropriate at this time to have a set payment rate for acquisition costs, rather than attempting a case-by-case determination of the reasonableness of these costs in each institution. We note there is precedent to exclude acquisition costs from the pass-through payment process. For example, stem cell transplants and corneal transplants do not have acquisition costs reimbursed as a cost pass-through payment.

We proposed that the add-on payment would be a single amount that includes pre-transplant tests and services, pancreas procurement, and islet isolation services. In addition, we proposed to use an add-on as opposed to increasing the DRG amount because the DRGs at issue are also applied in cases involving a variety of other procedures that do not include the costly islet cell acquisition required for this procedure. Thus, including these costs in the DRGs would have the potential of skewing the weights for all other DRGs. We solicited comments on whether an add-on payment amount is the appropriate way to reimburse islet cell acquisition costs, or whether another methodology may be more appropriate.

In addition, while we had some data available regarding the cost of pancreas procurement, in the proposed rule we specifically asked for any other data that supported the costs of acquisition and the costs of isolation cell resource centers. We stated that, because of insufficient data, we were unable to publish a proposed acquisition amount in the FY 2005 proposed rule. However, we indicated that, after analyzing data submitted during the comment period, other data acquired by CMS, and any suggested changes from the methodology proposed, the final organ acquisition payment amount would be announced in the FY 2005 IPPS final rule.

Pancreatic islet cell transplantation during the clinical trial will be performed to decrease or eliminate the need for insulin in patients with Type I diabetes. Patients with Type II islet diabetes are not included in this trial. Islet cells are acquired from a cadaveric pancreas donor (islet allotransplantation).

As described in II.B.1. of this preamble, ICD-9-CM diagnosis and procedure codes are used to determine DRG assignments. In 1996, CMS (then HCFA) created codes for islet cell transplantation:

- 52.84, Autotransplantation of cells of islets of Langerhans.
- 52.85, Allotransplantation of cells of islets of Langerhans.

The Medicare GROUPER does not consider codes 52.84 and 52.85 as O.R. procedures and, therefore, these codes do not move the case from a medical DRG into a surgical DRG unless another procedure is performed. Based on the circumstances noted above under which pancreatic islet cell transplantation would be performed, we identified the three most logical DRGs to which we believe cases should be assigned. If a patient has Type I diabetes mellitus with ESRD and a pancreatectomy is performed, the case would group to DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis). If a patient has Type I diabetes mellitus with ESRD and is also receiving a kidney transplant (simultaneous kidney and islet transplantation), the case would group to DRG 302 (Kidney Transplant). If a patient has Type I diabetes mellitus with ESRD and a history of a kidney transplant and then has the islet cells inserted via an open approach, the case would group to DRG 315 (Other Kidney and Urinary Tract O.R. Procedures). We note that this third scenario reflects incorrect coding practice. However, in this final rule we are modifying the structure of DRG 315 so that patients receiving infusions of

islet cells without any other surgical intervention will be appropriately assigned to this DRG.

As each case is assigned to a DRG based on all of the ICD-9-CM codes reported, cases could also be assigned to DRGs other than those mentioned above. In fact, as indicated in the proposed rule, our review of FY 2003 MedPAR data revealed that codes 52.84 and 52.85 were present in only four cases, and that each case was assigned to a different DRG. We found one case each in DRG 18 (Cranial and Peripheral Nerve Disorders With CC), DRG 192 (Pancreas, Liver, and Shunt Procedures Without CC), DRG 207 (Disorders of the Biliary Tract With CC), and DRG 302 (Kidney Transplant). As the GROUPER software program does not recognize codes for islet cell transplantation as O.R. procedure codes, the presence of these codes did not modify the DRG assignment in these four cases.

We were reluctant to propose assigning the islet cell codes to one specific DRG, as the islet cell infusion will have different indications depending on the merits of each case, as is shown from the MedPAR data mentioned above. In addition, we do not currently have accurate cost data or charges for patients in this type of clinical trial, which makes it difficult to determine an appropriate DRG weight. As a result, assignment of cases to a specific DRG might have the consequence of either overpaying or underpaying the cases. We believe that both of these consequences are unacceptable. Therefore, we did not propose that cases involved in the clinical trial be assigned to one specific DRG for payment purposes. As we believe that these cases will have been assigned to DRGs 302, 315, and 468, we proposed to establish an add-on payment for cases in these three DRGs containing procedure codes 52.84 or 52.85. As stated earlier, we were not able to establish the amount of this add-on until we had determined procurement costs for the islet cells. We solicited information from transplant centers and organ procurement organizations on costs for these types of transplantations.

Comment: Several commenters noted that the assignment of DRG 315, as currently constructed, to patients participating in the clinical trial does not reflect appropriate coding practice, as a laparotomy code for hepatic vessel catheterization should not be recorded.

Response: The commenters are correct in their assessment. Therefore, we are modifying the structure of DRG 315 so that patients receiving infusions of islet cells without any other surgical

intervention will appropriately be assigned to DRG 315. We are aware that patients will often require more than one admission for islet cell transplantation. We are making this modification in order to recognize the surgical aspects of islet cell transplantation in the absence of any other surgical procedure.

The logic for DRG 315 is modified as follows:

O.R. Procedures

This list remains the same as V21.0 of the GROUPER.

or

Non-O.R. Procedures

52.84, Autotransplantation of cells of islets of Langerhans

52.85, Allograft transplantation of cells of islets of Langerhans

or

Principal Diagnosis

This list remains the same as V21.0 of GROUPER.

and

Non-O.R. Procedure

This list remains the same as V21.0 of GROUPER.

Comment: One commenter stated that it was not clinically appropriate to categorize islet cell transplants into DRG 315, as these transplants do not involve either the kidney or the urinary tract directly. Rather, the islet cells are transplanted into the patient's liver. The commenter indicated that islet transplants have no relevance to the genito-urinary system, but rather to the hepatopancreaticobiliary system. Therefore, the commenter believed that the proposed classification to DRG 315 is clinically inappropriate.

Response: DRGs are diagnosis related groups. Each surgical DRG is comprised of procedure codes in combination with a principal diagnosis that causes the case to be assigned to a particular major diagnostic category (MDC). Because there are so many procedures in most DRGs, it is impossible to capture the purpose of all procedures in the title.

Comment: Some commenters suggested that the most appropriate resolution is to create a new DRG for islet transplants performed alone. The commenters mentioned that solid organ transplants are classified into their own DRGs, and that this precedent should be continued.

Response: DRGs are created based on the need of the program to identify clinical coherence and resource consumption. Ideally, both components will be part of the decision making process in DRG creation. In this case, we

have no substantial data upon which to determine an appropriate relative weight for the resources that will be utilized in all islet cell transplant cases. In addition, there may be different scenarios in which patients are transfused with islet cells. These cases could include patients receiving a kidney transplant during the same admission, or cases in which the islet cells comprise the only procedure during the admission. As cases will be varied in this clinical trial, we prefer to have MedPAR data and case histories prior to creating specific new DRGs for these cases.

Comment: Some commenters believed that the most closely related DRG from a clinical as well as resource perspective is DRG 513 (Pancreas Transplant). The commenters noted that the diagnoses are the same for islet and pancreas transplants, and that the patient populations involved in these two procedures are virtually identical in terms of comorbidities and the nature of their primary disease. In addition, the technical aspects of islet transplants are of a surgical nature, whether performed in an operating room or in the interventional radiology suite. One commenter noted that pancreas transplants are in reality just another method of transplanting the insulin producing islet cells since the other functions of the pancreas are superfluous.

Response: While the patient populations requiring intervention are similar, we do not believe that one can equate an operation of the magnitude of a pancreas transplant with a less intensive islet cell transplantation in which the portal vein is accessed and islet cells infused through a catheter. It is only because the technical aspects of islet transplants are of a surgical nature that we have modified surgical DRG 315 to reflect the transfusion of islet cells.

Comment: One commenter suggested that the most appropriate DRG for simultaneous kidney and islet cell transplantation would be DRG 512 (Simultaneous Pancreas/Kidney Transplant), as the resource allocation and patient population involved in both types of admissions are comparable. The commenter noted that so few of these combination procedures have been performed that no assumption can be projected based on the experience to date.

Response: We do not agree that an islet cell transplantation is the equivalent of a pancreas transplantation. Cases involving simultaneous kidney and islet cell transplantation will group to DRG 302, and will receive an add-on

payment for the infusion of the islet cells.

Comment: Some commenters believed CMS should pay for islet acquisition services as a cost pass-through. Several of these commenters stated that they found insufficient justification to pay for islet cell transplants through an add-on when pancreata used for solid organ transplantation are paid as a cost pass-through. These commenters stated that the costs of procuring a pancreas used for solid organ transplantation are the same as procuring a pancreas for islet cell transplantation. One commenter agreed that payment through an add-on is the best approach.

Response: We continue to believe that reimbursing acquisition costs as an add-on to the DRG is an appropriate reimbursement mechanism. However, we have decided that reimbursing pancreata procured for islet cells as an add-on while the acquisition of all other organs are reimbursed as a cost pass-through may be premature at this time. Accordingly, we will pay for organ acquisition costs as a cost pass-through. Costs associated with the procurement of the pancreata will be included in the islet acquisition costs center of the transplant center cost report. We will continue to study the appropriateness of paying for pancreata used for islets as an add-on in the future. Islet isolation will be paid as an add-on as proposed. We discuss this add-on below.

Comment: Some commenters were concerned that pre-transplant costs would not be appropriately reflected in the proposed add-on methodology. These commenters recommended that the pre-transplant costs be paid as a cost-pass through.

Response: After additional analysis, we agree that it may be difficult to ensure an appropriate payment amount for pre-transplant costs in an add-on methodology. Therefore, pre-transplant costs will be handled in the same manner as they are for all other solid organ transplantation and will be included in the islet acquisition cost center of the cost report. Pre-transplant costs will not be included as an add-on to the DRG payment.

Comment: Some commenters believed that islet isolation services should be paid on a cost pass-through rather than as an add-on. One commenter mentioned that islet centers have differing arrangements with transplant centers on how the isolation is performed. The commenters added that these same centers have differing processes in isolating the islet cells. Some commenters also indicated that there are inconsistencies in the isolation center data provided to CMS for use in

developing the add-on payment and expressed concerns about the validity of these data.

Response: We continue to believe that paying for islet isolation services as an add-on amount to the DRG is appropriate in the context of this clinical trial. We derived the isolation add-on amount through analysis of direct costs data submitted by 10 of the prominent isolation centers in the country. These centers may well have differing arrangements and differing processes, but despite these differences, the costs and components of costs showed reasonable similarities. The differences were also notable, but we were able to adjust for these differences. In addition to including direct costs, we added actuarially-derived overhead amounts that are used in the hospital payment methodology and provided a 20-percent capital adjustment for building and equipment and a market basket adjustment to take the payment amount to a FY 2005 funding level. Historically, capital costs are approximately 10 percent of the total hospital costs. However, we recognize that the isolation centers are equipment intensive, and to account for that equipment, we are doubling that rate so that capital costs are 20 percent of the total isolation payment. We believe that 20 percent is sufficient to account for capital at the isolation centers. In future years, we would like to obtain capital costs amortized on a per isolation basis. The varying processes and arrangements are all included in our computation, and \$18,848 will be paid as the islet isolation add-on to the DRG payment.

Comment: One commenter wanted to be sure that costs of transporting islet cells to and from the islet isolation center are included in the add-on payment.

Response: Shipping costs from the OPO to the islet isolation center are included in procurement costs. The islet isolation centers did not provide data on shipping to the transplant centers; however, we have included an actuarially based overhead amount that we believe is sufficient to cover these costs.

Comment: Some commenters noted that more than one infusion of islet cells is typically required to establish insulin independence and believed that this argued in favor of payment on a cost pass-through basis rather than as an add-on amount.

Response: We recognize that normally two or more infusions are required for islet transplants. We also understand that it is extremely rare for two infusions to be performed at the same time. Accordingly, we have constructed

our payment mechanism to pay one DRG for the infusion and one islet isolation add-on amount per discharge under most circumstances for allograft islet cell transplants. However, in those rare instances in which two infusions occur during the same hospital stay, two add-on payments for isolation of the islet cells can be made along with the single DRG payment. The cost associated with the procurement of two pancreata will be paid as an acquisition cost on a reasonable cost basis. We will issue billing instructions on this issue.

Comment: Some commenters asked for guidance on the appropriate methodology for OPOs to use in identifying costs incurred in procuring pancreata for islet cell transplantation. Some OPOs have indicated that they currently are providing pancreata for islet cell transplantation but do not receive their full standard acquisition charge (SAC) for the organ.

Response: In some cases, OPOs have been billing pancreata for islet cell transplant at a lower tissue rate. This is an improper billing method. The quality and resources required to procure the organ are identical, and a full charge should be made. Organs that are determined to be nonviable can be billed at a lesser research rate.

Comment: One commenter indicated that the costs included in pancreas acquisition at OPOs vary, making an add-on payment impractical.

Response: As mentioned above, we will continue paying acquisition costs as a cost pass-through. However, all OPOs should have included in their costs direct donor hospital charges, surgeon retrieval fee, registry fees, donor testing, and transportation. These costs should not be shifted to another organization.

Comment: One commenter noted that it was unclear how physicians' services involved in the oversight of the isolation process would be paid since it does not appear that there is an existing CPT code for these services.

Response: The commenter is correct that there is no CPT code for the physician's oversight services at the isolation center. CPT codes are for direct patient care services; the services at the isolation center do not meet that level of patient participation. In a similar vein, the medical directors at OPOs do not bill for their services using a CPT code. Rather, they are paid by the OPO both for organ retrieval and medical director services. We have included physician costs in the salary portion of the isolation portion of the add-on amount.

Comment: One commenter believed that the costs associated with the

isolation portion of the add-on amount should be between \$30,000 and \$40,000. This commenter further explained that isolation centers incur cost and time to develop improvements to the islet isolation technology and pointed out the startup costs associated with an FDA approved isolation center.

Response: As noted earlier, we have calculated the islet isolation portion of the add-on amount as \$18,848. We suspect that the \$30,000 to \$40,000 estimate referenced by the commenter included costs attributable to research and other services, which are not considered to be routine and reasonably necessary for patient care.

Comment: One commenter suggested two levels of add-on payments to account for the difference in expenses for autograft versus allograft islet cells transplants. While the proposed add-on methodology included the cost of pre-transplant tests and services, organ procurement and islet isolation services, autograft transplants have no associated organ procurement costs, as the islet cells are taken from the patient's own pancreas. Autograft transplants still require pre-transplant services and the actual islet isolation procedure itself.

Response: Our original understanding was that autograft transplants would not be included in the NIH study. After review of the legislation and accompanying Conference Report and consultation with NIH, we believe that an autograft should not occur in this trial. However, in the unlikely event that an autograft islet cell transplant is performed as part of the study on a Medicare beneficiary, we will provide an autograft add-on amount that includes payment for isolation but not for organ procurement. No acquisition cost of the pancreas will be provided because the cost of removal of the organ is included in the DRG payment for the native pancreatectomy procedure itself. The isolation add-on amount will be \$18,848 for an autograft islet cell transplant.

In this rule we are finalizing our proposed payment methodology for acquisition costs associated with procuring pancreata for islet cells with modification. We will pay for the organ acquisition costs as a cost pass-through rather than as an add-on payment to the DRG as proposed. In addition, we are finalizing our proposal to pay for islet isolation services as an add-on.

15. Changes to the ICD-9-CM Coding System

As described in section II.B.1. of this preamble, the ICD-9-CM is a coding system used for the reporting of diagnoses and procedures performed on

a patient. In September 1985, the ICD-9-CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD-9-CM system. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD-9-CM to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The Official Version of the ICD-9-CM contains the list of valid diagnosis and procedure codes. (The Official Version of the ICD-9-CM is available from the Government Printing Office on CD-ROM for \$25.00 by calling (202) 512-1800.) The Official Version of the ICD-9-CM is no longer available in printed manual form from the Federal Government; it is only available on CD-ROM. Users who need a paper version are referred to one of the many products available from publishing houses.

The NCHS has lead responsibility for the ICD-9-CM diagnosis codes included in the *Tabular List* and *Alphabetic Index for Diseases*, while CMS has lead responsibility for the ICD-9-CM procedure codes included in the *Tabular List* and *Alphabetic Index for Procedures*.

The Committee encourages participation in the above process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, medical record administrators, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2005 at public meetings held on April 3, 2003, December 4-5, 2003, and

April 1-2, 2004, and finalized the coding changes after consideration of comments received at the meetings and in writing by January 12, 2004. Those coding changes are announced in Tables 6A through 6F of the Addendum to this rule. Copies of the minutes of the procedure codes discussions at the Committee's 2003 meetings can be obtained from the CMS Web site: <http://www.cms.gov/paymentsystems/icd9/>. The minutes of the diagnoses codes discussions at the 2003 meetings are found at: <http://www.cdc.gov/nchs/icd9.htm>. Paper copies of these minutes are no longer available and the mailing list has been discontinued.

For a report of procedure topics discussed at the April 1-2, 2004, meeting, see the Summary Report at: <http://www.cms.hhs.gov/paymentsystems/icd9/>. For a report of the diagnosis topics discussed at the April 1-2, 2004 meeting, see the Summary Report at: <http://www.cdc.gov/nchs/icd9.htm>.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD-9-CM Coordination and Maintenance Committee, NCHS, Room 2404, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by e-mail to: dfp4@cdc.gov.

Questions and comments concerning the procedure codes should be addressed to: Patricia E. Brooks, Co-Chairperson, ICD-9-CM Coordination and Maintenance Committee, CMS, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, C4-08-06, 7500 Security Boulevard, Baltimore, MD 21244-1850. Comments may be sent by e-mail to: Patricia.Brooks1@cms.hhs.gov.

The ICD-9-CM code changes that have been approved will become effective October 1, 2004. The new ICD-9-CM codes are listed, along with their DRG classifications, in Tables 6A and 6B (New Diagnosis Codes and New Procedure Codes, respectively) in the Addendum to this final rule. As we stated above, the code numbers and their titles were presented for public comment at the ICD-9-CM Coordination and Maintenance Committee meetings. Both oral and written comments were considered before the codes were approved. In the May 18, 2004, proposed rule, we only solicited comments on the proposed classification of these new codes.

For codes that have been replaced by new or expanded codes, the corresponding new or expanded diagnosis codes are included in Table 6A. New procedure codes are shown in

Table 6B. Diagnosis codes that have been replaced by expanded codes or other codes or have been deleted are in Table 6C (Invalid Diagnosis Codes). These invalid diagnosis codes will not be recognized by the GROUPE beginning with discharges occurring on or after October 1, 2004. Table 6D usually contains invalid procedure codes, however, for FY 2005, there are no invalid procedure codes. Revisions to diagnosis code titles are in Table 6E (Revised Diagnosis Code Titles), which also includes the DRG assignments for these revised codes. Table 6F includes revised procedure code titles for FY 2005.

The first of the 2004 public meetings was held on April 1-2, 2004. In the September 7, 2001, final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the April meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108-173 includes a requirement for updating ICD-9-CM codes twice a year instead of the current process of annual updates on October 1 of each year. This requirement is included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by adding a new clause (vii) which states that the "Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) * * * until the fiscal year that begins after such date." Because this new statutory requirement will have a significant impact on health care providers, coding staff, publishers, system maintainers, software systems, among others, in the May 18, 2004, proposed rule, we solicited comments on our proposals described below to implement this requirement. This new requirement will improve the recognition of new technologies under the IPPS system by providing information on these new technologies at an earlier date. Under the proposal, data would be available 6 months earlier than would be possible with updates occurring only once a year on October 1. Many coding changes apply to longstanding medical issues.

While the new requirement states that the Secretary shall not adjust the payment of the DRG classification for the April 1 new codes, the Department

will have to update its DRG software and other systems in order to recognize and accept the new codes. We will also have to publicize the code changes and the need for a mid-year systems update by providers to capture the new codes. Hospitals will have to obtain the new code books and encoder updates, and make other system changes in order to capture and report the new codes. We indicated that we are aware of the additional burden this will have on health care providers.

The ICD-9-CM Coordination and Maintenance Committee has held its meetings in April and December of each year in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the ICD-9-CM Coordination and Maintenance Committee meeting if the request is received at least 2 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS website. The public decides whether or not to attend the meeting based on the topics listed on the agenda. In order to provide an update on April 1, it became clear that a December Committee meeting would not provide time to finalize and publicize these code revisions. Final decisions on code title revisions are currently made by March 1 so that these titles can be included in the IPPS proposed rule. A complete addendum describing details of all changes to ICD-9-CM, both tabular and index, are publicized on CMS and NCHS web pages in May of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4-5, 2003 ICD-9-CM Coordination and Maintenance Committee minutes. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this new update would have on providers. Therefore, we have rescheduled the second Committee meeting for 2004 for October 7-8, 2004. Those who wish to have a coding issue discussed at the October Committee meeting will be required to submit their request by August 7, 2004. The Department will

continue this process to accommodate all requesters who submit appropriate requests in a timely manner.

In the May 18, 2004 proposed rule, we proposed to implement section 503(a) by developing a mechanism for approving, in time for the April update, diagnoses and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also proposed the following process for making these determinations. Topics considered during the October ICD-9-CM Coordination and Maintenance Committee meeting would be considered for an April 1 update if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report would be provided the opportunity to comment on this expedited request. All other topics would be considered for the October 1 update. Participants at the Committee meeting would be encouraged to comment on all such requests.

We stated that we believe that this proposal captures the intent of section 503(a). This requirement was included in the provision revising the standards and process for recognizing new technology under the IPPS. In addition, the need for approval of new codes outside the existing cycle (October 1) arises most frequently and most acutely where the new codes will capture new technologies that are (or will be) under consideration for new technology add-on payments. Thus, we believe this provision was intended to expedite data collection through the assignment of new ICD-9-CM codes for new technologies seeking higher payments. We indicated that our proposal was designed to carry out that intention, while minimizing the additional administrative costs associated with mid-year changes to the ICD-9-CM codes.

Comment: Several comments expressed concerns about the impact the April 1 ICD-9-CM coding update will have on providers. While the commenters acknowledged the requirement was mandated by section 503(a) of Public Law 108-173, the commenters urged CMS to carefully consider the number of these mid-year coding updates. The commenters stated that these changes will have a significant impact on providers' systems. One commenter representing a

large hospital organization recommended that codes being considered for the April 1 update be limited only to new technologies that present a strong and convincing case for new technology add-on payment. The commenter recommended that the annual April 1 update be limited to as few codes as possible for the following reasons:

- The addition of a significant number of new codes outside the traditional October 1 implementation will result in doubling the costs associated with the purchase of new code books and updating encoder software programs, requiring hospitals to purchase new code books twice a year. The commenter stated that at least one publisher has already announced that two editions of the code books will be published every year.

- Many health plans, including Medicare, require a significant lead-time to incorporate new codes into their systems. The commenter expressed concern that some payers will not be able to support a large number of codes being implemented outside the traditional October 1 update.

- A considerable amount of education and coder training takes place every year with the introduction of new and updated codes. Introducing a large number of new codes on a twice-yearly basis, rather than annually, will increase this burden.

The commenter urged that the new codes be released with a 5-month lead-time as is the case now for ICD-9-CM updates. Currently the public is notified in May of the same year for ICD-9-CM codes being implemented on October 1. The commenter requested that the public be notified by November of codes that will be implemented on April 1.

The commenter pointed out that, by tradition, new ICD-9-CM codes have been published in the **Federal Register**, as part of the annual IPPS proposed rule. The commenter urged CMS to develop a process for the wide dissemination of new and modified ICD-9-CM codes for April 1 implementation. The commenter requested that this process be published in the IPPS final rule to inform users of the process.

These comments were supported by organizations representing State hospitals and coding specialists. The commenters agreed with CMS' proposal to use the public meetings of the ICD-9-CM Coordination and Maintenance Committee to consider requests for an April 1 implementation date for a new ICD-9-CM code. The commenters agreed that these updates should primarily focus on new technology

issues. When an individual or organization requests implementation of an ICD-9-CM code on April 1, the commenters agreed that the requestor should make a strong and convincing case as to why a new code is needed in April for purposes of the new technology process.

Response: We agree that section 503(a) of Public Law 108-173 requires that ICD-9-CM codes needed to capture new technology must be implemented on April 1 and October 1 of each year. We also agree that the April updates will be disruptive to current provider systems. Any April updates must be carefully considered and evaluated in order to capture new technology in an expedited manner. Those commenters who request an April implementation of a new ICD-9-CM code must make a strong and convincing case at the ICD-9-CM Coordination and Maintenance Committee as to why a new code is needed in April for purposes of the new technology process. The public will be provided an opportunity to discuss this request. Comments regarding the publication and dissemination of codes to be implemented on April 1 are discussed below.

Comment: One commenter called the twice a year updates of ICD-9-CM an important step forward in allowing new products to enter the market more quickly and receive adequate payment sooner. The commenter expressed some concerns about CMS' proposed approach to these updates. The commenter stated that, by using the April updates for new technology, we would not have a true twice yearly coding update, but rather an opportunity for only a small group of services or technologies to receive more prompt coding updates. The commenter stated that the April update should be an open opportunity for any coding updates to be considered.

Response: We agree with the commenter that the process for discussing updates to ICD-9-CM should be an open process. This has been the practice of the ICD-9-CM Coordination and Maintenance Committee since it was established in 1985. As previously stated, we will provide the opportunity for a requestor to make a clear and convincing case for the need to update specific ICD-9-CM codes in April. The public will be provided an opportunity to discuss the merits of any codes under consideration for the April updates.

Comment: Several commenters requested details on how the public will be notified of the April ICD-9-CM code updates. They requested clarification as to whether the current publication processes will be used. One commenter

representing a national organization of codes and health information managers urged CMS to provide information on April 1 code updates at least 4 months prior to implementation. Other commenters representing hospital organizations urged CMS to provide updates 5 months ahead of implementation, or by November of the prior year.

Response: Current addendum and code title information is published on the CMS Web page at: <http://www.cms.hhs.gov/paymentsystems/icd9>. Summary tables showing new, revised, and deleted code titles are also posted on the following CMS Web page: <http://www.cms.hhs.gov/medlearn/icd9code.asp>. Information on ICD-9-CM diagnosis codes can be found at: <http://www.cdc.gov/nchs/icd9.htm>. Information on new, revised, and deleted ICD-9-CM codes is also provided to the AHA for publication in the *Coding Clinic for ICD-9-CM*. AHA also distributes information to publishers and software vendors.

CMS also sends copies of all ICD-9-CM coding changes to its contractors for use in updating their systems and providing education to providers.

We agree that these same means of disseminating information on new, revised, and deleted ICD-9-CM codes should be used to notify providers, publishers, software vendors, contractors, and others of changes to the ICD-9-CM codes that will be implemented in April. We will continue to provide the information in this manner.

Currently, code titles are also published in the IPPS proposed and final rules. The code titles are adopted as part of the ICD-9-CM Coordination and Maintenance Committee process. The code titles are not subject to comment in the proposed or final rules. We will continue to publish the October code updates in this manner within the IPPS proposed and final rules. However, we do not publish a mid-year IPPS rule, so the April 1 code updates will not be published in a mid-year IPPS rule. We will assign the new procedure code to the same DRG in which its predecessor code was assigned so there will be no DRG impact as far as DRG assignment. This mapping was specified by Public Law 108-173. Any proposed coding updates will be available through the websites indicated above and through the *Coding Clinic for ICD-9-CM*. Publishers and software vendors currently obtain code changes through these sources in order to update their code books and software systems. We will strive to have the April 1 updates available through these websites 5

months prior to implementation (that is, early November of the previous year), as is the case for the October 1 updates. Code book publishers are evaluating how they will provide any code updates to their subscribers. Some publishers may decide to publish mid-year book updates. Others may decide to sell an addendum that lists the changes to the October 1 code book. Coding personnel should contact publishers to determine how they will update their books. CMS and its contractors will also consider developing provider education articles concerning this change to the effective date of certain ICD-9-CM codes.

Comment: Commenters requested clarification as to whether the April 1 updates would be limited to procedure codes. The commenters supported our proposed approach for implementing the new legislative requirement to update ICD-9-CM codes twice a year. Specifically, they agreed that limiting the implementation of new codes on April 1 to those for which a strong and convincing case is made for an expedited implementation is the best approach and will reduce the additional administrative costs associated with twice-yearly updates to the coding system. The commenters acknowledged that the section of 503(a) of Public Law 108-173 that includes the requirement for updating ICD-9-CM codes twice a year is primarily related to the recognition of new technology under the IPPS, but the language in the legislation does not limit the requirement to procedure codes. The commenters stated that CMS' proposed approach requires the requestor of a code proposal to identify the reason why a new code is needed on April 1 for purposes of the new technology process. One commenter stated that this requirement seems to preclude diagnosis code updates. Another commenter requested clarification in the final rule as to whether new diagnosis codes are intended to be included in the April 1 update.

Response: We agree that section 503(a) of Pub. L. 108-173 did not limit ICD-9-CM code updates to procedure codes. The legislation covered all of ICD-9-CM, which includes both diagnoses and procedures codes. Therefore, consideration will be given to updates to both the diagnosis and procedure parts of ICD-9-CM on April 1 if a strong and convincing case can be made that either a diagnosis or procedure code is necessary to capture a new technology. We acknowledge that it may be necessary to recognize a new disease, such as SARS, on April 1 so that a new technology directed toward the disease can be more easily

identified. We anticipate that most, if not all, requests for April 1 ICD-9-CM code updates will apply to procedure codes, as the commenters have stated. While it is unlikely that there will be many such disease code requests for an April 1 update, we will not restrict any such requests for consideration.

Comment: Commenters representing national and state hospital associations as well as other organizations suggested that providing twice-yearly updates to the ICD-9-CM is only a temporary solution to meeting the coding needs of providers who may need to report new technology. The organizations stated that a more permanent and long-term solution would be the implementation of ICD-10-CM and ICD-10-PCS as quickly as possible. Several other commenters recommended moving forward with the implementation of ICD-10 as quickly as possible. One commenter urged DHHS to adopt and implement ICD-10-CM and ICD-10-PCS as quickly as possible in the United States. The commenter further stated that the sooner the health care industry and CMS begin to use and collect data more closely representing actual diagnosis and procedures, the better the picture of our health services and healthcare services will be; reimbursement will be more accurate; and there will be less administrative burden on health care providers and on CMS. One commenter asked that the regulatory process for implementing ICD-10 be started by the end of 2004. Another commenter stated that ICD-9-CM is becoming increasingly difficult to update and progress should be made on implementing ICD-10.

Response: We acknowledge that there are some concerns with the ICD-9-CM code set. The National Committee on Vital and Health Statistics (NCVHS) has recommended that DHHS, under its HIPAA responsibilities, prepare a notice of proposed rulemaking regarding the proposed adoption of ICD-10 as a HIPAA standard to replace ICD-9-CM. We are assessing the NCVHS recommendations.

DHHS has been actively working on the development of new coding systems to replace the ICD-9-CM. In December 1990, the NCVHS issued a report noting that, while the ICD-9-CM classification system had been responsive to changing technologies and identifying new diseases, there was concern that the ICD classification might be stressed to a point where the quality of the system would soon be compromised. The ICD-10-CM (for diagnoses) and the ICD-10-PCS (for procedures) were developed in response to these concerns. These efforts have become increasingly

important because of the growing number of problems with the ICD-9-CM, which was implemented 25 years ago.

16. Other Issues

a. Craniotomy Procedures

As discussed in the August 1, 2003, IPPS final rule (68 FR 45353), for FY 2004 we conducted an analysis of the charges for various procedures and diagnoses within DRG 1 (Craniotomy Age > 17 With CC) and DRG 2 (Craniotomy Age > 17 Without CC) to determine whether further changes to these DRGs were warranted. Based on our analysis and consideration of public comments received on our May 19, 2003, IPPS proposed rule (68 FR 27161), in the August 1, 2003, IPPS final rule, we created three new DRGs: DRG 528 (Intracranial Vascular Procedures With a Principal Diagnosis of Hemorrhage) for patients with an intracranial vascular procedure and an intracranial hemorrhage; and DRGs 529 (Ventricular Shunt Procedures With CC) and 530 (Ventricular Shunt Procedures Without CC) for patients with only a vascular shunt procedure.

In the May 18, 2004, proposed rule, we indicated that we had received further comments (discussed below) regarding the composition of DRGs 1 and 2 that relate to the appropriate DRG assignment of unruptured cerebral aneurysm cases and cases involving implantation of GLIADEL® chemotherapy wafers. We had also received comments on possible revisions to DRG 3 (Craniotomy Age 0-17).

(1) Unruptured Cerebral Aneurysms

In the August 1, 2003, final rule (68 FR 45354), in response to a comment that suggested we create a companion DRG to DRG 528 for intracranial vascular procedures for unruptured cerebral aneurysms, we evaluated cases in the MedPAR file involving unruptured cerebral aneurysm and determined that the average charges for unruptured cerebral aneurysm cases were consistent with the variation of charges found in DRGs 1 and 2. Therefore, we did not propose a change in the DRG classification. We indicated that we would continue to monitor cases involving unruptured cerebral aneurysms.

In the May 18, 2004, proposed rule, we discussed our examination of cases in the FY 2003 MedPAR file that reported unruptured cerebral aneurysms. We found 657 unruptured aneurysm cases assigned to DRG 1 and 481 unruptured cerebral aneurysm cases

assigned to DRG 2. The average charges for these unruptured cerebral aneurysm cases in DRG 1 (\$50,879) are slightly lower than the overall charges for all cases in that DRG (\$51,300). For unruptured cerebral aneurysm cases assigned to DRG 2, we found the average charges of approximately \$29,524 are consistent with the overall average charges of that DRG of approximately \$28,416.

Based on the results of our analysis, we indicated that we still do not believe a proposal to modify the DRG assignment of unruptured cerebral aneurysm cases is warranted.

We received one comment on this issue from an organization representing hospitals. The commenter agreed that no change is warranted for the DRG assignment of unruptured cerebral aneurysm cases at this time.

(2) GLIADEL® Chemotherapy Wafers

In the August 1, 2003 final rule (68 FR 45354), we stated that we had received comments requesting a change to the DRG assignment of cases involving implantation of GLIADEL® chemotherapy wafers to treat brain tumors. One of the commenters had offered two options: (1) create a new DRG for cases involving implantation of GLIADEL® chemotherapy wafers; and (2) reassign these cases to DRG 484 (Craniotomy for Multiple Significant Trauma).

At that time, we had analyzed data in the March 2003 update of the FY 2003 MedPAR file and found a total of 61 cases in which procedure code 00.10 (Implantation of a chemotherapy agent) was reported for cases assigned to DRGs 1 and 2. There were 38 cases assigned to DRG 1 and 23 cases assigned to DRG 2. The GROUPEL logic for these DRGs assigns cases with CCs to DRG 1 and those without CCs to DRG 2. Consistent with the GROUPEL logic for these DRGs, we had found that the average standardized charges in DRGs 1 and 2 were approximately \$64,864 and \$42,624, respectively. However, while the estimated average charges for GLIADEL® wafer cases of \$50,394 may have been higher than the average standardized charges for DRG 2, they were within the normal variation of overall charges within each DRG. In addition, the volume of cases in these two DRGs was too small to warrant the establishment of a separate new DRG for this technology. Therefore, we stated that we wanted to review a full year of data and take the time to consider alternative options that might appear warranted before proposing a change.

In the May 18, 2004, proposed rule, we discussed our examination of more

complete MedPAR data (December 2003 update for FY 2003) on cases reporting GLIADEL® chemotherapy wafers. We found a total of 127 cases in which procedure code 00.10 was reported for cases assigned to DRGs 1 and 2. There were 80 cases assigned to DRG 1 and 47 cases assigned to DRG 2. The average charges for these cases in DRGs 1 and 2 were approximately \$61,866 and \$47,189, respectively. The average charges for these cases were higher than the overall charges of DRGs 1 and 2 of approximately \$51,300 and \$28,416, respectively. Although the average charges for the GLIADEL® wafer cases within these DRGs are higher than the average charges of all cases in these DRGs, they remain within the range of average charges for other procedures included in these DRGs. The majority of the GLIADEL® wafer cases are assigned to the second highest weighted DRG in MDC 1 behind DRG 528 (Intracranial Vascular Procedure With a Principal Diagnosis of Hemorrhage) in which the weights were derived from average charges of approximately \$113,884. In DRG 1, there are 10 procedures that have higher average charges than the GLIADEL® wafer cases. However, in DRG 2, the charges associated with GLIADEL® wafer cases are the highest of the procedures included within the DRG.

DRGs are based on the principal diagnosis, secondary diagnosis, and procedures performed on the patient. DRGs are not generally created to recognize the presence or absence of specific technologies for each patient. In the past, we have made one exception to this rule. The exception was the creation of two new DRGs for drug-eluting stents: DRG 526 (Percutaneous Cardiovascular Procedure With Drug-Eluting Stent With Acute Myocardial Infarction) and DRG 527 (Percutaneous Cardiovascular Procedure With Drug-Eluting Stent Without Acute Myocardial Infarction) (67 FR 50003). We took this unprecedented approach in response to the unique circumstances surrounding the potential breakthrough nature of this technology. We currently have 59,613 drug-eluting stent cases annually, far more cases than the volume for GLIADEL® wafers. We believe that the volume of GLIADEL® wafer cases remains too small to warrant the taking of the exceptional step of establishing a separate new DRG for this technology.

Commenters also have proposed the reassignment of GLIADEL® wafer cases to other existing DRGs, such as DRG 484 (Craniotomy for Multiple Significant Trauma), DRG 528 (Intracranial Vascular Procedures With Principal Diagnosis of Hemorrhage), DRG 492

(Chemotherapy With Acute Leukemia as a Secondary Diagnosis or With Use of a High Dose Chemotherapeutic Agent), or DRG 481 (Bone Marrow Transplant). In the proposed rule, we stated that we had examined these alternatives, and had come to the conclusion that none of these alternatives meets the standard of clinical coherence under the DRG system. For example, reconfiguring DRG 484 to include GLIADEL® wafer cases would not produce a clinically coherent DRG because DRG 484 contains cases where craniotomy is performed in the setting of multiple significant trauma. Similarly, assigning GLIADEL® wafer cases to DRG 528 would not produce a clinically coherent DRG because DRG 528 contains cases where craniotomy is performed as part of a vascular procedure with a primary diagnosis of hemorrhage, as in the case of a ruptured aneurysm. DRG 492 is clinically inappropriate because it contains cases of acute leukemia treated with chemotherapy, and DRG 481 is clinically inappropriate because it contains cases involving bone marrow transplant. None of these DRGs contains cases of glioblastoma multiforme or other primary brain tumors. Therefore, in the May 18, 2004 proposed rule, we did not propose to adopt any of these changes.

As discussed in the May 18, 2004 proposed rule, we also considered several other approaches to reassigning GLIADEL® wafer cases in a manner that is appropriate both in terms of clinical coherence and resource use. For example, we considered the creation of a new DRG that includes GLIADEL® wafer cases along with other types of local therapy for intracerebral malignant disease. Specifically, we considered the creation of a new DRG that includes GLIADEL® wafers and a Gliosite Radiation Therapy System, a relatively new form of intracavitary brachytherapy. Such a DRG would be clinically coherent because it would contain cases of malignant brain tumors treated with local therapy. However, our analysis of existing FY 2003 MedPAR data suggested that such a DRG would probably not provide enhanced reimbursement for the GLIADEL® wafer cases, and that, in fact, decreased reimbursement for GLIADEL® wafer cases is a more likely result. Therefore, we did not propose a specific change. However, we stated that we would continue to monitor our data to determine whether a change is warranted in the future.

We recognize that the implantation of chemotherapeutically active wafers for local therapy of malignant brain tumors represents a significant medical

technology that currently offers clinical benefits to patients and holds out the promise of future innovation in the treatment of these brain tumors.

In our proposed rule (69 FR 28221), we invited comments and suggestions regarding the appropriate DRG assignment for this technology.

Comment: One comment agreed with the current DRG assignment of DRG 1 or 2 for GLIADEL® cases.

Response: We appreciate the commenter's support for the current DRG assignment for these cases.

Comment: Four commenters supported the reassignment of Gliadel® cases to DRG 528 (Intracranial Vascular Procedure With a Principal Diagnosis of Hemorrhage). The commenters stated that the average cost of a patient receiving Gliadel® chemotherapy wafer treatment is consistent with the average DRG 528 payments to providers. The commenters also believed that treatment using the Gliadel® wafer is clinically consistent with the treatment under procedures currently assigned to DRG 528.

Response: As we stated in the May 18, 2004 proposed rule (69 FR 28222), we do not believe that the GLIADEL® cases meet the clinical coherence criteria for inclusion in DRG 528. DRG 528 includes hemorrhage or ruptured cerebral aneurysm cases. While the surgical approach may be similar to GLIADEL®, cases assigned to DRG 528 involve patients who have an acute condition with a high severity of illness and a significantly higher rate of mortality during surgery than GLIADEL® cases (20.6 percent for DRG 528 cases compared to 3.15 for GLIADEL® cases). In addition, the average charges for cases in DRG 528, approximately \$97,540, are significantly higher than the average charges for GLIADEL® cases in DRG 1, approximately \$61,866. Thus, we do not believe that GLIADEL® cases and those assigned to DRG 528 are clinically coherent and similar in resource use. We continue to believe that reassigning GLIADEL® cases to DRG 528 is inappropriate and would result in overpayment for GLIADEL® cases.

Comment: One commenter suggested that we reassign GLIADEL® cases to DRG 528 for FY 2005 and eventually create a DRG for intracerebral therapies. The commenter proposed a new DRG that would include implantation of a chemotherapeutic agent and seven new drugs that are currently in FDA Phase II and III clinical trials and are expected to receive FDA approval in 2 to 5 years. According to the commenter, the new drugs are also indicated for glioblastoma multiforme and the mode of therapy is

chemotherapy, radiotherapy, or brachytherapy.

Response: As we discussed above, we do not believe assignment to DRG 528 is appropriate. We review DRG assignments every year and will determine the appropriate assignment of the new technologies when it is appropriate to do so.

Comment: Many commenters encouraged CMS to reassign Gliadel® chemotherapy wafer treatment to a new or higher paying DRG. The commenters believed that higher payment would ensure access to life-extending treatment for patients suffering from malignant brain tumors. These commenters offered no specific recommendations on reassignment of these cases to other DRGs.

Response: In this final rule, we are creating a new DRG that would include implantation of chemotherapeutic agent (procedure code 00.10) cases or cases in which an acute complex central nervous system diagnosis was reported as the principal diagnosis. An example of an acute complex diagnosis is an intracranial abscess. GLIADEL® chemotherapy wafer cases would be reassigned to this new DRG.

Although we did not propose this specific solution to the issue of payment for GLIADEL® in the proposed rule, we indicated that we would continue to consider appropriate changes to the DRG assignment of cases involving GLIADEL®. Furthermore, we believe that the creation of a new DRG for cases involving implantation of a

chemotherapeutic agent or cases with an acute complex central nervous system diagnosis as the principal diagnosis ensures that GLIADEL® cases are assigned to a DRG that is clinically coherent and reflects the resources used to treat these cases and appropriately addresses the concerns of those commenters who raised questions regarding the DRG assignment for these cases.

The new DRG 543 (Craniotomy with Implantation of Chemotherapeutic Agent or Acute Complex Central Nervous System Principal Diagnosis) is being placed in MDC 1. It was created from existing DRGs 1 and 2 (Craniotomy Age >17 With and Without CC, respectively) by removing three types of patients based on their principal diagnosis. Therefore, new DRG 543 will contain patients who undergo a craniotomy procedure with a principal diagnosis belonging to one of the following three categories:

1. Patients with a major central nervous system infection, such as bacterial meningitis, encephalitis, or an intracranial abscess.
2. Patients with a subarachnoid hemorrhage, intracranial hemorrhage, or an acute stroke.
3. Patients with central nervous system trauma resulting in brain laceration or brain injury associated with an open head wound.

In addition, new DRG 543 will include cases involving treatment using chemotherapeutic agents and devices

implanted in the brain, such as implantable chemotherapeutic wafers.

The cases remaining in DRGs 1 and 2 will be the following types of patients:

1. Patients with chronic central nervous system conditions such as malignancies, degenerative conditions, and cerebrovascular disease without acute infarct.
2. Patients with subdural hematoma not associated with an open head wound.
3. Patients with lesser degrees of central nervous system trauma, such as skull fracture or other injury but without brain laceration.

Patients in new DRG 543 would, on average, consume more resources because they require greater pre-operative and post-operative care, and in many cases require more complicated operative procedures. The FY 2003 MedPAR data for the new DRG includes 5,413 cases with overall average charges of approximately \$63,409. These charges are similar to the current average charges for Gliadel® cases in DRG 1 of approximately \$61,866.

For FY 2005, we will be implementing new DRG 543 with the following logic:

- Craniotomy procedure from DRGs 1 and 2 and procedure code 00.10, Implantation of chemotherapeutic agent; or
- Craniotomy procedure from DRGs 1 and 2 and principal diagnosis of acute complex central nervous system listed below.

Principal Diagnosis (PDX) of Acute Complex CNS Diagnosis

Diagnosis Code	Description
003.21	Salmonella meningitis
006.5	Amebic brain abscess
013.00	Tuberculous meningitis,unspecified
013.01	Tuberculous meningitis,bacteriological or histological examination not done
013.02	Tuberculous meningitis,bacteriological or histological examination unknown(at present)
013.03	Tuberculous meningitis,tubercle bacilli found in sputum) by microscopy
013.04	Tuberculous meningitis,tubercle bacilli not found(in sputum)by microscopy,but found by bacterial culture
013.05	Tuberculous meningitis, tubercle bacilli not found by bacteriological examination, but tuberculosis confirmed histologically
013.06	Tuberculous meningitis, tubercle bacilli not found by bacteriological or histological examination, but tuberculosis confirmed by other methods [inoculation of animals]
013.10	Tuberculoma of meninges,unspecified
013.11	Tuberculoma of meninges, bacteriological or histological examination not done
013.12	Tuberculoma of meninges, bacteriological or histological examination unknown(at present)
013.13	Tuberculoma of meninges, tubercle bacilli found in sputum) by microscopy
013.14	Tuberculoma of meninges, tubercle bacilli not found(in sputum)by microscopy, but found by bacterial culture
013.15	Tuberculoma of meninges, tubercle bacilli not found by bacteriological examination, but tuberculosis confirmed histologically
013.16	Tuberculoma of meninges, tubercle bacilli not found by bacteriological or histological examination, but tuberculosis confirmed by other methods [inoculation of animals]
013.20	Tuberculoma of brain, unspecified
013.21	Tuberculoma of brain, bacteriological or histological examination not done
013.22	Tuberculoma of brain, bacteriological or histological examination unknown(at present)
013.23	Tuberculoma of brain, tubercle bacilli found in sputum) by microscopy

Diagnosis Code	Description
013.24	Tuberculoma of brain, tubercle bacilli not found (in sputum) by microscopy, but found by bacterial culture
013.25	Tuberculoma of brain, tubercle bacilli not found by bacteriological examination, but tuberculosis confirmed histologically
013.26	Tuberculoma of brain, tubercle bacilli not found by bacteriological or histological examination, but tuberculosis confirmed by other methods [inoculation of animals]
013.30	Tuberculous abscess of brain, unspecified
013.31	Tuberculous abscess of brain, bacteriological or histological examination not done
013.32	Tuberculous abscess of brain, bacteriological or histological examination unknown (at present)
013.33	Tuberculous abscess of brain, tubercle bacilli found in sputum) by microscopy
013.34	Tuberculous abscess of brain, tubercle bacilli not found (in sputum)by microscopy, but found by bacterial culture
013.35	Tuberculous abscess of brain, tubercle bacilli not found by bacteriological examination, but tuberculosis confirmed histologically
013.36	Tuberculous abscess of brain, tubercle bacilli not found by bacteriological or histological examination, but tuberculosis confirmed by other methods [inoculation of animals]
013.40	Tuberculoma of spinal cord,unspecified
013.41	Tuberculoma of spinal cord, bacteriological or histological examination not done
013.42	Tuberculoma of spinal cord, bacteriological or histological examination unknown(at present)
013.43	Tuberculoma of spinal cord, tubercle bacilli found in sputum) by microscopy
013.44	Tuberculoma of spinal cord,tubercle bacilli not found(in sputum)by microscopy, but found by bacterial culture
013.45	Tuberculoma of spinal cord, tubercle bacilli not found by bacteriological examination, but tuberculosis confirmed histologically
013.46	Tuberculoma of spinal cord, tubercle bacilli not found by bacteriological or histological examination, but tuberculosis confirmed by other methods [inoculation of animals]
013.50	Tuberculous abscess of spinal cord,unspecified
013.51	Tuberculous abscess of spinal cord, bacteriological or histological examination not done
013.52	Tuberculous abscess of spinal cord, bacteriological or histological examination unknown(at present)
013.53	Tuberculous abscess of spinal cord, tubercle bacilli found in sputum) by microscopy
013.54	Tuberculous abscess of spinal cord, tubercle bacilli not found (in sputum)by microscopy, but found by bacterial culture
013.55	Tuberculous abscess of spinal cord, tubercle bacilli not found by bacteriological examination, but tuberculosis confirmed histologically

Diagnosis Code	Description
013.56	Tuberculous abscess of spinal cord, tubercle bacilli not found by bacteriological or histological examination, but tuberculosis confirmed by other methods [inoculation of animals]
013.60	Tuberculous encephalitis or myelitis, unspecified
013.61	Tuberculous encephalitis or myelitis, bacteriological or histological examination not done
013.62	Tuberculous encephalitis or myelitis, bacteriological or histological examination unknown(at present)
013.63	Tuberculous encephalitis or myelitis, tubercle bacilli found in sputum) by microscopy
013.64	Tuberculous encephalitis or myelitis, tubercle bacilli not found (in sputum) by microscopy, but found by bacterial culture
013.65	Tuberculous encephalitis or myelitis, tubercle bacilli not found by bacteriological examination, but tuberculosis confirmed histologically
013.66	Tuberculous encephalitis or myelitis, tubercle bacilli not found by bacteriological or histological examination, but tuberculosis confirmed by other methods [inoculation of animals]
013.80	Other specified tuberculosis of central nervous system, unspecified
013.81	Other specified tuberculosis of central nervous system, bacteriological or histological examination not done
013.82	Other specified tuberculosis of central nervous system, bacteriological or histological examination unknown (at present)
013.83	Other specified tuberculosis of central nervous system, tubercle bacilli found in sputum) by microscopy
013.84	Other specified tuberculosis of central nervous system, tubercle bacilli not found (in sputum) by microscopy, but found by bacterial culture
013.85	Other specified tuberculosis of central nervous system, tubercle bacilli not found by bacteriological examination, but tuberculosis confirmed histologically
013.86	Other specified tuberculosis of central nervous system, tubercle bacilli not found by bacteriological or histological examination, but tuberculosis confirmed by other methods [inoculation of animals]
013.90	Unspecified tuberculosis of central nervous system, unspecified
013.91	Unspecified tuberculosis of central nervous system, bacteriological or histological examination not done
013.92	Unspecified tuberculosis of central nervous system, bacteriological or histological examination unknown (at present)
013.93	Unspecified tuberculosis of central nervous system, tubercle bacilli found in sputum) by microscopy
013.94	Unspecified tuberculosis of central nervous system, tubercle bacilli not found (in sputum) by microscopy, but found by bacterial culture

Diagnosis Code	Description
013.95	Unspecified tuberculosis of central nervous system, tubercle bacilli not found by bacteriological examination, but tuberculosis confirmed histologically
013.96	Unspecified tuberculosis of central nervous system, tubercle bacilli not found by bacteriological or histological examination, but tuberculosis confirmed by other methods [inoculation of animals]
036.0	Meningococcal meningitis
036.1	Meningococcal encephalitis
045.00	Acute paralytic poliomyelitis specified as bulbar, poliovirus, unspecified type
045.01	Acute paralytic poliomyelitis specified as bulbar, poliovirus type I
045.02	Acute paralytic poliomyelitis specified as bulbar, poliovirus type II
045.03	Acute paralytic poliomyelitis specified as bulbar, poliovirus type III
045.10	Acute poliomyelitis with other paralysis, poliovirus, unspecified type
045.11	Acute poliomyelitis with other paralysis, poliovirus type I
045.12	Acute poliomyelitis with other paralysis, poliovirus type II
045.13	Acute poliomyelitis with other paralysis, poliovirus type III
045.90	Acute poliomyelitis, unspecified, poliovirus, unspecified type
045.91	Acute poliomyelitis, unspecified, poliovirus type I
045.92	Acute poliomyelitis, unspecified, poliovirus type II
045.93	Acute poliomyelitis, unspecified, poliovirus type III
054.3	Herpetic Meningoencephalitis
054.72	Herpes simplex meningitis
055.0	Postmeasles encephalitis
062.0	Japanese encephalitis
062.1	Western equine encephalitis
062.2	Eastern equine encephalitis
062.3	St Louis encephalitis
062.4	Australian encephalitis
062.5	California virus encephalitis
062.8	Other specified mosquito-borne viral encephalitis
062.9	Mosquito-borne viral encephalitis, unspecified
063.0	Russia spring-summer [Taiga]encephalitis
063.1	Louping ill
063.2	Central European encephalitis
063.8	Other specified tick-borne viral encephalitis
063.9	Tick-borne viral encephalitis, unspecified
064	Viral encephalitis transmitted by other and unspecified arthropods
066.2	Venezuelan equine fever
071	Rabies
072.1	Mumps meningitis

Diagnosis Code	Description
072.2	Mumps encephalitis
091.81	Acute syphilitic meningitis (secondary)
094.2	Syphilitic meningitis
094.81	Syphilitic encephalitis
098.82	Gonococcal meningitis
100.81	Leptospiral meningitis (aseptic)
100.89	Other specified leptospiral infections
112.83	Candidal meningitis
114.2	Coccidioidal meningitis
115.01	Infection by histoplasma capsulatum, meningitis
115.11	Infection by histoplasma duboisii, meningitis
115.91	Histoplasmosis, unspecified, meningitis
130.0	Meningoencephalitis due to toxoplasmosis
320.0	Hemophilus meningitis
320.1	Pneumococcal meningitis
320.2	Streptococcal meningitis
320.3	Staphylococcal meningitis
320.7	Meningitis in other bacterial diseases classified elsewhere
320.81	Anaerobic meningitis
320.82	Meningitis due to gram-negative bacteria, Not elsewhere classified
320.89	Meningitis due to other specified bacteria
320.9	Meningitis due to unspecified bacterium
321.0	Cryptococcal meningitis
321.1	Meningitis in other fungal diseases
321.2	Meningitis due to viruses, not elsewhere classified
321.3	Meningitis due to trypanosomiasis
323.0	Encephalitis in viral diseases
323.1	Encephalitis in rickettsial diseases classified elsewhere
323.2	Encephalitis in protozoal diseases classified elsewhere
323.4	Other encephalitis due to infection classified elsewhere
323.5	Encephalitis following immunization procedures
323.6	Postinfectious encephalitis
323.7	Toxic encephalitis
323.8	Other causes of encephalitis
323.9	Unspecified cause of encephalitis
324.0	Intracranial abscess
324.1	Intraspinal abscess
324.9	Intracranial and intraspinal abscess of unspecified site
325	Phlebitis and thrombophlebitis of intracranial venous sinuses

Diagnosis Code	Description
430	Subarachnoid hemorrhage
431	Intracerebral hemorrhage
432.9	Unspecified intracranial hemorrhage
433.01	Basilar artery, with cerebral infarction
433.11	Carotid artery, with cerebral infarction
433.21	Vertebral artery, with cerebral infarction
433.31	Multiple and bilateral, with cerebral infarction
433.81	Other specified precerebral artery, with cerebral infarction
433.91	Unspecified precerebral artery, with cerebral infarction
434.01	Cerebral thrombosis, with cerebral infarction
434.11	Cerebral embolism, with cerebral infarction
434.91	Cerebral artery occlusion,unspecified, with cerebral infarction
851.10	Cortex (cerebral) contusion with open intracranial wound, unspecified state of consciousness
851.11	Cortex (cerebral) contusion with open intracranial wound, with no loss of consciousness
851.12	Cortex (cerebral) contusion with open intracranial wound, with brief [less than one hour]loss of consciousness
851.13	Cortex (cerebral) contusion with open intracranial wound, with moderate[1-24 hours]loss of consciousness
851.14	Cortex (cerebral) contusion with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level
851.15	Cortex (cerebral) contusion with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
851.16	Cortex (cerebral) contusion with open intracranial wound, with loss of consciousness of unspecified duration
851.19	Cortex (cerebral) contusion with open intracranial wound, with concussion, unspecified
851.20	Cortex (cerebral) laceration without mention of open intracranial wound, unspecified state of consciousness
851.21	Cortex (cerebral) laceration without mention of open intracranial wound, with no loss of consciousness
851.22	Cortex (cerebral) laceration without mention of open intracranial wound, with brief [less than one hour] loss of consciousness
851.23	Cortex (cerebral) laceration without mention of open intracranial wound, with moderate [1-24 hours] loss of consciousness
851.24	Cortex (cerebral) laceration without mention of open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level

Diagnosis Code	Description
851.25	Cortex (cerebral) laceration without mention of open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
851.26	Cortex (cerebral) laceration without mention of open intracranial wound, with loss of consciousness of unspecified duration
851.29	Cortex (cerebral) laceration without mention of open intracranial wound, with concussion, unspecified
851.30	Cortex (cerebral) laceration with open intracranial wound, unspecified state of consciousness
851.31	Cortex (cerebral) laceration with open intracranial wound, with no loss of consciousness
851.32	Cortex (cerebral) laceration with open intracranial wound, with brief [less than one hour] loss of consciousness
851.33	Cortex (cerebral) laceration with open intracranial wound, with moderate [1-24 hours] loss of consciousness
851.34	Cortex (cerebral) laceration with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level
851.35	Cortex (cerebral) laceration with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
851.36	Cortex (cerebral) laceration with open intracranial wound, with loss of consciousness of unspecified duration
851.39	Cortex (cerebral) laceration with open intracranial wound, with concussion, unspecified
851.50	Cerebellar or brain stem contusion with open intracranial wound, unspecified state of consciousness
851.51	Cerebellar or brain stem contusion with open intracranial wound, with no loss of consciousness
851.52	Cerebellar or brain stem contusion with open intracranial wound, with brief [less than one hour] loss of consciousness
851.53	Cerebellar or brain stem contusion with open intracranial wound, with moderate [1-24 hours] loss of consciousness
851.54	Cerebellar or brain stem contusion with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level
851.55	Cerebellar or brain stem contusion with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
851.56	Cerebellar or brain stem contusion with open intracranial wound, with loss of consciousness of unspecified duration
851.59	Cerebellar or brain stem contusion with open intracranial wound, with concussion, unspecified
851.60	Cerebellar or brain stem laceration without mention of open intracranial wound, unspecified state of consciousness

Diagnosis Code	Description
851.61	Cerebellar or brain stem laceration without mention of open intracranial wound, with no loss of consciousness
851.62	Cerebellar or brain stem laceration without mention of open intracranial wound, with brief [less than one hour] loss of consciousness
851.63	Cerebellar or brain stem laceration without mention of open intracranial wound, with moderate [1-24 hours] loss of consciousness
851.64	Cerebellar or brain stem laceration without mention of open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level
851.65	Cerebellar or brain stem laceration without mention of open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
851.66	Cerebellar or brain stem laceration without mention of open intracranial wound, with loss of consciousness of unspecified duration
851.69	Cerebellar or brain stem laceration without mention of open intracranial wound, with concussion, unspecified
851.70	Cerebellar or brain stem laceration with open intracranial wound, unspecified state of consciousness
851.71	Cerebellar or brain stem laceration with open intracranial wound, with no loss of consciousness
851.72	Cerebellar or brain stem laceration with open intracranial wound, with brief [less than one hour] loss of consciousness
851.73	Cerebellar or brain stem laceration with open intracranial wound, with moderate [1-24 hours] loss of consciousness
851.74	Cerebellar or brain stem laceration with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level
851.75	Cerebellar or brain stem laceration with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
851.76	Cerebellar or brain stem laceration with open intracranial wound, with loss of consciousness of unspecified duration
851.79	Cerebellar or brain stem laceration with open intracranial wound, with concussion, unspecified
851.80	Other and unspecified cerebral laceration and contusion, without mention of open intracranial wound, unspecified state of consciousness
851.81	Other and unspecified cerebral laceration and contusion, without mention of open intracranial wound, with no loss of consciousness
851.82	Other and unspecified cerebral laceration and contusion, without mention of open intracranial wound, with brief [less than one hour] loss of consciousness
851.83	Other and unspecified cerebral laceration and contusion, without mention of open intracranial wound, with moderate [1-24 hours] loss of consciousness

Diagnosis Code	Description
851.84	Other and unspecified cerebral laceration and contusion, without mention of open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level
851.85	Other and unspecified cerebral laceration and contusion, without mention of open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
851.86	Other and unspecified cerebral laceration and contusion, without mention of open intracranial wound, with loss of consciousness of unspecified duration
851.89	Other and unspecified cerebral laceration and contusion, without mention of open intracranial wound, with concussion, unspecified
851.90	Other and unspecified cerebral laceration and contusion, with open intracranial wound, unspecified state of consciousness
851.91	Other and unspecified cerebral laceration and contusion, with open intracranial wound, with no loss of consciousness
851.92	Other and unspecified cerebral laceration and contusion, with open intracranial wound, with brief [less than one hour] loss of consciousness
851.93	Other and unspecified cerebral laceration and contusion, with open intracranial wound, with moderate [1-24 hours] loss of consciousness
851.94	Other and unspecified cerebral laceration and contusion, with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level
851.95	Other and unspecified cerebral laceration and contusion, with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
851.96	Other and unspecified cerebral laceration and contusion, with open intracranial wound, with loss of consciousness of unspecified duration
851.99	Other and unspecified cerebral laceration and contusion, with open intracranial wound, with concussion, unspecified
852.00	Subarachnoid hemorrhage following injury without mention of open intracranial wound, unspecified state of consciousness
852.01	Subarachnoid hemorrhage following injury without mention of open intracranial wound, with no loss of consciousness
852.02	Subarachnoid hemorrhage following injury without mention of open intracranial wound, with brief [less than one hour] loss of consciousness
852.03	Subarachnoid hemorrhage following injury without mention of open intracranial wound, with moderate [1-24 hours] loss of consciousness
852.04	Subarachnoid hemorrhage following injury without mention of open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level

Diagnosis Code	Description
852.05	Subarachnoid hemorrhage following injury without mention of open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
852.06	Subarachnoid hemorrhage following injury without mention of open intracranial wound, with loss of consciousness of unspecified duration
852.09	Subarachnoid hemorrhage following injury without mention of open intracranial wound, with concussion, unspecified
852.10	Subarachnoid hemorrhage following injury with open intracranial wound, unspecified state of consciousness
852.11	Subarachnoid hemorrhage following injury with open intracranial wound, with no loss of consciousness
852.12	Subarachnoid hemorrhage following injury with open intracranial wound, with brief [less than one hour] loss of consciousness
852.13	Subarachnoid hemorrhage following injury with open intracranial wound, with moderate [1-24 hours] loss of consciousness
852.14	Subarachnoid hemorrhage following injury with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level
852.15	Subarachnoid hemorrhage following injury with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
852.16	Subarachnoid hemorrhage following injury with open intracranial wound, with loss of consciousness of unspecified duration
852.19	Subarachnoid hemorrhage following injury with open intracranial wound, with concussion, unspecified
852.30	Subdural hemorrhage following injury with open intracranial wound, unspecified state of consciousness
852.31	Subdural hemorrhage following injury with open intracranial wound, with no loss of consciousness
852.32	Subdural hemorrhage following injury with open intracranial wound, with brief [less than one hour] loss of consciousness
852.33	Subdural hemorrhage following injury with open intracranial wound, with moderate [1-24 hours] loss of consciousness
852.34	Subdural hemorrhage following injury with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level
852.35	Subdural hemorrhage following injury with open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
852.36	Subdural hemorrhage following injury with open intracranial wound, with loss of consciousness of unspecified duration

Diagnosis Code	Description
852.39	Subdural hemorrhage following injury with open intracranial wound, with concussion, unspecified
853.00	Other and unspecified intracranial hemorrhage following injury, Without mention of open intracranial wound, unspecified state of consciousness
853.01	Other and unspecified intracranial hemorrhage following injury, Without mention of open intracranial wound, with no loss of consciousness
853.02	Other and unspecified intracranial hemorrhage following injury, Without mention of open intracranial wound, with brief [less than one hour] loss of consciousness
853.03	Other and unspecified intracranial hemorrhage following injury, Without mention of open intracranial wound, with moderate [1-24 hours] loss of consciousness
853.04	Other and unspecified intracranial hemorrhage following injury, Without mention of open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level
853.05	Other and unspecified intracranial hemorrhage following injury, Without mention of open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
853.06	Other and unspecified intracranial hemorrhage following injury, Without mention of open intracranial wound, with loss of consciousness of unspecified duration
853.09	Other and unspecified intracranial hemorrhage following injury, Without mention of open intracranial wound, with concussion, unspecified
853.10	Other and unspecified intracranial hemorrhage following injury, With open intracranial wound, unspecified state of consciousness
853.11	Other and unspecified intracranial hemorrhage following injury, With open intracranial wound, with no loss of consciousness
853.12	Other and unspecified intracranial hemorrhage following injury, With open intracranial wound, with brief [less than one hour] loss of consciousness
853.13	Other and unspecified intracranial hemorrhage following injury, With open intracranial wound, with moderate [1-24 hours] loss of consciousness
853.14	Other and unspecified intracranial hemorrhage following injury, With open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level
853.15	Other and unspecified intracranial hemorrhage following injury, With open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
853.16	Other and unspecified intracranial hemorrhage following injury, With open intracranial wound, with loss of consciousness of unspecified duration
853.19	Other and unspecified intracranial hemorrhage following injury, With open intracranial wound, with concussion, unspecified
854.10	Intracranial injury of other and unspecified nature, With open intracranial wound, unspecified state of consciousness

Diagnosis Code	Description
854.11	Intracranial injury of other and unspecified nature, With open intracranial wound, with no loss of consciousness
854.12	Intracranial injury of other and unspecified nature, With open intracranial wound, with brief [less than one hour] loss of consciousness
854.13	Intracranial injury of other and unspecified nature, With open intracranial wound, with moderate [1-24 hours] loss of consciousness
854.14	Intracranial injury of other and unspecified nature, With open intracranial wound, with prolonged [more than 24 hours] loss of consciousness and return to pre-existing conscious level
854.15	Intracranial injury of other and unspecified nature, With open intracranial wound, with prolonged [more than 24 hours] loss of consciousness without return to pre-existing conscious level
854.16	Intracranial injury of other and unspecified nature, With open intracranial wound, with loss of consciousness of unspecified duration
854.19	Intracranial injury of other and unspecified nature, With open intracranial wound, with concussion, unspecified

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(3) DRG 3 (Craniotomy Age 0-17)

In the May 18, 2004, proposed rule, we addressed a comment we had received stating concern that DRG 3 has not been reviewed, while DRGs 1 and 2 have had some revisions. The commenter believed that, particularly with the removal of major trauma cases, age distinctions may no longer be significant for craniotomies and the other intracranial procedures classified in DRGs 1 through 3. The commenter stated that it may be more consistent, from both a clinical and resource perspective, to simply eliminate DRG 3 and redistribute the pediatric and juvenile cases to DRGs 1 and 2 based on the procedures performed and the complications or comorbidities present, instead. We stated that this analysis would require supplemental data from non-MedPAR sources.

We noted in the proposed rule that the primary focus of updates to the Medicare DRG classification system is on changes relating to the Medicare patient population, not the pediatric patient population. In the FY 2003 data, there were only two cases assigned to DRG 3. Therefore, we did not believe a proposal to address the commenter's request was warranted. We indicated that we are aware that the Medicare DRGs are sometimes used to classify other patient populations. We advised those non-Medicare systems that need a more up-to-date system to consider choosing from other systems that are currently in use in this country, or developing their own modifications.

Comment: One commenter agreed that there does not appear to be a need to address DRG 3 at this time. However, the commenter noted that other payers, such as many Medicaid payers, reimburse based on DRG groupings and requested that we consider those payers when addressing proposed changes to the DRG system in the future.

Response: For this final rule, we will not be making any changes to DRG 3. Decisions about the use of DRGs in Medicaid are made by the states. As we stated previously, the primary focus of our updates to the Medicare DRG classification system is on changes relating to the Medicare patient population.

b. Coronary Stent Procedures

In the May 18, 2004, proposed rule, we addressed recommendations that we had received from several industry representatives about the DRG assignments for coronary artery stents. These representatives expressed concern about whether the reimbursement for stents is adequate, especially for insertion of multiple stents. They also expressed concern about whether the current DRG structure represents the most clinically coherent classification of stent cases.

We received two comprehensive recommendations for refinement and restructuring of the current coronary stent DRGs. The current DRG structure incorporates stent cases into the following two pairs of DRGs, depending on whether bare metal or drug-eluting stents are used and whether acute myocardial infarction (AMI) is present:

- DRG 516 (Percutaneous Cardiovascular Procedures With AMI)
- DRG 517 (Percutaneous Cardiovascular Procedures With Nondrug-Eluting Stent Without AMI)
- DRG 526 (Percutaneous Cardiovascular Procedures With Drug-Eluting Stent With AMI)
- DRG 527 (Percutaneous Cardiovascular Procedures With Drug-Eluting Stent Without AMI)

One of the recommendations involved restructuring these DRGs to create two additional stent DRGs that are closely patterned after these existing pairs and that would reflect insertion of multiple stents with and without AMI. The manufacturer recommended incorporating either stenting code 36.06 (Insertion of nondrug-eluting coronary artery stent(s)) or code 36.07 (Insertion of drug-eluting coronary artery stent(s)) when they are reported along with code 36.05 (Multiple vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent). The manufacturer expressed concern that hospitals are steering patients toward coronary artery bypass graft surgery in place of stenting in order to avoid significant financial losses due to what it considered the inadequate reimbursement for inserting multiple stents.

We appreciated receiving the manufacturer's recommendation, and agree that the DRG classification of cases involving coronary stents must be clinically coherent and provide for adequate reimbursement, including

adequate reimbursement of cases requiring multiple stents. We also agree that the recommendation has some merits and deserves further study. However, as stated in the proposed rule, we believed that it was premature to act on this recommendation for two reasons. One reason is that the current coding structure for coronary artery stents cannot distinguish cases in which multiple stents are inserted from cases in which only a single stent is inserted. Current codes are able to identify performance of PTCA in more than one vessel by use of code 36.05. However, while this code indicates that PTCA was performed in more than one vessel, its use does not reflect the exact number of procedures performed or the exact number of vessels treated. Similarly, when codes 36.06 and 36.07 are used, they document the insertion of at least one stent. However, these stenting codes do not identify how many stents were inserted in a procedure, nor distinguish insertion of a single stent from insertion of multiple stents. Even the use of one of the stenting codes in conjunction with multiple-PTCA code 36.05 does not distinguish insertion of a single stent from insertion of multiple stents. The use of code 36.05 in conjunction with code 36.06 or code 36.07 indicates only performance of PTCA in more than one vessel, along with insertion of at least one stent. The precise numbers of PTCA-treated vessels, the number of vessels into which stents were inserted, and the total number of stents inserted in all treated vessels cannot be determined. Therefore, the capabilities of the current coding structure do not permit the distinction between single vessel stenting and multiple vessel stenting that would be required under the recommended restructuring of the stenting DRGs.

In addition, because the FDA approved drug-eluting stents for use in April 2003, the distinct DRGs for drug-eluting stents have only been effective for payment for a little over a year. The MedPAR file thus does not contain a full year of data with which to conduct the requisite analysis to evaluate the adequacy of the current structure of four stenting DRGs. In the proposed rule, we indicated that we would consider this recommendation as we evaluate the current DRG structure once adequate data on the current stenting DRGs become available. We also stated in the proposed rule that we believe it is still premature to undertake such a thorough restructuring of the stent DRGs.

The second recommendation was that we transform the current structure of stenting DRGs into two new pairs of DRGs, reclassifying stenting cases

according to whether bare metal or drug-eluting stents are used (as with the present DRGs) and whether the cases are "complex" or "noncomplex." The manufacturer indicated that complex cases are those that include certain comorbid conditions or procedural factors such as hypertensive renal failure, diabetes, AMI, and multivessel PCI. The manufacturer further indicated that this structure would provide an improvement in both clinical and resource coherence over the current structure that classifies cases according to the type of stent inserted and the presence or absence of AMI alone, without considering other complicating conditions. Specifically, the manufacturer recommended replacing the current structure with the following four DRGs:

- Recommended restructured DRG 516 (Complex percutaneous cardiovascular procedures with nondrug-eluting stents)
- Recommended restructured DRG 517 (Noncomplex percutaneous cardiovascular procedures with nondrug-eluting stents)
- Recommended restructured DRG 526 (Complex percutaneous cardiovascular procedures with drug-eluting stents)
- Recommended restructured DRG 527 (Noncomplex percutaneous cardiovascular procedures with drug-eluting stents)

The manufacturer presented an analysis based on FY 2002 MedPAR data, in which it evaluated charges and lengths of stay for cases with expected high resource use, and reclassified cases into the recommended new structure of paired "complex" and "noncomplex" DRGs. The analysis shows some evidence of clinical and resource coherence in the recommended DRG structure. However, as we stated in the proposed rule, the analysis does not yet provide a convincing case for adopting the recommended restructure. First, the analysis does not reveal significant gains in resource coherence compared to existing DRGs for stenting cases. Second, the analysis is limited in assessing the feasibility of using the recommended DRG restructure versus the current DRG structure for classification of stent cases. Because the manufacturer used FY 2002 MedPAR data in its analysis, it was not able to compare the resource coherence of the recommended structure with the current structure of four DRGs, but only with the two DRGs that preceded the approval of drug-eluting stents. While the manufacturer asserted that "similar results would be expected" from a comparison between its recommended

DRG restructure and the current DRG structure, we do not believe that it is advisable to undertake a critical DRG restructuring without examining the recommendation against actual experience under the current structure. As we stated in the proposed rule, we believe that this recommendation may have merit, and we will conduct a full analysis of the recommendation in comparison to the other recommendation for DRG revision and to the current DRG structure once adequate data become available.

The drug-eluting stents had not yet been FDA approved when we calculated the relative weights for DRGs 526 and 527 for the FY 2003 IPPS final rule. Therefore, in the absence of MedPAR data, we based our FY 2003 relative weight calculations on prices in countries where drug-eluting stents were already being used. A full discussion of this process can be found in the FY 2004 IPPS final rule (68 FR 45370). For computation of the proposed relative weights for FY 2005 in the May 18, 2004 proposed rule, we used the December update of FY 2003 MedPAR data. (As stated in the June 25, 2004 correction notice (69 FR 35921), there have been a total of approximately 11,084 cases in DRG 526, and 48,097 cases in DRG 527, with adjustments made for transfers to other facilities.) For computation of the final FY 2005 relative weights, we are using the March FY 2004 update of the FY 2003 MedPAR data file for cases in these two DRGs. No foreign data have been used to compute the relative weights for DRGs 526 and 527 in FY 2005.

We received a number of comments concerning coronary stents, both bare and drug-eluting in response to the May 18, 2004, proposed rule. As noted above, we had discussed two external recommendations for refinement or restructuring of the current coronary stent DRGs (69 FR 28222). At that time, we indicated that we believed that arguments for change might have merit. However, as there was not an adequate database upon which to structure a DRG revision, and because the two proposals were so dissimilar, we indicated that we would continue to monitor the coronary stent DRGs and would review the DRG structure once adequate data became available. We will continue to review the data carefully and will assess whether a revised DRG structure is appropriate when we have more than 11 months of data experience. The FDA approved the drug-eluting stent for use in April 2003. Therefore, our MedPAR payment data collection began at that time.

Comment: Two commenters supported the complex vs. noncomplex case-mix DRG pairs option. The commenters suggested that the complexities be based on diagnoses of congestive heart failure, cerebral vascular disease, renal failure, AMI, and the presence of a multiple vessel procedure. (We believe that the commenter intended the latter complexity to be the presence of code 36.05 (Multiple vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent) in the same inpatient episode.)

Response: We take this opportunity to clarify that we did not offer a choice between two options in the proposed rule. We discussed the two options that had been suggested to us. However, we determined that it was premature to

undertake a thorough restructuring of the four current stent DRGs, both because the recommendations differed so completely from each other and because we lacked data of adequate historical duration with which to make a comprehensive analysis.

We note that FDA is in the process of determining the efficacy of drug-eluting stents in high-risk patient clinical trials, and acute myocardial infarction (AMI) has been identified as one of the high-risk triggers. We do not believe it is appropriate to further use high-risk triggers such as AMI to structure the stent DRGs until FDA's work is complete.

Comment: One commenter recommended restructuring of the four existing stent DRGs (DRG 516, 517, 526, and 527) by complex and noncomplex components. Specifically, the commenter suggested replacing the existing DRG structure that

distinguishes between "with and without AMI" and the presence of bare or drug-eluting stents with a structure distinguishing between "with and without complexity." In performing its analysis, the commenter reviewed charges within each of the four stent DRGs and then stratified the cases into groups with and without the following comorbidities or procedural characteristics: a principal diagnosis of AMI, or any secondary diagnosis of congestive heart failure, renal failure, cerebrovascular disease, or cases including code 36.05, reflecting multiple vessel procedure. The commenter classified cases with the above characteristics as "complex" and cases without these characteristics as "noncomplex."

The commenter included the following table for comparison purposes:

Group	Number	Mean Charge
Current DRG 516	10,520	\$41,788
Current DRG 517	21,472	34,616
"Complex" DRG 516 - proposed by commenter	17,413	41,762
"Noncomplex" DRG 517 - proposed by commenter	14,579	31,256
Current DRG 526	3,337	51,746
Current DRG 527	12,645	41,849
"Complex" Complex DRG 526 - proposed by commenter	7,437	51,054
"Noncomplex" DRG 527 - proposed by commenter	8,585	37,767

The commenter's conclusion was that a diagnosis of AMI, by itself, was not an accurate reflection of the most resource-intensive procedures associated with coronary stenting.

Response: We appreciate the considerable thought and study that went into the analysis that was submitted. However, in reviewing the comparison, we identified the similarities of the mean charges between the current DRGs and the proposed complex DRGs, and the fact that in every single comparison, the mean charges go down in the complex DRGs. For example, according to the table, current DRG 516 has mean charges of \$41,788, while the proposed complex revision of DRG 516 has mean charges of \$41,762. This is a decrease of \$26. Also, current DRG 526 has mean charges of \$51,746, while the proposed complex

revision of DRG 526 has mean charges of \$51,054. This is a decrease of \$692. These results indicate to us that the current DRG structure is accurate in terms of resource consumption.

In addition, we note that under the commenter's proposal, the number of cases in the complex DRG categories, while the number of noncomplex cases decreases. There would be a shift in the number of cases per DRG, but each case would have lower average charges per case, which would reduce the relative weight of all four DRGs. We are hesitant to adopt this approach, given the comments and concerns that reimbursement for stenting procedures is already under funded.

Comment: One commenter supported our proposal to maintain temporary DRGs 526 and 527.

Response: We appreciate the commenter's support of these temporary DRGs. In the FY 2003 IPPS final rule (67 FR 50004), we stated that we expect that when claims data are available that reflect the use of drug-eluting stents, we would combine drug-eluting stents cases with other stent cases in DRGs 516 and 517. A change of that nature would be subject to an analysis of the claims data to determine whether these data reflect a significant reduction in the use of bare stents, due to the overwhelming industry acceptance of the more efficacious drug-eluting stent. At this time, with only 11 months of claims data, we believe that changes to these DRG pairs would be premature. We will continue our analysis and monitor the data for these cases.

Comment: One commenter expressed concern that the relative weights

published in Table 5 of the Addendum to the proposed rule (69 FR 28642) were inadequate to cover the costs of procedures involving this technology and might provide financial incentives for hospitals to use less effective technologies (such as bare metal stents) or more invasive coronary artery bypass graft (CABG) procedures for Medicare beneficiaries.

Response: We note that the relative weights listed in Table 5 of the proposed rule are based on MedPAR hospital charge data as of the December 2003 update of the files, which were not as complete for FY 2003 as the data are now. The relative weights in this final rule are based on the March FY 2004 update of the FY 2003 MedPAR file, and reflect a more comprehensive picture of hospital charges. The final weight for DRG 516 is 2.6457, for DRG 517 is 2.1106, for DRG 526 is 2.9741, and for DRG 527 is 2.3282.

We also point out that the DRG base rate computed using relative weights is only part of the formula used to determine what each hospital is paid for each case. Additional payment is made to each hospital based on its unique structure, including indirect medical education, area wage levels, disproportionate share adjustment, and any applicable cost-of-living adjustments in Alaska and Hawaii. Hospitals may also receive outlier payments for certain cases involving extraordinary high costs.

We are concerned by the comment regarding the provision of CABG procedures when less appropriate to the patient than drug-eluting therapy. One commenter believed the conversion from CABG to drug-eluting stent therapy has already begun and cited MedPAR data to prove its point. These data show that during the first quarter of full drug-eluting stent availability (July, August, and September 2003), Medicare CABG discharges declined 9.3 percent from the same quarter in the previous year. The commenter also noted a corresponding increase in stenting procedures.

In addition, it has come to our attention that there may be some coding errors that are contributing to an erroneous data and reimbursement case-mix profile for hospitals. Specifically, it has been suggested that some hospitals may be reluctant to include a code for vessel angioplasty in conjunction with stent placement. Apparently some hospital staff have expressed concerns that a "true" angioplasty is not being performed, and that they will therefore be censured by regulatory agencies for erroneous coding. Therefore, these hospitals have instructed their coding staff not to include a code describing

angioplasty of a vessel and only to include a code for insertion of a stent or stents.

This action is not proper. The AHA publication, *Coding Clinic for ICD-9-CM*, Fourth Quarter, 1996, specifically instructs that a code for angioplasty, by any technique, be used when an angioplasty is performed in the placement of a stent or stents (page 63). Therefore, the correct coding for insertion of coronary stent(s) requires two codes. One code describes the angioplasty: 36.01 (Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy without mention of thrombolytic agent); 36.02 (Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy with mention of thrombolytic agent); or 36.03 (Open chest coronary artery angioplasty, or 36.05. The second code describes which stent was inserted: either 36.06 (Insertion of non drug-eluting coronary artery stent(s)) or 36.07 (Insertion of drug-eluting coronary artery stent(s)). Failure to record the angioplasty procedure will result in assignment of the case to the medical DRG instead of the correct surgical DRG. This erroneous coding action will have an impact on many levels. It will result in incorrect data in the database, which in turn will result in an erroneous base upon which future DRG relative weights are calculated. In addition, in the short term, it will result in reduced revenue to the hospitals because of the incorrect DRG assignment for all cases in which incorrect coding occurs.

Comment: One commenter indicated that there is a disincentive for the insertion of multiple drug-eluting stents placed during the same inpatient admission. This commenter indicated that there might be pressures on physicians to bring patients back for an additional stent procedure on a subsequent admission. Another commenter suggested that, as an interim approach, code 36.05 be used as a trigger for DRG assignment to a newly created DRG, or act as a trigger for an add-on payment for each stent. The commenter's justification for this suggestion was that, because current medical practice indicates that over 85 percent of balloon angioplasties currently involve a concurrent insertion of a stent, code 36.05 could serve as a good surrogate code until such time as new codes are created and available for use.

Response: One of the suggestions received that we discussed in the proposed rule recommended that two new DRGs be created based on multiple-

vessel procedures with drug-eluting stent(s) and the presence or absence of an AMI. The suggester's argument was that the presence of code 36.05, which shows treatment of multiple vessels, also indicates that more than one stent was inserted. We considered this assertion in the proposed rule because we recognize that current ICD-9-CM codes do not adequately describe the insertion of more than one stent. However, as we discussed in the proposed rule, we believe that the presence of code 36.05 only indicates that more than one vessel was surgically treated. It does not indicate that more than one stent was placed in all cases. We reiterate that no conclusions can be drawn regarding the number of stents inserted based upon the number of vessels treated. Therefore, we are not prepared to make DRG adjustments based on the commenter's assertion. In addition, we are not prepared to assume that the presence of code 36.05 is solely responsible for any higher charges associated with these cases.

We do believe that there is a need to further identify the insertion of multiple stents and will work with industry representatives to conceptualize the most appropriate ICD-9-CM procedure code or codes to capture this data. The topic of a new code or codes for multiple stent insertion will be addressed at the October 7, 2004 ICD-9-CM Coordination and Maintenance Committee meeting at CMS' headquarters in Baltimore, MD.

Comment: One commenter expressed concern about the implication of maintaining separate and distinct DRGs for drug-eluting stents and encouraged CMS to consider fully the impact on less expensive technologies, such as intravascular brachytherapy (IVBT). IVBT is the use of vascular radiation delivered inside an artery to reduce the incidence of restenosis. The commenter noted that the DRG system should not create financial incentives to use drug-eluting stents when the clinical outcomes and costs of other treatments are similar or better in the appropriate patient populations.

Response: As we have stated above in response to other comments, in the absence of more complete data and without thorough evaluation, we are reluctant to undertake any restructuring of these four DRGs (516, 517, 526, and 527) for FY 2005. Therefore, these DRGs will continue to be structured as they currently are. In the upcoming fiscal year, as in the past, we will be closely monitoring our own data, outside data, and any FDA decision on the efficacy of stent placement in a high-risk AMI population. We will also consider

alternative therapies, such as IVBT, as part of that process.

c. Severe Sepsis

In the May 18, 2004, proposed rule, we addressed a comment we had received that recommended a separate DRG be assigned to the diagnosis of severe sepsis. Patients admitted with sepsis currently are assigned to DRG 416 (Septicemia Age > 17) and DRG 417 (Septicemia Age 0–17) in MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites). The commenter contended that the costs of caring for patients with severe sepsis exceed those costs associated with other types of sepsis. Therefore, the commenter indicated, severe sepsis should be given a separate, unique DRG. Furthermore, the commenter requested that all cases in which severe sepsis is present on admission, as well as those cases in which it develops after admission (which are currently classified elsewhere) be included in this new DRG. The commenter suggested using various coexisting conditions and their corresponding ICD–9–CM codes (for example, respiratory failure or hypotension and renal failure) to identify patients with severe sepsis. The conditions suggested do not describe a clinically coherent set of patients that have severe sepsis. Using this list of conditions would erroneously identify patients as having severe sepsis.

We acknowledge the high costs of caring for seriously ill patients with sepsis. However, we do not find, from a clinical perspective, that a subset of patients with severe sepsis exists to the degree that a separate DRG classification is justified. Sepsis in all forms is quite common across many DRGs in the Medicare population. In addition, we do not believe that the commenter's suggested defining criteria for severe sepsis are specific, accurate, or unique enough to warrant a new DRG classification. Therefore, in the May 18, 2004, proposed rule, we did not propose any change to the current DRG structure for sepsis.

Comment: Several commenters agreed with our proposal not to create a new DRG for severe sepsis. Some of the commenters mentioned coding problems that exist with new codes 995.90 through 995.94 that were created to capture Systemic Inflammatory Response Syndrome (SIRS). The commenters acknowledged that the codes were specifically created to capture severe sepsis. However, they indicated that there has been much confusion among coders in their use. The commenters mentioned coding notes included in the ICD–9–CM book

that appear to be contradictory. The commenters agreed that it was not appropriate to modify the DRGs at this time, given the uncertainty about the use of the SIRS codes and the accuracy of the reported data.

One commenter recommended continued monitoring of the population with severe sepsis in the future. Another commenter supported our proposal not to create a new DRG for severe sepsis, given the data and information provided.

Response: We agree with the commenters that there has been confusion in the correct use of the SIRS codes based on use of the ICD–9–CM code book. The related section of the ICD–9–CM code book is being revised on October 1, 2004, to help resolve this confusion. Additional coding instructions are also being developed on the correct use of these codes. These instructions will be published in the American Hospital Association's *Coding Clinic for ICD–9–CM*. These actions should lead to more consistency in identifying and reporting cases of severe sepsis. Once this information is available, CMS will review the data to determine any needed modifications to the DRG to better capture severe sepsis. We agree with the commenters that we should not create a new DRG for severe sepsis based on the currently available data, and that we should continue to monitor the population with severe sepsis in order to better characterize resource utilization in these patients.

Comment: One commenter expressed disagreement with our decision not to modify the DRGs to capture severe sepsis. The commenter asserted that using the accepted definition of severe sepsis—"a systemic inflammatory response to infection associated with acute organ dysfunction"—was adequate to identify patients for the purpose of creating new DRGs. The commenter also asserted that severe sepsis is common, deadly, and costly; that it involves extensive use of intensive care unit resources; and that it is inadequately represented by the use of ICD–9–CM procedure code 00.11 (Infusion of diotrecogin alfa (activated)).

Response: We agree with the commenter that severe sepsis is a common, deadly, and costly clinical entity. We also acknowledge that the current coding for all forms of sepsis is problematic. We believe that the creation of code 00.17 (Infusion of vasopressor agent), which goes into effect on October 1, 2004, in combination with code 00.11 and the SIRS codes 995.90 through 995.94, will help to better identify patients with

severe sepsis. We also note, as mentioned above, that improved and modified coding instructions and guidelines will be available in October 2004. However, we continue to believe that a separate DRG for severe sepsis is not appropriate at this time based on the available data. We believe that the defining criteria for severe sepsis, using the currently available ICD–9–CM codes, are not specific, accurate, or unique enough to warrant a new DRG classification. However, we anticipate receiving data using the new and modified codes and instructions and will consider this issue again in the future.

Comment: One commenter disagreed with our decision not to create a new DRG for severe sepsis. The commenter urged CMS to "recognize severe sepsis as a clinically coherent condition associated with high mortality and a patient population displaying similar characteristics in terms of outcome and costs incurred for treatment, which thereby deserves its own DRG." The commenter asserted that the current DRG for sepsis uses the clinically obsolete term "septicemia." The commenter also stated that severe sepsis cases now classify to 339 different DRGs; however, these DRGs do not distinguish between cases with and without severe sepsis. The commenter believed that payment for cases in which severe sepsis occurs is inadequate and urged us to work closely with the Critical Care Work Group in the development of a new DRG.

Response: We agree with the commenter that severe sepsis cases fall into a wide spectrum of DRGs, and therein lies the problem. The ICD–9–CM coding system has lacked the requisite specificity and accuracy needed to identify patients with severe sepsis. While new codes were created specifically for this purpose (codes 995.90 through 995.94), coders have had difficulty in consistently using the codes. We have worked closely with the Centers for Disease Control and Prevention to make refinements to the coding notes and instructions so that these codes can be more consistently applied. These revised notes and instructions will go into effect on October 1, 2004. We believe that when more consistent data are submitted, we will have the necessary information to propose further refinements in the DRGs to better capture severe sepsis. As mentioned before, CMS will closely monitor the classification of patients with severe sepsis in the near future, particularly with regard to the use of other codes commonly reported for patients with severe sepsis such as new

code 00.17 (Infusion of vasopressor agent) and code 00.11 (Infusion of diotrecogin alfa (activated)). We will also work closely with the American Hospital Association and the American Health Information Management Association on their efforts to provide education to coders in the correct use of the severe sepsis codes (SIRS codes 995.90 through 995.94).

Comment: One commenter believed that CMS was shortsighted in its failure to create a new DRG for severe sepsis. The commenter also noted that severe sepsis is a widespread and deadly disease that has been defined since 1992, and that severe sepsis cases currently classify into 339 DRGs. The commenter asserted that grouping these cases together in at least one DRG would enhance hospitals and practitioners' ability to understand the disease and its treatment as well as to evaluate the costs of care. This commenter further asserted that only a small proportion of patients with severe sepsis and organ dysfunction are assigned to DRG 416 (Septicemia Age >17) and DRG 417 (Septicemia Age 0–17), and that a large number of surgical cases with severe sepsis are ignored. The commenter also noted that cases of severe sepsis that develop after admission typically are classified in other DRGs.

This commenter mentioned the set of proposed criteria put forth by another commenter to define severe sepsis (“a systemic inflammatory response syndrome associated with organ dysfunction, hypoperfusion, or hypotension”) and asserted that this definition has been widely accepted within the international clinical community, that it is encompassed by code 995.92 (Systemic inflammatory response syndrome due to infectious process with organ dysfunction), and that it should be used to identify patients for classification to a new DRG.

Response: As mentioned earlier, we recognize that severe sepsis is a widespread and deadly disease that accompanies a wide spectrum of other diagnoses. We also recognize that it frequently develops after admission, and that it is a frequent complication of surgical cases. In addition, we recognize that current coding practices are problematic, and we look forward to better refining our ability to identify patients with severe sepsis by using codes 00.11 and 00.17 and the SIRS series of codes. We look forward to working with groups represented by the commenters in the future to optimize the DRG system to best serve this important Medicare patient population.

d. Implantable Cardiac Defibrillators

There is a range of implantable cardiac defibrillators (ICDs) available on the market from extremely complex devices with multiple leads, settings, and functions to simpler models with a single lead and simpler functions. ICDs deliver electrical shocks to the heart to eliminate the life-threatening abnormal rhythms such as ventricular fibrillation or ventricular tachycardia.

As indicated in the May 18, 2004, proposed rule, we received a coverage request to expand the indications for implantable defibrillators to include the population studied in the Sudden Cardiac Death in Heart Failure Trial (SCD–HeFT) sponsored by the National Institutes of Health. SCD–HeFT treated heart failure patients with conventional therapy and randomized them to one of three additional treatment strategies: (1) Placebo; (2) amiodarone (drug therapy); or (3) single lead implantable defibrillator. The SCD–HeFT investigators presented results at the American College of Cardiology annual meeting that the basic single-lead implantable defibrillator is effective for saving lives in a population at low-moderate risk for sudden cardiac death. As part of CMS' coverage decisions, we are considering whether to restrict the use of complex defibrillators to patients for whom they are medically necessary, that is, the population at low-moderate risk for sudden cardiac death.

Given the potential increase of implantable defibrillator use in our population, in the May 18, 2004, proposed rule, we solicited input on how to encourage physicians to use the simpler, less costly device when advanced devices are not medically preferred. We also solicited input on the appropriate measures within the payment systems to accommodate payment for classes of defibrillators with very different costs. Ideally, we would like not only to align payments with relative costs, but also to align the incentives within the payment system with medically appropriate uses of different technologies.

We believe that, within the PPS for inpatient hospital operating costs, there are several ways to deal with the expanding use of simpler, lower cost defibrillators. One possibility is to maintain the current DRG configuration, under which complex, expensive devices and simpler, less costly devices would remain within the same DRGs and receive the same payment rates. This approach would encourage use of the simpler devices, which would receive relatively higher reimbursement because their lower charges would be

averaged in with the higher charges for the more complex devices in setting the DRG weights. However, it could lead to complaints that the program is underpaying for the more complex, expensive devices as the lower charges for simpler, less expensive devices begin to affect (lower) the DRG weights.

Another approach would be to recognize the cost differences between various classes of defibrillators by establishing separate DRGs for basic single-lead implantable defibrillators as opposed to more complex, expensive models. This approach would prevent payments for the use of more expensive defibrillators (where medically necessary) from being diluted by the effect of the lower charges for basic single-lead implantable defibrillators on the weights within common DRGs. However, this policy would arguably provide less incentive for use of the lower cost devices: the weights for the DRGs containing the less expensive devices would be driven solely by their relatively lower charges, without being lifted by the higher charges for the more expensive models. This approach might also be criticized for departing from the averaging principle within the DRG system by basing too much on the cost differential alone in reconfiguring these DRGs.

We solicited comments on these and other approaches to paying for defibrillators under the IPPS. We discuss an application for new technology add-on payments for a Cardiac Resynchronization Therapy with Defibrillator (CRT–D) in section II.E.4.c. of this final rule. We discuss comments regarding payments for these devices in that section.

e. Intestinal Transplantation

Even though we did not address the issue of DRG payment for intestinal transplantation in the May 18, 2004, proposed rule, we received a comment from an institution that performs intestinal transplantation.

Comment: The commenter expressed concern that the current payment policy utilizes a relatively low weight DRG that imposes a significant financial burden on health care providers. The commenter requested a new DRG for each of three main types of intestinal transplantation: isolated intestine, liver plus intestine, and multivisceral (liver, stomach, duodenum, pancreas, and small bowel).

Due to the small patient population associated with these transplantations, the commenter suggested that CMS lower the number of cases required to create a new DRG. In addition, the commenter suggested that CMS utilize

data on non-Medicare patients and the pediatric population to supplement current MedPAR data.

Response: We have been monitoring intestinal transplantation cases since October 2000, when Medicare issued a national coverage decision for this transplant, to determine whether it may be appropriate to establish a new DRG. An ICD-9-CM procedure code 46.97 (Transplant of intestine) was created in October 1, 2000, to uniquely capture isolated intestinal transplantation. Acquisition cost centers were established for intestines and multivisceral organs to be paid on a reasonable cost basis. Based on our past annual reviews, we did not find a sufficient number of cases to warrant the creation of a new DRG. The commenter provided some rationale for the absence of cases, including the time lag between the actual transplant date and the submission of the bill and the limited patient population involved.

If an intestinal transplantation alone is performed on a patient with a principal diagnosis in MDC 6 (Diseases and Disorders of the Digestive System), the case would be assigned to either DRG 148 (Major Small & Large Bowel Procedures With CC) or DRG 149 (Major Small & Large Bowel Procedures Without CC). If an intestinal transplantation was performed and the patient required a tracheostomy, the case would be assigned to DRG 483 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth & Neck Diagnosis). In cases where multiple surgical procedures are performed, the case is assigned to the DRG associated with the most resource-intensive surgical class. If an intestinal and liver transplantation were performed simultaneously, the case would be assigned to DRG 480 (Liver Transplant). It is not uncommon that a liver transplant would be performed with an intestinal transplant. If a multivisceral transplantation is performed, the case is also assigned to DRG 480.

Based on our review of the FY 2003 MedPAR data, we identified six cases with procedure code 46.97 all performed at one facility. We are concerned that only one facility's data is contained in the MedPAR file when there are five Medicare-approved intestinal transplant centers. Of the six cases, three cases were assigned to DRG 148, with total charges ranging from \$839,802 to \$903,518 and an average length of stay of 36 days. Two cases were assigned to DRG 483. One case was assigned to DRG 154 (Stomach, Esophageal, & Duodenal Procedures Age >17 With CC) because, in addition to the

intestinal transplantation, there was another operation on the stomach. The total charge for the one case in DRG 154 was \$1,105,627, with a length of stay of 32 days.

We are open to receiving non-MedPAR data but would limit the data to Medicare patients, rather than using non-Medicare data as suggested by the commenter. We believe that, if we received data from the five approved intestinal transplant centers regarding all Medicare patients receiving intestinal transplantations during the fiscal year, the minimum requirement of cases may be met. When we receive sufficient data, we will again consider a separate intestinal transplant DRG.

We agree that payment for isolated intestinal transplant is too low in DRGs 148 and 149. The average payments for DRGs 148 and 149 are approximately \$15,314 and \$6,567, respectively. As mentioned earlier, it is not uncommon for an intestinal transplant to be performed in conjunction with transplants of other organs, such as the liver. As a matter of fact, intestinal transplants are assigned to DRG 480 now since these patients frequently have both an intestinal transplant and a liver transplant. Therefore, DRG 480 already contains cases with intestinal transplants. Therefore, we would not be disrupting the clinical cohesiveness of DRG 480 by adding intestinal transplant.

Furthermore, intestinal transplantation has become a definitive treatment for patients with short gut syndrome and intestinal diseases who no longer can be maintained on total parenteral nutrition (TPN). Liver failure may be induced by TPN. The average charges for DRG 480 are approximately \$157,129. While the total charges for intestinal transplantation are higher than the average charges for DRG 480, we believe that DRG 480 is a better assignment of these cases.

Given this practice, we are moving intestinal transplantation cases out of DRGs 148 and 149 and into DRG 480 (Liver Transplant), effective FY 2005. ICD-9-CM procedure code 46.97 will be assigned to pre-MDC, DRG 480. The title for DRG 480 will change to "Liver Transplant and/or Intestinal Transplant". The result of this reassignment would move intestinal transplant cases from a weight of 3.3871 in DRG 148 and 1.4352 in DRG 149 to a weight of 9.8696. We are aware that, with this change, the three main types of intestinal transplantation; isolated intestine, liver plus intestine, and multivisceral, will be assigned to DRG 480. We will continue to monitor

intestinal transplantation to determine appropriate assignment of these cases.

f. Cochlear Implants

Even though we did not specifically address issues relating to the DRG payment for cochlear implants in the May 18, 2004, proposed rule, we received public comments on this area.

Comment: One commenter expressed concern about the low reimbursement for cochlear implants. Cochlear implants are currently assigned to DRG 49 (Major Head and Neck Procedures). The commenter stated that cochlear implants represent the only procedure in DRG 49 involving implantation of a high cost medical device. It was stated that the acquisition cost alone represent 85 percent of the total cost of the procedure. The commenter noted that although CMS has acknowledged the disparity between payment and cost and vowed to further evaluate possible reclassification options for cochlear implants, nothing has been done to mitigate this payment shortfall.

Response: Although cochlear implants was not addressed in our May 18, 2004 proposed rule, we have continued to monitor these cases. In our analysis of the FY 2003 MedPAR file, we found 120 cochlear implant cases with average charges of approximately \$44,366. There were a total of 1,602 cases assigned to DRG 49 with average charges of approximately \$24,971. Cochlear implant cases represent more than 7 percent of the total cases in DRG 49.

We have been unable to identify an alternative DRG assignment for these cases. As we discussed in the August 1, 2003, final rule (68 FR 45367), we continue to believe that assignment of cochlear implant cases to DRG 482 (Tracheostomy for Face, Mouth and Neck Diagnoses) is inappropriate. A tracheostomy must be performed in order for the case to be assigned to this DRG. We remain reluctant to create a new DRG for specific, low-volume procedures. Doing so would create a proliferation of DRGs and a loss of some of the efficiency incentives inherent in the current system.

g. Artificial Hearts

Comment: One commenter requested that newly created procedure codes 37.52 (Implantation of total replacement heart system), 37.53 (Replacement or repair of thoracic unit of total replacement heart system), and 37.54 (Replacement or repair of other implantable component of total replacement heart system) be assigned to DRG 103 instead of DRG 525.

Response: Codes 37.52, 37.53, and 37.54 are not new codes. They were created for the October 1, 2003 ICD-9-CM update. In the proposed rule, CMS discussed the restructuring of DRG 525 (69 FR 28208) and further listed the codes that were included in that DRG. Codes 37.52, 37.53, and 37.54 are part of that list. We did not propose the addition of codes 37.52, 37.53, or 37.54 to DRG 525 for FY 2005. These codes were assigned to DRG 525 upon their formation, as it is our practice to assign all codes to DRGs when they are created. We take this opportunity to note that Medicare does not cover the use of an artificial heart as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplant. Therefore, we believe that a DRG reassignment would be inappropriate at this time. No DRG assignment changes will be made to codes 37.52, 37.53, or 37.54 for FY 2005.

h. Left Atrial Appendage Devices: DRG Assignment for New Code 37.90

The issue of the DRG assignment of new code 37.90 (Insertion of left atrial appendage device) was not presented as a topic in the May 18, 2004, proposed rule. At the April 1, 2004, ICD-9-CM Coordination and Maintenance Committee meeting, we discussed these devices. A new code was created for use in upcoming clinical trials and was fast-tracked so that the code could be used beginning October 1, 2004, for

discharges for FY 2005. The new code is listed in Table 6B of the Addendum (69 FR 28672 in the proposed rule). Table 6B represents a listing of approved final new codes. The codes themselves are not subject to comment but their assignment regarding placement as an O.R. procedure and the MDC and DRG placement are open to comment. As discussed elsewhere in this preamble, the announcement of the adoption of the codes as final in the IPPS proposed rule is included in the ICD-9-CM Coordination and Maintenance Committee meeting process.

Background: Atrial fibrillation is a common heart rhythm disorder that can lead to cardiovascular blood clot formation leading to increased risk of stroke. According to product literature, nearly all strokes are from embolic clots arising in the left atrial appendage of the heart; an appendage for which there is no useful function. Standard therapy uses anticoagulation drugs. However, these drugs may be contraindicated in certain patients and may cause complications such as bleeding. The underlying concept behind the left atrial appendage device is to block off the left atrial appendage so that blood clots formed therein cannot travel to other sites in the vascular system. The device is implanted using a percutaneous catheter procedure under fluoroscopy through the femoral vein. Implantation is performed in a hospital

catheterization laboratory using standard transseptal technique, with the patient generally under local anesthesia. The procedure takes approximately one hour, and most patients stay overnight in the hospital.

We received several comments concerning the proposal to assign new code 37.90 to DRG 518 (Percutaneous Cardiovascular Procedure Without Coronary Artery Stent or AMI).

Comment: All of the commenters discussed the surgical technique required for insertion of the device and cited the risk and complexity of the procedure, especially due to the transseptal catheterization required. The commenters noted that because comparatively simple procedures are already grouped to DRG 518, DRG 518 does not reflect the resources used in this procedure. The commenters suggested that insertion of a left atrial appendage device more closely resembles the insertion of an atrial septal defect occluder.

Response: Insertion of an atrial septal defect occluder would be coded to the 35.xx series of ICD-9-CM procedure codes. DRG 108 includes code 35.52 (Repair of atrial septal defect with prosthesis, closed technique) which may be similar to insertion of the left atrial appendage device. Codes in the 35.xx series are assigned to DRG 108 (Other Cardiothoracic Procedures). We reviewed the MedPAR data and found the following:

	Number of Cases	Average Length of Stay	Average Standardized Charges
Code 35.52	423	2.69	\$29,231
DRG 108 Total	5,293	10.1	76,274
DRG 518 Total	39,553	4.3	31,955

Because code 37.90 was created for use beginning on October 1, 2004, we have no data history regarding its utilization. However, given that the atrial appendage device is percutaneously inserted, and that most of the procedures in DRG 108 are open chest procedures, we do not believe that DRG 108 is the most appropriate clinical placement for new code 37.90. In addition, review of the data in the table above shows a large variance between the hospital charges and length of stay between DRG 518 and DRG 108. According to one manufacturer, the projected length of stay for insertion of an atrial appendage is overnight for observation purposes. The many open

chest procedures in DRG 108, some requiring the use of cardiopulmonary bypass, would also seem to indicate that DRG 108 is not the best choice for clinical coherence. We are disinclined to assign this new code to such a resource intensive DRG without appropriate data to reinforce and justify such a decision. Therefore, we are maintaining the assignment of code 37.90 to DRG 518 in this final rule.

Review of code 35.52 (Repair of atrial septal defect with prosthesis, closed technique) in the table above shows a decided similarity to the cases found in DRG 518. We will analyze the placement of code 35.52 as part of next year's proposed rule. We will analyze

these cases for both clinical coherence and charge data as part of the process of identifying the most appropriate DRG assignment for code 35.52.

i. Carotid Artery Stents

DRG Assignment for New Codes

At the April 1, 2004, ICD-9-CM Coordination and Maintenance Committee meeting, we discussed creation of a new code or codes to identify carotid artery stenting, along with a concomitant percutaneous angioplasty or atherectomy (PTA) code for delivery of the stent(s). This subject was addressed in response to the need to identify carotid artery stenting for use

in clinical trials in the upcoming fiscal year. Public comment confirmed the need for specific codes for this procedure. Implementation of the code was fast-tracked so that the code could be used beginning October 1, 2004, for discharges in FY 2005 for patients who are enrolled in an FDA-approved clinical trial and are using on-label FDA approved stents and embolic protection devices.

The newly created codes 00.61 (Percutaneous angioplasty or atherectomy of precerebral (extracranial vessel(s)) and 00.63 (Percutaneous insertion of carotid artery stent(s)) were published in Table 6B, New Procedure Codes in the proposed rule (69 FR 28671). Table 6B in the proposed rule represents final codes and the codes themselves were not subject to comment, as the notice and comments are part of the ICD-9-CM Coordination and Maintenance Committee process. However, their assignment regarding placement as an OR procedure, as well as MDC and DRG placement, were open to public comment.

New code 00.61 was assigned to four MDCs and seven DRGs. The most likely scenario will have cases being assigned to MDC 1 (Diseases and Disorders of the Nervous System in DRGs 533 (Extracranial Procedures With CC) and 534 (Extracranial Procedures Without CC). Cases could also be assigned to MDC 5 (Diseases and Disorders of the Circulatory System), MDC 21 (Injuries, Poisoning, and Toxic Effects of Drugs), and MDC 24 (Multiple Significant Trauma). The less likely DRG assignments can be reviewed in Table 6B in the Addendum to this final rule.

Background: Stroke is the third leading cause of death in the United States and the leading cause of serious, long-term disability. Approximately 70 percent of all strokes occur in people age 65 and older. The carotid artery is located in the neck and is the principal artery supplying the head and neck with blood. Accumulation of plaque in the carotid artery can lead to stroke either by decreasing the blood flow to the brain or by having plaque break free and

lodge in the brain or in other arteries to the head. The PTA procedure involves inflating a balloon-like device in the narrowed section of the carotid artery to reopen the vessel. A carotid stent is then placed in the artery to prevent the vessel from closing and to prevent pieces of plaque from entering the bloodstream.

Effective July 1, 2001, Medicare covers PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the FDA-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials. PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be a reasonable and necessary service only when provided in the context of such clinical trials, and therefore is considered a covered service for the purposes of these trials. Performance of PTA in the carotid artery when used to treat obstructive lesions outside of approved protocols governing Category B IDE clinical trials remains a noncovered service.

We received several comments concerning the proposed assignment of new code 00.61 to MDC 1, DRG 533 and DRG 534.

Comment: All commenters suggested that instead of code 00.61 grouping to both DRGs 533 and 534, the cases should only be assigned to DRG 533. Commenters have suggested that the patients in Category B IDE clinical trials will not have the kinds of CCs that would assure assignment to DRG 533. Commenters cited other complications such as bilateral occlusion, certain anatomical conditions such as a "surgically hostile neck," and complex diseases, as complications in their cases. However, most of the CCs cited by the commenters are not able to be captured using current ICD-9-CM codes, and therefore would not contribute to the assignment of these cases to DRG 533.

All of the commenters stated that the payment for DRG 534 is inadequate, but did not furnish data regarding the cost of the stent(s) and the embolic

protection devices, possibly because these devices are still in the trial stage and no hospital costs have yet been established. Two commenters stated that they knew of reports that a number of sites in one of the clinical trials have indicated a reluctance to enroll patients due to the low level of payment under DRG 534. One commenter reviewed cases in the FY 2002 MedPAR data file and noted that the cases are primarily clinical trial cases that do not include a charge for the carotid stent and embolic protection device. Therefore, the commenter added, the reported hospital charges significantly understate the charges that would be associated with the carotid stenting procedure in a nonclinical trial setting.

Response: As we have created code 00.61 for use beginning October 1, 2004, we have no data history regarding its utilization.

In FY 2003, any carotid stenting procedures performed would have been assigned to DRG 5. Insertion of a carotid stent or stents was a procedure for which there was no specific coverage decision. In addition, the ICD-9-CM codes describing insertion of a stent were nonspecific, and the codes used to describe that procedure also applied to many other procedures for which there was a coverage decision. The commenter is correct that any cases in our data may have been performed within the setting of a clinical trial. In FY 2004, we restructured DRG 5, splitting all those cases into DRGs 533 and 534, and ordered the DRGs based on the presence or absence of CCs. When we reviewed the available MedPAR data, we used the following proxy: Principal diagnosis code 433.10 (Occlusion and stenosis of carotid artery, without mention of cerebral infarction), and procedure codes 39.50 (Angioplasty or atherectomy of noncoronary vessel), plus code 39.90 (Insertion of nondrug-eluting, noncoronary artery stent(s)). The following table shows the results of our review:

Data Year	DRG	Total Discharges by DRG	Arithmetic Mean Length of Stay	Number of Stent Cases	Length of Stay for Stent Cases	Average Charges for Stents	Relative Weights
2001 (FY 2003)	5	93,559	3.07	1,321	2.6	\$25,029	1,3837
2002 (FY 2004)	533	new	4.10**	890	3.28	\$27,328	1.6678
2002 (FY 2004)	534	new	2.0**	934	1.59	\$19,514	1.0748
2003 (FY 2005)	533	43,418***	4.0***	1,444	3.20	\$32,617	1.6498**
2003 (FY 2005)	534	50,974***	1.9***	1,453	1.56	\$23,042	1.0515***

*Table 7A, MedPAR update March 2002 (67 FR 50249)

**Table 5, MedPAR update March 2003 (68 FR 45594)

***Final rule Table 5 and Table7A, MedPAR update March 2004

When we evaluated the data in the above table, we found relative weights have increased for DRG 533 over the past two reporting periods compared to the cases in DRG 5. In addition, we found that, although the hospital charges had increased between reporting years 2002 and 2003, the charges were within the mean and .75 standard deviation. As the DRG system is one of averages, we are reassured that this payment structure is appropriate.

The FDA has not given final approval to the safety and efficacy of carotid PTA with stenting as clinical trials are still ongoing. CMS has not yet approved this procedure and device under Medicare, outside of the clinical trial setting. To reiterate, specific codes were recently created and have not yet been put into use in hospitals. We believe that the data that we have reviewed in DRGs 5, 533, and 534 are reasonably correct regarding hospital charges for this procedure. We believe that adjusting the IPPS system for a specific device that has not been used outside the clinical trial setting, without substantiating data, obviates the intent of the diagnosis-related groups. Therefore, we believe the assignment of code 00.61 to DRGs 533 and 534 as proposed is appropriate at this time. We will continue to monitor DRGs 533 and 534 and procedure codes 00.61 in combination with 00.63 in upcoming annual DRG reviews.

At the April 1, 2004, ICD-9-CM Coordination and Maintenance Committee Meeting, we also created procedure codes 00.62 (Percutaneous angioplasty or atherectomy of

intracranial vessel(s), 00.64 (Percutaneous insertion of other precerebral (extracranial) artery stent(s), and 00.65 (Percutaneous insertion of intracranial vascular stent(s). We assigned procedure code 00.62 to the same MDCs and DRGs as code 00.61, mimicking the DRG assignment for predecessor codes.

Comment: One commenter encouraged CMS to assign intracranial angioplasty cases containing procedure code 00.62 to DRGs 1 and 2 instead of DRGs 533 and 534. The commenter believed that DRGs 1 and 2 better reflect the grouping logic for clinical homogeneity and resource utilization.

Response: When new ICD-9-CM codes are created, they are automatically assigned to an MDC and a DRG(s). We generally assign new codes to the predecessor DRGs until we have compelling MedPAR data that indicate otherwise. In the case of code 00.62, the point is moot. Medicare does not cover PTA of intracranial vessels, and we are not aware of any clinical trials during the upcoming fiscal year. We refer readers to the discussion of changes to Edit 11 (Non-Covered Procedures) of the Medicare Code Editor under section II.B.10. of this preamble. Therefore, in the absence of compelling evidence, we are not making any changes to the MDC or DRG assignments of code 00.62.

In addition, it has come to our attention that there may be some coding errors that are contributing to an erroneous reimbursement case-mix profile for hospitals. Specifically, it has been suggested that some hospitals may be reluctant to include a code for vessel

angioplasty in conjunction with stent placement. Apparently, some hospital staff have expressed concerns that a “true” angioplasty is not being performed, and that, therefore, they will be censured by regulatory agencies for erroneous coding. As a result, these hospitals have instructed their coding staff not to include a code describing angioplasty of a vessel, and to only include a code for insertion of a stent or stents.

This is incorrect. The AHA publication *Coding Clinic for ICD-9-CM* specifically instructs that a code for angioplasty, by any technique, is performed in the placement of a stent or stents (Fourth Quarter, 1996, page 63). Therefore, the correct coding for insertion of coronary stent(s) requires two codes. One code describes the angioplasty with 00.61, and the second code describes the stent insertion with code 00.63. To fail to record the angioplasty procedure will result in assignment of the case to the medical DRG instead of the correct surgical DRG. This erroneous coding action will have an impact on many levels. It will result in incorrect data in the database, which in turn will result in an erroneous base upon which future DRG relative weights are calculated. In addition, in the short term, it will result in reduced revenue to the hospital because of the incorrect DRG assignment for all cases in which this occurs. To reiterate, the correct procedure coding for insertion of a carotid stent combines codes 00.61 and 00.63.

j. Acute Intermittent Porphyria

In the May 18, 2004 IPPS proposed rule, we did not present as an issue the DRG assignment of the code used for acute intermittent porphyria. However, we did receive one comment concerning this condition.

Comment: One commenter requested that we give consideration to assignment of a DRG to an orphan biologic intended to treat acute intermittent porphyria. This condition is a rare metabolic disorder affecting fewer than 1,000 persons in the United States. The drug manufacturer was concerned that Medicare hospitalization payments do not accurately reflect the cost of the treatment. The condition is coded to Code 277.1 (Disorders of porphyrin metabolism) and is assigned to DRG 299 (Inborn Errors of Metabolism).

Response: The DRG assignment of code 277.1 was not an issue that was addressed in the May 18, 2004 proposed rule. We will take this comment into consideration in the future as we conduct analysis of the MedPAR data for next year's proposed rule.

C. Recalibration of DRG Weights

As we proposed, in this final rule, we used the same basic methodology for the FY 2005 recalibration as we did for FY 2004 (August 1, 2003 IPPS final rule (68 FR 45373)). That is, we have recalibrated the DRG weights based on charge data for Medicare discharges using the most current charge information available (the FY 2003 MedPAR file).

The MedPAR file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2003 MedPAR data used in this final rule include discharges occurring between October 1, 2002, and September 30, 2003, based on bills received by CMS through March 31, 2004, from all hospitals subject to the IPPS and short-term acute care hospitals in Maryland (which are under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2003 MedPAR file includes data for approximately 11,740,557 Medicare discharges. Discharges for Medicare beneficiaries enrolled in a Medicare+Choice managed care plan are excluded from this analysis. The data excludes CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken.

The methodology used to calculate the DRG relative weights from the FY 2003 MedPAR file is as follows:

- To the extent possible, all the claims were regrouped using the DRG

classification revisions discussed in section II.B. of this preamble.

- The transplant cases that were used to establish the relative weight for heart and heart-lung, liver, and lung transplants (DRGs 103, 480, and 495) were limited to those Medicare-approved transplant centers that have cases in the FY 2001 MedPAR file. (Medicare coverage for heart, heart-lung, liver, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)

- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average charge for the DRG and before eliminating statistical outliers.

- Charges were standardized to remove the effects of differences in area wage levels, indirect medical education and disproportionate share payments, and, for hospitals in Alaska and Hawaii, the applicable cost-of-living adjustment.

- The average standardized charge per DRG was calculated by summing the standardized charges for all cases in the DRG and dividing that amount by the number of cases classified in the DRG. A transfer case is counted as a fraction of a case based on the ratio of its transfer payment under the per diem payment methodology to the full DRG payment for nontransfer cases. That is, a transfer case receiving payment under the transfer methodology equal to half of what the case would receive as a nontransfer would be counted as 0.5 of a total case.

- Statistical outliers were eliminated by removing all cases that are beyond 3.0 standard deviations from the mean of the log distribution of both the charges per case and the charges per day for each DRG.

- The average charge for each DRG was then recomputed (excluding the statistical outliers) and divided by the national average standardized charge per case to determine the relative weight.

The new weights are normalized by an adjustment factor of 1.46795 so that the average case weight after recalibration is equal to the average case weight before recalibration. This adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We used that same case threshold in recalibrating the final DRG weights for FY 2005. Using the FY 2003 MedPAR data set, there are 41 DRGs that contain fewer than 10 cases. We computed the weights for these low-volume DRGs by adjusting the FY 2004 weights of these DRGs by the percentage change in the average weight of the cases in the other DRGs.

Section 1886(d)(4)(C)(iii) of the Act requires that, beginning with FY 1991, reclassification and recalibration changes be made in a manner that assures that the aggregate payments are neither greater than nor less than the aggregate payments that would have been made without the changes. Although normalization is intended to achieve this effect, equating the average case weight after recalibration to the average case weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case weight. Therefore, as we have done in past years and as discussed in section II.A.4.a. of the Addendum to this final rule, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

Comment: Two commenters addressed the proposed DRG weights for three DRGs. One commenter was appreciative of the increased proposed DRG weight for DRG 36 (Retinal Procedures). The current DRG weight is 0.6298 and the proposed weight was 0.6766. Another commenter expressed concern that the proposed weights for DRGs 535 (Cardiac Defibrillator Implant With Cardiac Catheterization With AMI, Heart Failure, or Shock) and DRG 536 (Cardiac Defibrillator Implant With Cardiac Catheterization Without AMI, Heart Failure or Shock) believes this would not cover the cost of the Cardiac Resynchronization Therapy Defibrillator (CRT-D), much less the procedure and nursing care costs associated with these procedures. The commenter believed that the DRG weight data are problematic because they are based on hospital charges. The commenter stated that hospitals do not like to mark up the cost of an item at \$34,000. The commenter inquired whether CMS has evaluated the cost of the CRT-Ds from the claims which was calculated using the cost-to-charge ratio compared to outside data on the cost of the CRT-Ds.

Response: In the process of recalibration of the DRG weights, we

consider the most recent charge data available. Both high and low cost technologies are absorbed gradually into the data that are used to determine the DRG weight.

D. LTC-DRG Reclassifications and Relative Weights for LTCHs for FY 2005

1. Background

In the June 6, 2003, LTCH PPS final rule (68 FR 34122), we changed the LTCH PPS annual payment rate update cycle to be effective July 1 through June 30 instead of October 1 through September 30. In addition, because the patient classification system utilized under the LTCH PPS is based directly on the DRGs used under the IPPS for acute care hospitals, in that same final rule, we explained that the annual update of the long-term care diagnosis-related group (LTC-DRG) classifications and relative weights will continue to remain linked to the annual reclassification and recalibration of the CMS-DRGs used under the IPPS.

The annual update to the IPPS DRGs is based on the annual revisions to the ICD-9-CM codes and is effective each October 1. In the health care industry, annual changes to the ICD-9-CM codes are effective for discharges occurring on or after October 1 each year. The use of the ICD-9-CM coding system is also compliant with the requirements of the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191, under 45 CFR parts 160 and 162. Therefore, the manual and electronic versions of the GROUPE software, which are based on the ICD-9-CM codes, are also revised annually and effective for discharges occurring on or after October 1 each year. Because the LTC-DRGs are based on the patient classification system used under the IPPS (CMS-DRGs), which is updated annually and effective for discharges occurring on or after October 1 through September 30 each year, in the May 7, 2004, LTCH PPS final rule (69 FR 25674), we specified that we will continue to update the LTC-DRG classifications and relative weights to be effective for discharges occurring on or after October 1 through September 30 each year. Furthermore, we stated that we will publish the annual update of the LTC-DRGs in the proposed and final rules for the IPPS.

In the May 18, 2004, IPPS proposed rule (69 FR 28225), we proposed revisions to the LTC-DRG classifications and relative weights. We are finalizing them in this IPPS final rule, to be effective October 1, 2004, through September 30, 2005, using the latest available data. The final LTC-

DRGs and relative weights for FY 2005 in this final rule are based on the IPPS DRGs (GROUPE Version 22.0) discussed in section II. of this final rule.

Comment: One commenter questioned whether the rate update cycle for the LTCH PPS will revert from a July 1 through June 30 cycle to the Federal fiscal year cycle (October 1 through September 30) since we proposed to update the LTC-DRGs effective for discharges on or after October 1, 2004.

Response: In the June 6, 2003 LTCH PPS final rule (68 FR 34122), we changed the LTCH PPS annual payment rate update cycle to be effective July 1 through June 30 instead of October 1 through September 30. As we discussed in that same LTCH PPS final rule and as we discussed in the May 18, 2004, IPPS proposed rule (69 FR 28225), because the patient classification system utilized under the LTCH PPS is based directly on the DRGs used under the IPPS for acute care hospitals, the annual update of the LTC-DRG classifications and relative weights will continue to remain linked to the annual reclassification and recalibration of the CMS-DRGs used under the IPPS.

The most recent annual LTCH PPS payment rate update and policy changes for the 2005 LTCH PPS rate year (July 1, 2004 through June 30, 2004) was published in the **Federal Register** on May 7, 2004 (69 FR 25674 through 25749). In that same LTCH PPS final rule, we established rate updates and policy changes that were effective for discharges occurring on or after July 1, 2004, including an update to the standard Federal LTCH PPS rate, the LTCH PPS wage index and the LTCH PPS outlier threshold. However, because the LTC-DRGs are linked to the IPPS DRGs, the LTC-DRG classifications and relative weights established in the August 1, 2003, final rule (68 FR 45374), which were effective beginning in Federal FY 2004, remain in effect through September 30, 2004. The updated LTC-DRG classifications and relative weights established for FY 2005 shown in Table 11 of this final rule will be effective for LTCH discharges on or after October 1, 2004 and before September 30, 2005. As we stated in the June 6, 2003 LTCH PPS final rule, the rate update cycle for the LTCH PPS will continue to remain on a July 1 through June 30 cycle while the annual update to the LTC-DRG classifications and relative weights will remain on a Federal fiscal year cycle (October 1 through September 30). Accordingly, the updated LTCH PPS Federal rate (\$36,833.69) and other payment factors (such as the outlier threshold and wage index values) effective July 1, 2004 (see

May 7, 2004, (69 FR 25674)), are applied in conjunction with the LTC-DRGs and relative weights established in the August 1, 2003, IPPS final rule (68 FR 45374) that are in effect through September 30, 2004, for LTCH discharges occurring from July 1, 2004 through September 30, 2004. However, beginning with discharges occurring on or after October 1, 2004, the LTC-DRGs and relative weights established in this final rule will be applied in conjunction with the LTCH PPS Federal rate (\$36,833.69) and other payment factors (such as the outlier threshold and wage index values) effective July 1, 2004, as established in the May 7, 2004 LTCH PPS final rule (69 FR 25674), for discharges occurring through June 30, 2005.

2. Changes in the LTC-DRG Classifications

a. Background

Section 123 of Public Law 106-113 specifically requires that the PPS for LTCHs be a per discharge system with a DRG-based patient classification system reflecting the differences in patient resources and costs in LTCHs while maintaining budget neutrality. Section 307(b)(1) of Public Law 106-554 modified the requirements of section 123 of Public Law 106-113 by specifically requiring that the Secretary examine "the feasibility and the impact of basing payment under such a system [the LTCH PPS] on the use of existing (or refined) hospital diagnosis-related groups (DRGs) that have been modified to account for different resource use of long-term care hospital patients as well as the use of the most recently available hospital discharge data."

In accordance with section 307(b)(1) of Public Law 106-554 and § 412.515 of our existing regulations, the LTCH PPS uses information from LTCH patient records to classify patient cases into distinct LTC-DRGs based on clinical characteristics and expected resource needs. The LTC-DRGs used as the patient classification component of the LTCH PPS correspond to the DRGs under the IPPS for acute care hospitals. Thus, as we proposed in the May 18, 2004, IPPS proposed rule, we will use the IPPS GROUPE Version 22.0 for FY 2005 to process LTCH PPS claims in this final rule. The changes to the IPPS DRG classification system for FY 2005 (GROUPE Version 22.0) are discussed in section II.B. of this preamble.

Under the LTCH PPS, we determine relative weights for each of the CMS DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical

problems characteristic of LTCH patients. In a departure from the IPPS, as we discussed in the August 30, 2002, final rule (67 FR 55985), which implemented the LTCH PPS, and the August 1, 2003, IPPS final rule (68 FR 45374), we use low-volume quintiles in determining the LTC-DRG weights for LTC-DRGs with less than 25 LTCH cases, since LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Specifically, we group those low-volume LTC-DRGs (LTC-DRGs with fewer than 25 cases) into 5 quintiles based on average charge per discharge. (A listing of the composition of low-volume quintiles for the FY 2004 LTC-DRGs (based on FY 2002 MedPAR data) appears in section II.D.3. of the August 1, 2003 IPPS final rule (68 FR 45377 through 45380).) We also adjust for cases in which the stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay; that is, short-stay outlier cases (§ 412.529), as discussed below in section II.D.4. of this preamble.

b. Patient Classifications Into DRGs

Generally, under the LTCH PPS, Medicare payment is made at a predetermined specific rate for each discharge; that is, payment varies by the LTC-DRG to which a beneficiary's stay is assigned. Similar to case classification for acute care hospitals under the IPPS (see section II.B. of this preamble), cases are classified into LTC-DRGs for payment under the LTCH PPS based on the principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the stay, as well as age, sex, and discharge status of the patient. The diagnosis and procedure information is reported by the hospital using codes from the ICD-9-CM.

As discussed in section II.B. of this preamble, the CMS DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Accordingly, the principal diagnosis determines MDC assignment. Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Some surgical and medical DRGs are further differentiated based on the presence or absence of CCs. (See section II.B. of this preamble for further discussion of surgical DRGs and medical DRGs.)

Because the assignment of a case to a particular LTC-DRG will help determine the amount that is paid for the case, it is important that the coding is accurate. As used under the IPPS, classifications and terminology used

under the LTCH PPS are consistent with the ICD-9-CM and the Uniform Hospital Discharge Data Set (UHDDS), as recommended to the Secretary by the National Committee on Vital and Health Statistics ("Uniform Hospital Discharge Data: Minimum Data Set, National Center for Health Statistics, April 1980") and as revised in 1984 by the Health Information Policy Council (HIPC) of the U.S. Department of Health and Human Services. We wish to point out again that the ICD-9-CM coding terminology and the definitions of principal and other diagnoses of the UHDDS are consistent with the requirements of the Administrative Simplification Act of 1996 of the HIPAA (45 CFR parts 160 and 162).

The emphasis on the need for proper coding cannot be overstated. Inappropriate coding of cases can adversely affect the uniformity of cases in each LTC-DRG and produce inappropriate weighting factors at recalibration and result in inappropriate payments under the LTCH PPS. LTCHs are to follow the same coding guidelines used by the acute care hospitals to ensure accuracy and consistency in coding practices. There will be only one LTC-DRG assigned per long-term care hospitalization; it will be assigned at the discharge. Therefore, it is mandatory that the coders continue to report the same principal diagnosis on all claims and include all diagnostic codes that coexist at the time of admission, that are subsequently developed, or that affect the treatment received. Similarly, all procedures performed during that stay are to be reported on each claim.

Upon the discharge of the patient from a LTCH, the LTCH must assign appropriate diagnosis and procedure codes from the ICD-9-CM. As of October 16, 2002, a LTCH that was required to comply with the HIPAA Administrative Simplification Standards and that had not obtained an extension in compliance with the Administrative Compliance Act (Pub. L. 107-105) is obligated to comply with the standards at 45 CFR 162.1002 and 45 CFR 162.1102. Completed claim forms are to be submitted to the LTCH's Medicare fiscal intermediary. Medicare fiscal intermediaries enter the clinical and demographic information into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into an LTC-DRG can be made.

After screening through the MCE, each LTCH claim will be classified into the appropriate LTC-DRG by the

Medicare LTCH GROUPER. The LTCH GROUPER is specialized computer software based on the same GROUPER used under the IPPS. After the LTC-DRG is assigned, the Medicare fiscal intermediary determines the prospective payment by using the Medicare LTCH PPS PRICER program, which accounts for LTCH hospital-specific adjustments. As provided for under the IPPS, we provide an opportunity for the LTCH to review the LTC-DRG assignments made by the fiscal intermediary and to submit additional information within a specified timeframe (§ 412.513(c)).

The GROUPER is used both to classify past cases in order to measure relative hospital resource consumption to establish the LTC-DRG weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible DRG classification changes and to recalibrate the DRG weights during our annual update (as discussed in section II. of this preamble). The LTC-DRG relative weights are based on data for the population of LTCH discharges, reflecting the fact that LTCH patients represent a different patient mix than patients in short-term acute care hospitals.

3. Development of the FY 2005 LTC-DRG Relative Weights

a. General Overview of Development of the LTC-DRG Relative Weights

As we stated in the August 30, 2002, LTCH PPS final rule (67 FR 55981), one of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly. To accomplish these goals, we adjust the LTCH PPS standard Federal prospective payment system rate by the applicable LTC-DRG relative weight in determining payment to LTCHs for each case.

Under the LTCH PPS, relative weights for each LTC-DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each LTC-DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight

for each LTC-DRG that represents the resources needed by an average inpatient LTCH case in that LTC-DRG. For example, cases in an LTC-DRG with a relative weight of 2 will, on average, cost twice as much as cases in an LTC-DRG with a weight of 1.

b. Data

To calculate the LTC-DRG relative weights for FY 2005 in this final rule, we obtained total Medicare allowable charges from FY 2003 Medicare hospital bill data from the March 2004 update of the MedPAR file, and we used Version 22.0 of the CMS GROUPER for IPPS, as discussed in section II.B. of this preamble, to classify cases. Consistent with the methodology under the IPPS, we recalculated the FY 2005 LTC-DRG relative weights based on the best available data for this final rule.

As we discussed in the May 18, 2004 proposed rule (69 FR 28227), we have excluded the data from LTCHs that are all-inclusive rate providers and LTCHs that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90-248 (42 U.S.C. 1395b-1) or section 222(a) of Public Law 92-603 (42 U.S.C. 1395b-1). Therefore, in the development of the FY 2005 LTC-DRG relative weights, we have excluded the data of the 22 all-inclusive rate providers and the 3 LTCHs that are paid in accordance with demonstration projects that had claims in the FY 2003 MedPAR file.

In the August 1, 2003, final rule (68 FR 45367), we discussed coding inaccuracies that were found in claims data for a large chain of LTCHs in the FY 2002 MedPAR file used to determine the LTC-DRG relative weights for FY 2004. Specifically, the principal diagnosis was not reported correctly on many of those LTCHs' claims, which resulted in those claims being incorrectly assigned to an LTC-DRG. As we explained in the same final rule, we were able to determine the correct diagnoses and procedure codes for the claims that contained the coding errors, and we used them to group each LTCH case to the appropriate LTC-DRG for determining the LTC-DRG relative weights for FY 2004. In addition, we stated that since the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002 (FY 2003), we believe that this problem will be self-correcting as LTCHs submit more completely coded data in the future.

As we discussed in the May 7, 2004, LTCH PPS final rule (69 FR 25674), an analysis of LTCH claims data from the September 2003 update of the FY 2003

MedPAR file contained coding errors. Specifically, a large hospital chain of LTCHs continued to consistently code diagnoses inaccurately on the claims it submitted, and these coding errors were reflected in the September 2003 update of the FY 2003 MedPAR file. Upon discovering the coding errors, we notified the large chain of LTCHs whose claims contained the coding inaccuracies to request that they resubmit those claims with the correct diagnoses codes by December 31, 2003, so that those corrected claims would be contained in the December 2003 update of the FY 2003 MedPAR file. As we discussed in that same final rule, it appears that those claims were submitted timely with the correct diagnoses codes. Therefore, it was not necessary to correct the FY 2003 MedPAR data for the development of the rates and factors established in the May 7, 2004, LTCH PPS final rule. Accordingly, in the May 18, 2004, IPPS proposed rule, we used LTCH claims data from the December 2003 update of the FY 2003 MedPAR file for the determination of the proposed FY 2005 LTC-DRG relative weights. For this final rule, we used the latest available LTCH claims data from the March 2004 update of the FY 2003 MedPAR file.

c. Hospital-Specific Relative Value Methodology

By nature LTCHs often specialize in certain areas, such as ventilator-dependent patients and rehabilitation and wound care. Some case types (DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonarbitrary distribution of cases with relatively high (or low) charges in specific LTC-DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, we use a hospital-specific relative value method to calculate the LTC-DRG relative weights instead of the methodology used to determine the DRG relative weights under the IPPS described above in section II.C. of this preamble. We believe this method will remove this hospital-specific source of bias in measuring LTCH average charges. Specifically, we reduce the impact of the variation in charges across providers on any particular LTC-DRG relative weight by converting each LTCH's charge for a case to a relative value based on that LTCH's average charge.

Under the hospital-specific relative value method, we standardize charges for each LTCH by converting its charges

for each case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, averages 1.0 for each LTCH). The average relative weight for a LTCH is its case-mix, so it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the cases it treats relative to the complexity of the cases treated by all other LTCHs (the average case-mix of all LTCHs).

In accordance with the methodology established under § 412.523, we standardize charges for each case by first dividing the adjusted charge for the case (adjusted for short-stay outliers under § 412.529 as described in section II.D.4. (step 3) of this preamble) by the average adjusted charge for all cases at the LTCH in which the case was treated. Short-stay outliers under § 412.529 are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the LTC-DRG. The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio is multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

Multiplying by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight in a LTCH with higher average costs than they would at a LTCH with low average costs which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. Because we standardize charges in this manner, we count charges for a Medicare patient at a LTCH with high average charges as less resource intensive than they would be at a LTCH with low average charges. For example, a \$10,000 charge for a case in a LTCH with an average adjusted charge of \$17,500 reflects a higher level of relative resource use than a \$10,000 charge for a case in a LTCH with the same case-mix, but an average adjusted charge of \$35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

Comment: MedPAC supported the use of the hospital-specific relative value methodology for determining the LTC-DRG relative weights, stating that "[t]his method eliminates distortions in

weights due to systematic differences among hospitals in the level of costs per case and in charge markups." The Commission believed that we should explore the use of this methodology for the DRG relative weights used under the IPPS.

Response: We appreciate MedPAC's support of the use of the hospital-specific relative value methodology for determining the LTC-DRG relative weights. As we discuss above, because by nature LTCHs often specialize in certain types of care, we believe it is important to remove any hospital-specific source of bias in measuring LTCHs' average charges. Therefore, we have continued to use of the hospital-specific relative value methodology for determining the final FY 2005 LTC-DRG relative weights shown in Table 11 of this final rule.

As discussed above, we believe that the LTCHs' charge data are particularly vulnerable to having a hospital-specific source of bias when measuring LTCHs' average charges because of the small number of LTCHs (approximately 300 hospitals with approximately 100,00 discharges annually) and the relatively high degree of specialization of many LTCHs. There are over 4,000 short-term acute care hospitals paid under the IPPS, with approximately 11.9 million discharges annually, that generally treat a wide range of conditions, rather than specializing in one or two types of conditions. Therefore, although we agree with the Commission that the hospital-specific relative value methodology eliminates distortions in relative weights due to systematic differences among hospitals' charges, we do not believe that it is necessary to use the hospital-specific relative value methodology under the IPPS since short-term acute care hospitals' charge data is not as susceptible to having a hospital-specific source of bias when measuring average charges.

Furthermore, as we discussed in the August 1, 2000, IPPS final rule (65 FR 47103), in 1995 the MedPAC's predecessor, the Prospective Payment Assessment Commission, made a similar recommendation to adopt the hospital-specific relative value methodology under the IPPS. In the June 2, 1995, proposed rule (60 FR 29246), we agreed with the Commission's judgment that basing the

IPPS DRG weights on standardized charges results in weights that are somewhat distorted as measures of the relative costliness of treating a typical case in each DRG, and that the hospital-specific relative value method of setting weights may reduce or eliminate distortions present in the current system. However, in our discussion on DRG refinements under the IPPS in the same rule (60 FR 29209), we reiterated our position published in the final rule on September 1, 1992 (57 FR 39761), that we would not propose to make significant changes to the DRG classification system under the IPPS, unless we are able to either improve our ability to predict coding changes by validating in advance the impact that potential DRG changes may have on coding behavior, or to make methodological changes to prevent building the inflationary effects of the coding changes into future program payments. Without further evaluation, we do not believe it would be appropriate to change the methodology for determining the DRG relative weights under the IPPS at this time. The development of the FY 2005 DRG relative weights used under the IPPS for short-term acute care hospitals is discussed in section II.C. of this preamble.

d. Low-Volume LTC-DRGs

In order to account for LTC-DRGs with low-volume (that is, with fewer than 25 LTCH cases), in accordance with the methodology discussed in the August 30, 2002, LTCH PPS final rule (67 FR 55984) and in the May 18, 2004, IPPS proposed rule (69 FR 28228), we group those low-volume LTC-DRGs into one of five categories (quintiles) based on average charges, for the purposes of determining relative weights. For this final rule, using LTCH cases from the March 2004 update of the FY 2003 MedPAR file, we identified 172 LTC-DRGs that contained between 1 and 24 cases. This list of LTC-DRGs was then divided into one of the 5 low-volume quintiles, each containing a minimum of 34 LTC-DRGs ($172/5 = 34$ with 2 LTC-DRGs as the remainder). For FY 2005, as we described in the May 18, 2004 IPPS proposed rule, we are making an assignment to a specific low-volume quintile by sorting the low-volume LTC-DRGs in ascending order by

average charge. For this final rule, this results in an assignment to a specific low volume quintile of the sorted 172 low-volume LTC-DRGs by ascending order by average charge. Since the number of LTC-DRGs with less than 25 LTCH cases is not evenly divisible by five, the average charge of the low-volume LTC-DRG was used to determine which low-volume quintile received the additional LTC-DRG. After sorting the 172 low-volume LTC-DRGs in ascending order, we grouped the first fifth (34) of low-volume LTC-DRGs with the lowest average charge would be grouped into Quintile 1. The highest average charge cases are grouped into Quintile 5. Since the average charge of the 103rd LTC-DRG in the sorted list is closer to the previous LTC-DRG's average charge (assigned to Quintile 3) than to the average charge of the 104th LTC-DRG in the sorted list (to be assigned to Quintile 4), we placed it into Quintile 3. This process was repeated through the remaining low-volume LTC-DRGs so that 3 low-volume quintiles contain 34 LTC-DRGs and 2 low-volume quintiles contain 35 LTC-DRGs.

In order to determine the relative weights for the LTC-DRGs with low volume for FY 2005, in accordance with the methodology described in the August 30, 2002 LTCH PPS final rule (67 FR 55984) and cited in the May 18, 2004 IPPS proposed rule, we used the five low-volume quintiles described above. The composition of each of the five low-volume quintiles shown below in Table 1 is used in determining the LTC-DRG relative weights for FY 2005. We determine a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the formula that we apply to the regular LTC-DRGs (25 or more cases), as described below in section II.D.4. of this preamble. We assign the same relative weight and average length of stay to each of the LTC-DRGs that make up that low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of LTC-DRGs with a low volume of LTCH cases will vary in the future. We use the best available claims data in the MedPAR file to identify low-volume LTC-DRGs and to calculate the relative weights based on our methodology.

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Table 1.--Composition of Low-Volume Quintiles

LTC-DRG	Description
QUINTILE 1	
11	NERVOUS SYSTEM NEOPLASMS W/O CC
43	HYPHEMA
45	NEUROLOGICAL EYE DISORDERS
47	OTHER DISORDERS OF THE EYE AGE >17 W/O CC
84	MAJOR CHEST TRAUMA W/O CC
93	INTERSTITIAL LUNG DISEASE W/O CC
95	PNEUMOTHORAX W/O CC
110	MAJOR CARDIOVASCULAR PROCEDURES W CC
119	VEIN LIGATION & STRIPPING
143	CHEST PAIN
149	MAJOR SMALL & LARGE BOWEL PROCEDURES W/O CC
178	UNCOMPLICATED PEPTIC ULCER W/O CC
193	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W CC
208	DISORDERS OF THE BILIARY TRACT W/O CC
229	HAND OR WRIST PROC, EXCEPT MAJOR JOINT PROC, W/O CC
237	SPRAINS, STRAINS, & DISLOCATIONS OF HIP, PELVIS & THIGH
241	CONNECTIVE TISSUE DISORDERS W/O CC
260	SUBTOTAL MASTECTOMY FOR MALIGNANCY W/O CC
273	MAJOR SKIN DISORDERS W/O CC
275	MALIGNANT BREAST DISORDERS W/O CC
284	MINOR SKIN DISORDERS W/O CC
324	URINARY STONES W/O CC
326	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W/O CC
339	TESTES PROCEDURES, NON-MALIGNANCY AGE >17
347	MALIGNANCY, MALE REPRODUCTIVE SYSTEM, W/O CC
367	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM W/O CC
404	LYMPHOMA & NON-ACUTE LEUKEMIA W/O CC
427	NEUROSES EXCEPT DEPRESSIVE
433	ALCOHOL/DRUG ABUSE OR DEPENDENCE, LEFT AMA
450	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W/O CC
500	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W/O CC
509	FULL THICKNESS BURN W/O SKIN GRFT OR INH INJ W/O CC OR SIG TRAUMA
522	ALC/DRUG ABUSE OR DEPEND W REHABILITATION THERAPY W/O CC
532	SPINAL PROCEDURES W/O CC
QUINTILE 2	
8	PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W/O CC
17	NONSPECIFIC CEREBROVASCULAR DISORDERS W/O CC
22	HYPERTENSIVE ENCEPHALOPATHY
25	SEIZURE & HEADACHE AGE >17 W/O CC
31	CONCUSSION AGE >17 W CC
46	OTHER DISORDERS OF THE EYE AGE >17 W CC
69	OTITIS MEDIA & URI AGE >17 W/O CC
83	MAJOR CHEST TRAUMA W CC
109	CORONARY BYPASS W/O PTCA OR CARDIAC CATH
117	CARDIAC PACEMAKER REVISION EXCEPT DEVICE REPLACEMENT
129	CARDIAC ARREST, UNEXPLAINED
140	ANGINA PECTORIS
142	SYNCOPE & COLLAPSE W/O CC
181	G.I. OBSTRUCTION W/O CC
206	DISORDERS OF LIVER EXCEPT MALIG,CIRR,ALC HEPA W/O CC
227	SOFT TISSUE PROCEDURES W/O CC
250	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W CC

LTC-DRG	Description
251	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W/O CC
276	NON-MALIGANT BREAST DISORDERS
295	DIABETES AGE 0-35
305	KIDNEY, URETER & MAJOR BLADDER PROC FOR NON-NEOPL W/O CC
323	URINARY STONES W CC, &/OR ESW LITHOTRIPSY
328	URETHRAL STRICTURE AGE >17 W CC
348	BENIGN PROSTATIC HYPERTROPHY W CC
349	BENIGN PROSTATIC HYPERTROPHY W/O CC
399	RETICULOENDOTHELIAL & IMMUNITY DISORDERS W/O CC
414	OTHER MYELOPROLIF DIS OR POORLY DIFF NEOPL DIAG W/O CC
441	HAND PROCEDURES FOR INJURIES
449	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W CC
455	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W/O CC
467	OTHER FACTORS INFLUENCING HEALTH STATUS
479	OTHER VASCULAR PROCEDURES W/O CC
511	NON-EXTENSIVE BURNS W/O CC OR SIGNIFICANT TRAUMA
518	PERC CARDIO PROC W/O CORONARY ARTERY STENT OR AMI
QUINTILE 3	
29	TRAUMATIC STUPOR & COMA, COMA <1 HR AGE >17 W/O CC
44	ACUTE MAJOR EYE INFECTIONS
86	PLEURAL EFFUSION W/O CC
122	CIRCULATORY DISORDERS W AMI W/O MAJOR COMP, DISCHARGED ALIVE
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG
128	DEEP VEIN THROMBOPHLEBITIS
136	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE >17 W/O CC
159	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W CC
175	G.I. HEMORRHAGE W/O CC
177	UNCOMPLICATED PEPTIC ULCER W CC
200	HEPATOBIILIARY DIAGNOSTIC PROCEDURE FOR NON-MALIGNANCY
228	MAJOR THUMB OR JOINT PROC, OR OTH HAND OR WRIST PROC W CC
234	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W/O CC
262	BREAST BIOPSY & LOCAL EXCISION FOR NON-MALIGNANCY
266	SKIN GRAFT &/OR DEBRID EXCEPT FOR SKIN ULCER OR CELLULITIS W/O CC
270	OTHER SKIN, SUBCUT TISS & BREAST PROC W/O CC
288	O.R. PROCEDURES FOR OBESITY
301	ENDOCRINE DISORDERS W/O CC
307	PROSTATECTOMY W/O CC
310	TRANSURETHRAL PROCEDURES W CC
319	KIDNEY & URINARY TRACT NEOPLASMS W/O CC
325	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W CC
369	MENSTRUAL & OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS
447	ALLERGIC REACTIONS AGE >17
454	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W CC
476	PROSTATIC O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS
496	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION
497	SPINAL FUSION EXCEPT CERVICAL W CC
505	EXTENSIVE BURNS OF FULL THICKNESS BURNS WITH MECH VENT 96+HRS WITHOUT SKIN GRAFT

LTC-DRG	Description
517	PERC CARDIO PROC W NON-DRUG ELUTING STENT W/O AMI
519	CERVICAL SPINAL FUSION W CC
523	ALC/DRUG ABUSE OR DEPEND W/O REHABILITATION THERAPY W/O CC
535	CARDIAC DEFIB IMPLANT W CARDIAC CATH W AMI/HF/SHOCK
538	LOCAL EXCIS & REMOV OF INT FIX DEV EXCEPT HIP & FEMUR W/O CC
539	LYMPHOMA & LEUKEMIA W MAJOR OR PROCEDURE W CC
QUINTILE 4	
1	CRANIOTOMY AGE >17 W CC
21	VIRAL MENINGITIS
63	OTHER EAR, NOSE, MOUTH & THROAT O.R. PROCEDURES
102	OTHER RESPIRATORY SYSTEM DIAGNOSES W/O CC
108	OTHER CARDIOTHORACIC PROCEDURES
115	PRM CARD PACEM IMPL W AMI/HR/SHOCK OR AICD LEAD OR GNRTR
157	ANAL & STOMAL PROCEDURES W CC
168	MOUTH PROCEDURES W CC
173	DIGESTIVE MALIGNANCY W/O CC
201	OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES
218	LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE >17 W CC
292	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W CC
299	INBORN ERRORS OF METABOLISM
303	KIDNEY, URETER & MAJOR BLADDER PROCEDURES FOR NEOPLASM
304	KIDNEY, URETER & MAJOR BLADDER PROC FOR NON-NEOPL W CC
306	PROSTATECTOMY W CC
308	MINOR BLADDER PROCEDURES W CC
312	URETHRAL PROCEDURES, AGE >17 W CC
336	TRANSURETHRAL PROSTATECTOMY W CC
352	OTHER MALE REPRODUCTIVE SYSTEM DIAGNOSES
394	OTHER O.R. PROCEDURES OF THE BLOOD AND BLOOD FORMING ORGANS
401	LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W CC
408	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W OTHER O.R. PROC
410	CHEMOTHERAPY W/O ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS
419	FEVER OF UNKNOWN ORIGIN AGE >17 W CC
420	FEVER OF UNKNOWN ORIGIN AGE >17 W/O CC
485	LIMB REATTACHMENT, HIP AND FEMUR PROC FOR MULTIPLE SIGNIFICANT TRA
493	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W CC
499	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W CC
501	KNEE PROCEDURES W PDX OF INFECTION W CC
502	KNEE PROCEDURES W PDX OF INFECTION W/O CC
503	KNEE PROCEDURES W/O PDX OF INFECTION
506	FULL THICKNESS BURN W SKIN GRAFT OR INHAL INJ W CC OR SIG TRAUMA
529	VENTRICULAR SHUNT PROCEDURES W CC
531	SPINAL PROCEDURES W CC
QUINTILE 5	
55	MISCELLANEOUS EAR, NOSE, MOUTH & THROAT PROCEDURES
77	OTHER RESP SYSTEM O.R. PROCEDURES W/O CC
116	OTHER PERMANENT CARDIAC PACEMAKER IMPLANT
118	CARDIAC PACEMAKER DEVICE REPLACEMENT

LTC-DRG	Description
125	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG
150	PERITONEAL ADHESIOLYSIS W CC
152	MINOR SMALL & LARGE BOWEL PROCEDURES W CC
154	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W CC
161	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W CC
171	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W/O CC
191	PANCREAS, LIVER & SHUNT PROCEDURES W CC
197	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W CC
209	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF LOWER EXTREMITY
210	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W CC
216	BIOPSIES OF MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE
226	SOFT TISSUE PROCEDURES W CC
230	LOCAL EXCISION & REMOVAL OF INT FIX DEVICES OF HIP & FEMUR
261	BREAST PROC FOR NON-MALIGNANCY EXCEPT BIOPSY & LOCAL EXCISION
267	PERIANAL & PILONIDAL PROCEDURES
268	SKIN, SUBCUTANEOUS TISSUE & BREAST PLASTIC PROCEDURES
338	TESTES PROCEDURES, FOR MALIGNANCY
341	PENIS PROCEDURES
344	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES FOR MALIGNANCY
345	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROC EXCEPT FOR MALIGNANCY
365	OTHER FEMALE REPRODUCTIVE SYSTEM O.R. PROCEDURES
406	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R.PROC W CC
424	O.R. PROCEDURE W PRINCIPAL DIAGNOSES OF MENTAL ILLNESS
443	OTHER O.R. PROCEDURES FOR INJURIES W/O CC
486	OTHER O.R. PROCEDURES FOR MULTIPLE SIGNIFICANT TRAUMA
488	HIV W EXTENSIVE O.R. PROCEDURE
515	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH
533	EXTRACRANIAL PROCEDURES W CC
536	CARDIAC DEFIB IMPLANT W CARDIAC CATH W/O AMI/HF/SHOCK
543	CRANIOTOMY W IMPLANT OF CHEMO AGENT OR ACUTE COMPLEX CNS PDX

* One of the original 172 low-volume LTC-DRGs initially assigned to this low-volume quintile; removed from the low-volume quintiles in addressing nonmonotonicity (see step 5 below).

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4. Steps for Determining the FY 2005 LTC-DRG Relative Weights

As we noted previously, the FY 2005 LTC-DRG relative weights are determined in accordance with the methodology described in the August 1, 2003 IPSS final rule (68 FR 45367) and cited in the May 18, 2004 IPSS proposed rule (69 FR 28231). In summary, LTCH cases must be grouped in the appropriate LTC-DRG, while taking into account the low-volume LTC-DRGs as described above, before the FY 2005 LTC-DRG relative weights can be determined. After grouping the cases in the appropriate LTC-DRG, we calculate the relative weights for FY 2005 in this final rule by first removing statistical

outliers and cases with a length of stay of 7 days or less. Next, we adjust the number of cases in each LTC-DRG for the effect of short-stay outlier cases under § 412.529. The short-stay adjusted discharges and corresponding charges are used to calculate "relative adjusted weights" in each LTC-DRG using the hospital-specific relative value method described above.

Below we discuss in detail the steps for calculating the FY 2005 LTC-DRG relative weights.

Step 1—Remove statistical outliers.

The first step in the calculation of the FY 2005 LTC-DRG relative weights is to remove statistical outlier cases. We define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of

both charges per case and the charges per day for each LTC-DRG. These statistical outliers are removed prior to calculating the relative weights. We believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among the LTC-DRGs.

Step 2—Remove cases with a length of stay of 7 days or less.

The FY 2005 LTC-DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay 7 days or less do not belong in a LTCH because these stays do

not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH. If we were to include stays of 7 days or less in the computation of the FY 2005 LTC-DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate.

We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at a LTCH, in order to include data from these very short-stays. Thus, in determining the FY 2005 LTC-DRG relative weights, we remove LTCH cases with a length of stay of 7 days or less.

Comment: One commenter believes that it is inappropriate to exclude cases with a length of stay of 7 days or less from the calculation of the proposed LTC-DRG relative weights since it is not uncommon for very resource intensive patients to expire within the first 7 days of the stay. The commenter also suggested that we consider creating a separate LTC-DRG for LTCH patients that expire within the first 7 days of the stay.

Response: While we understand the commenters concerns, as we discussed in the August 30, 2002, final rule (67 FR 55989) which implemented the LTCH PPS, in calculating the LTC-DRG relative weights, we exclude cases with a length of stay of 7 days or less because we believe that, generally, cases with a length of stay of 7 days or less do not belong in a LTCH. In general, LTCHs are defined by statute as hospitals having an average length of stay of greater than 25 days. LTCHs typically furnish extended medical and rehabilitative care for patients who are clinically complex and have multiple or chronic conditions. Generally, LTCH cases with very short lengths of stay (that is, 7 days or less) are discharged from the LTCH before the patient receives a full course of treatment, and therefore do not use the same amount or type of resources as typical LTCH "inlier" cases (that is, cases in which Medicare covered days exceed five-sixths of the geometric average length of stay for the LTC-DRG and the patient is discharged prior to receiving a LTCH PPS high cost outlier payment). We believe that the length of stay of an "inlier" case is indicative of a LTCH patient receiving a full course of treatment because such cases include cases with stays that received a full LTC-DRG payment, which represents the average resources used for that DRG (that is, the case does not receive an

adjusted short-stay outlier payment or a high-cost outlier payment). LTCH discharges with very short lengths of stay (that is, 7 days or less) often occur when it is determined, following admission to a LTCH, that the beneficiary would receive more appropriate care at another setting. Other circumstances that result in cases with very short stays (that is, 7 days or less) would involve patients who were either discharged to their home or who expired within the first 7 days of being admitted to an LTCH. Because LTCH cases with very short lengths of stay (that is, 7 days or less) do not use the same amount or type of resources as typical LTCH inlier cases, our simulations indicate that including these cases would significantly bias payments against LTCH inlier cases to a point where LTCH inlier cases would be underpaid.

As we also discussed in the August 30, 2002, LTCH PPS final rule (65 FR 55989), the LTC-DRG relative weights reflect the average resources used on representative cases of a specific type. Stays of 7 days or less generally do not fully receive or benefit from treatment that is typical in a LTCH stay because the patient is discharged prior to receiving a full course of treatment that a LTCH inlier patient would receive. In addition, full resources are often not used in the earlier stages of an admission to a LTCH because the patient is often medically unstable, and initial efforts are focused on stabilizing the patient before beginning treatment of the patient's additional complications and comorbidities. If we did include stays of 7 days or less in the calculation of the LTC-DRG relative weights, the value of many relative weights would decrease for cases that do, in fact, receive a full course of treatment, and, therefore, LTCH inlier payments could decrease to a level that would not be appropriate (that is, provide sufficient payment). We continue to believe that it is not appropriate to compromise the integrity of the payment amounts for LTCH inlier cases that actually benefit from and receive a full course of treatment at a LTCH in order to include data from cases with stays of 7 days or less. Therefore, we disagree with the commenter that cases with lengths of stay of 7 days or less should be included in the calculation of the LTC-DRG relative weights. Accordingly, in this final rule, in calculating the FY 2005 LTC-DRG relative weights, as we proposed, we have removed cases with a length of stay of 7 days or less.

With regard to the commenter's suggestion that we create a separate LTC-DRG for patients who expire, as we

also discussed in the August 30, 2002, LTCH PPS final rule (67 FR 56002), we do not believe that a separate LTC-DRG for patients who expire is necessary. We continue to believe that the short-stay outlier policy at § 412.529 adequately addresses payments for patients who expire August 30, 2002, LTCH PPS final rule (65 FR 56006), because a case with a length of stay up to and including five-sixths of the average length of stay of the LTC-DRG is paid under the short-stay outlier policy regardless of whether or not the patient expires. Under the short-stay outlier policy (§ 412.529), generally a case is paid the least of 120 percent of the estimated cost of the case, 120 percent of the LTC-DRG specific per diem amount, or the full LTC-DRG payment.

We continue to believe that adjusted payments under the short-stay outlier policy for cases that expire generally compensate for any increased costs associated with treating a severely ill patient who dies, including those who expire within 7 days of being admitted to a LTCH. We note that one of the principles underlying prospective payment is that it is a system of payments based on average costs that assumes that some patient stays will consume more resources than the typical stay, while other patients will demand fewer resources. Thus, an efficiently operated hospital should be able to deliver care to its Medicare patients for an overall cost that is at or below the amount paid under the LTCH PPS. We continue to believe the LTCH PPS payment adequately address payments for patients who expire, and therefore, we are not adopting the commenter's suggestion to create a separate LTC-DRG for LTCH patients that expire within the first 7 days of the stay. Accordingly, in establishing the final FY 2005 LTC-DRG relative weights, we continue to exclude cases with a length of stay of 7 days or less and we continue to include the total charges of cases with a length of stay of 8 days or more, including patients who expire, in the LTC-DRG to which the case is assigned based on version 22.0 of the GROUPE.

Step 3—Adjust charges for the effects of short-stay outliers.

The third step in the calculation of the FY 2005 LTC-DRG relative weights is to adjust each LTCH's charges per discharge for short-stay outlier cases (that is, a patient with a length of stay that is less than or equal to five-sixths the average length of stay of the LTC-DRG).

We make this adjustment by counting a short-stay outlier as a fraction of a discharge based on the ratio of the

length of stay of the case to the average length of stay for the LTC-DRG for nonshort-stay outlier cases. This has the effect of proportionately reducing the impact of the lower charges for the short-stay outlier cases in calculating the average charge for the LTC-DRG. This process produces the same result as if the actual charges per discharge of a short-stay outlier case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the LTC-DRG.

As we explained in the May 18, 2004 proposed rule (69 FR 28231), counting short-stay outlier cases as full discharges with no adjustment in determining the LTC-DRG relative weights would lower the LTC-DRG relative weight for affected LTC-DRGs because the relatively lower charges of the short-stay outlier cases would bring down the average charge for all cases within an LTC-DRG. This would result in an "underpayment" to nonshort-stay outlier cases and an "overpayment" to short-stay outlier cases. Therefore, in this final rule, we adjust for short-stay outlier cases under § 412.529 in this manner because it results in more appropriate payments for all LTCH cases.

Step 4—Calculate the FY 2005 LTC-DRG relative weights on an iterative basis.

The process of calculating the LTC-DRG relative weights using the hospital specific relative value methodology is iterative. First, for each LTCH case, we calculate a hospital-specific relative charge value by dividing the short-stay outlier adjusted charge per discharge (see step 3) of the LTCH case (after removing the statistical outliers (see step 1)) and LTCH cases with a length of stay of 7 days or less (see step 2) by the average charge per discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. An initial case-mix index value of 1.0 is used for each LTCH.

For each LTC-DRG, the FY 2005 LTC-DRG relative weight is calculated by dividing the average of the adjusted hospital-specific relative charge values (from above) for the LTC-DRG by the overall average hospital-specific relative charge value across all cases for all LTCHs. Using these recalculated LTC-DRG relative weights, each LTCH's average relative weight for all of its cases (case-mix) is calculated by dividing the sum of all the LTCH's LTC-DRG relative weights by its total number of cases. The LTCHs' hospital-specific relative charge values above are

multiplied by these hospital specific case-mix indexes. These hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of LTC-DRG relative weights across all LTCHs. In this final rule, this iterative process is continued until there is convergence between the weights produced at adjacent steps, for example, when the maximum difference is less than 0.0001.

Step 5—Adjust the FY 2005 LTC-DRG relative weights to account for nonmonotonically increasing relative weights.

As explained in section II.B. of this preamble, the FY 2005 CMS DRGs, which the FY 2005 LTC-DRGs are based, contain "pairs" that are differentiated based on the presence or absence of CCs. The LTC-DRGs with CCs are defined by certain secondary diagnoses not related to or inherently a part of the disease process identified by the principal diagnosis, but the presence of additional diagnoses does not automatically generate a CC. As we discussed in the May 18, 2004 IPPS proposed rule (69 FR 28232), the value of monotonically increasing relative weights rises as the resource use increases (for example, from uncomplicated to more complicated). The presence of CCs in an LTC-DRG means that cases classified into a "without CC" LTC-DRG are expected to have lower resource use (and lower costs). In other words, resource use (and costs) are expected to decrease across "with CC"/"without CC" pairs of LTC-DRGs.

For a case to be assigned to a LTC-DRG with CCs, more coded information is called for (that is, at least one relevant secondary diagnosis), than for a case to be assigned to an LTC-DRG "without CCs" (which is based on only one principal diagnosis and no relevant secondary diagnoses). Currently, the LTCH claims data include both accurately coded cases without complications and cases that have complications (and cost more), but were not coded completely. Both types of cases are grouped to an LTC-DRG "without CCs" because only one principal diagnosis was coded. Since the LTCH PPS was only implemented for cost reporting periods beginning on or after October 1, 2002 (FY 2003) and LTCHs were previously paid under cost-based reimbursement, which is not based on patient diagnoses, coding by LTCHs for these cases may not have been as detailed as possible.

Thus, in developing the FY 2003 LTC-DRG relative weights for the LTCH PPS based on FY 2001 claims data, as we discussed in the August 30, 2002

LTCH PPS final rule (67 FR 55990), we found on occasion that the data suggested that cases classified to the LTC-DRG "with CCs" of a "with CC"/"without CC" pair had a lower average charge than the corresponding LTC-DRG "without CCs." Similarly, based on FY 2003 claims data, we also found on occasion that the data suggested that cases classified to the LTC-DRG "with CCs" of a "with CC"/without CC" pair have a lower average charge than the corresponding LTC-DRG "without CCs" for FY 2005.

We believe this anomaly may be due to coding that may not have fully reflected all comorbidities that were present. Specifically, LTCHs may have failed to code relevant secondary diagnoses, which resulted in cases that actually had CCs being classified into a "without CC" LTC-DRG. It would not be appropriate to pay a lower amount for the "with CC" LTC-DRG. Therefore, in this final rule, we grouped both the cases "with CCs" and "without CCs" together for the purpose of calculating the FY 2005 LTC-DRG relative weights in this final rule. As we stated in the August 30, 2002 LTCH PPS final rule (67 FR 55990), we will continue to employ this methodology to account for nonmonotonically increasing relative weights until we have adequate data to calculate appropriate separate weights for these anomalous LTC-DRG pairs. We expect that, as was the case when we first implemented the IPPS, this problem will be self-correcting, as LTCHs submit more completely coded data in the future.

There are three types of "with CC" and "without CC" pairs that could be nonmonotonic, that is, where the "without CC" LTC-DRG would have a higher average charge than the "with CC" LTC-DRG. For this final rule, using the LTCH cases in the March 2004 update of the FY 2003 MedPAR file, we identified two of the three types of nonmonotonic LTC-DRG pairs.

The first category of nonmonotonically increasing relative weights for FY 2005 LTC-DRG pairs "with and without CCs" contains 2 pairs of LTC-DRGs in which both the LTC-DRG "with CCs" and the LTC-DRG "without CCs" had 25 or more LTCH cases and, therefore, did not fall into one of the 5 low-volume quintiles. For those nonmonotonic LTC-DRG pairs, as discussed in the May 18, 2004, proposed rule, we combine the LTCH cases and compute a new relative weight based on the case-weighted average of the combined LTCH cases of the LTC-DRGs. The case-weighted average charge is determined by dividing the total charges for all LTCH

cases by the total number of LTCH cases for the combined LTC-DRG. This new relative weight is then assigned to both of the LTC-DRGs in the pair. In this final rule, for FY 2005, LTC-DRGs 144 and 145 and LTC-DRGs 444 and 445 are in this category.

The second category of nonmonotonically increasing relative weights for LTC-DRG pairs with and without CCs consists of zero pairs of LTC-DRGs that has fewer than 25 cases, and each LTC-DRG is grouped to different low-volume quintiles in which the "without CC" LTC-DRG is in a higher-weighted low-volume quintile than the "with CC" LTC-DRG. For those pairs, as we discussed in the May 18, 2004, proposed rule (69 FR 28232), we combine the LTCH cases and determine the case-weighted average charge for all LTCH cases. The case-weighted average charge is determined by dividing the total charges for all LTCH cases by the total number of LTCH cases for the combined LTC-DRG. Based on the case-weighted average LTCH charge, we determine which low-volume quintile the "combined LTC-DRG" is grouped. Both LTC-DRGs in the pair are then grouped into the same low-volume quintile, and thus have the same relative weight. In this final rule, for FY 2005, there are no LTC-DRGs that fall into this category.

The third category of nonmonotonically increasing relative weights for LTC-DRG pairs with and without CCs consists of 10 pairs of LTC-DRGs where one of the LTC-DRGs has fewer than 25 LTCH cases and is grouped to a low-volume quintile and the other LTC-DRG has 25 or more LTCH cases and has its own LTC-DRG relative weight, and the LTC-DRG "without CCs" has the higher relative weight. As discussed in the May 18, 2004 proposed rule (69 FR 28232), we remove the low-volume LTC-DRG from the low-volume quintile and combine it with the other LTC-DRG for the computation of a new relative weight for

each of these LTC-DRGs. This new relative weight is assigned to both LTC-DRGs, so they each have the same relative weight. In this final rule, for FY 2005, the following LTC-DRGs are in this category: LTC-DRGs 85 and 86; LTC-DRGs 101 and 102; LTC-DRGs 141 and 142; LTC-DRGs 170 and 171; LTC-DRGs 172 and 173; LTC-DRGs 175 and 175; LTC-DRGs 300 and 301; LTC-DRGs 318 and 319; LTC-DRGs 442 and 443; and LTC-DRGs 521, 522 and 523 (We note, 3 LTC-DRGs make up this non-monotonic "pair" of DRGs because the "without CCs" DRG is further divided into two DRGs based on the presence or absence of rehabilitation therapy, so that there is one DRG in this non-monotonic "pair" with CCs and two DRGs in this non-monotonic "pair" without CCs).

Step 6—Determine an FY 2005 LTC-DRG relative weight for LTC-DRGs with no LTCH cases.

As we stated above, we determine the relative weight for each LTC-DRG using charges reported in the March 2004 update of the FY 2003 MedPAR file. Of the 520 LTC-DRGs for FY 2005, we identified 171 LTC-DRGs for which there were no LTCH cases in the database. That is, based on data from the FY 2003 MedPAR file used in this final rule, no patients who would have been classified to those LTC-DRGs were treated in LTCHs during FY 2003 and, therefore, no charge data were reported for those LTC-DRGs. Thus, in the process of determining the LTC-DRG relative weights, we are unable to determine weights for these 171 LTC-DRGs using the methodology described in steps 1 through 5 above. However, because patients with a number of the diagnoses under these LTC-DRGs may be treated at LTCHs beginning in FY 2005, we assign relative weights to each of the 171 "no volume" LTC-DRGs based on clinical similarity and relative costliness to one of the remaining 349 (520 - 171 = 349) LTC-DRGs for which

we are able to determine relative weights, based on FY 2003 claims data.

As there are currently no LTCH cases in these "no volume" LTC-DRGs, as we discussed in the May 18, 2004 proposed rule (69 FR 28233), we determine relative weights for the 171 LTC-DRGs with no LTCH cases in the FY 2003 MedPAR file used in this final rule by grouping them to the appropriate low-volume quintile. This methodology is consistent with our methodology used in determining relative weights to account for the low-volume LTC-DRGs described above.

Our methodology for determining relative weights for the "no volume" LTC-DRGs is as follows: We crosswalk the no volume LTC-DRGs by matching them to other similar LTC-DRGs for which there were LTCH cases in the FY 2003 MedPAR file based on clinical similarity and intensity of use of resources as determined by care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, post-operative care, and length of stay. We assign the relative weight for the applicable low-volume quintile to the no volume LTC-DRG if the LTC-DRG to which it is crosswalked is grouped to one of the low-volume quintiles. If the LTC-DRG to which the no volume LTC-DRG is crosswalked is not one of the LTC-DRGs to be grouped to one of the low-volume quintiles, we compare the relative weight of the LTC-DRG to which the no volume LTC-DRG is crosswalked to the relative weights of each of the five quintiles and we assign the no volume LTC-DRG the relative weight of the low-volume quintile with the closest weight. For this final rule, a list of the no volume FY 2005 LTC-DRGs and the FY 2005 LTC-DRG to which it is crosswalked in order to determine the appropriate low-volume quintile for the assignment of a relative weight for FY 2005 is shown below in Table 2.

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Table 2.--No Volume LTC-DRG Crosswalk and Quintile Assignment for FY 2005

LTC-DRG	Description	Cross-Walked LTC-DRG	Low-Volume Quintile Assigned
2	CRANIOTOMY AGE >17 W/O CC	1	Quintile 4
3	CRANIOTOMY AGE 0-17	1	Quintile 4
6	CARPAL TUNNEL RELEASE	251	Quintile 2
26	SEIZURE & HEADACHE AGE 0-17	25	Quintile 2
30	TRAUMATIC STUPOR & COMA, COMA <1 HR AGE 0-17	29	Quintile 3
32	CONCUSSION AGE >17 W/O CC	25	Quintile 2
33	CONCUSSION AGE 0-17	25	Quintile 2
36	RETINAL PROCEDURES	47	Quintile 1
37	ORBITAL PROCEDURES	47	Quintile 1
38	PRIMARY IRIS PROCEDURES	47	Quintile 1
39	LENS PROCEDURES WITH OR WITHOUT VITRECTOMY	47	Quintile 1
40	EXTRAOCULAR PROCEDURES EXCEPT ORBIT AGE >17	47	Quintile 1
41	EXTRAOCULAR PROCEDURES EXCEPT ORBIT AGE 0-17	47	Quintile 1
42	INTRAOCULAR PROCEDURES EXCEPT RETINA, IRIS & LENS	47	Quintile 1
48	OTHER DISORDERS OF THE EYE AGE 0-17	47	Quintile 1
49	MAJOR HEAD & NECK PROCEDURES	64	Quintile 4
50	SIALOADENECTOMY	63	Quintile 4
51	SALIVARY GLAND PROCEDURES EXCEPT SIALOADENECTOMY	63	Quintile 4
52	CLEFT LIP & PALATE REPAIR	63	Quintile 4
53	SINUS & MASTOID PROCEDURES AGE >17	63	Quintile 4
54	SINUS & MASTOID PROCEDURES AGE 0-17	63	Quintile 4
56	RHINOPLASTY	63	Quintile 4
57	T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17	69	Quintile 2
58	T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0-17	69	Quintile 2
59	TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17	69	Quintile 2
60	TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0-17	69	Quintile 2
61	MYRINGOTOMY W TUBE INSERTION AGE >17	69	Quintile 2
62	MYRINGOTOMY W TUBE INSERTION AGE 0-17	69	Quintile 2
66	EPISTAXIS	69	Quintile 2

LTC-DRG	Description	Cross-Walked LTC-DRG	Low-Volume Quintile Assigned
67	EPIGLOTTITIS	63	Quintile 4
70	OTITIS MEDIA & URI AGE 0-17	69	Quintile 2
71	LARYNGOTRACHEITIS	97	Quintile 1
72	NASAL TRAUMA & DEFORMITY	73	Quintile 3
74	OTHER EAR, NOSE, MOUTH & THROAT DIAGNOSES AGE 0-17	69	Quintile 2
81	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE 0-17	69	Quintile 2
91	SIMPLE PNEUMONIA & PLEURISY AGE 0-17	90	Quintile 3
98	BRONCHITIS & ASTHMA AGE 0-17	97	Quintile 1
104	CARDIAC VALVE & OTH MAJOR CARDIOTHORACIC PROC W CARD CATH	110	Quintile 1
105	CARDIAC VALVE & OTH MAJOR CARDIOTHORACIC PROC W/O CARD CATH	110	Quintile 1
106	CORONARY BYPASS W PTCA	110	Quintile 1
107	CORONARY BYPASS W CARDIAC CATH	110	Quintile 1
111	MAJOR CARDIOVASCULAR PROCEDURES W/O CC	110	Quintile 1
137	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE 0-17	136	Quintile 3
146	RECTAL RESECTION W CC	148	Quintile 5
147	RECTAL RESECTION W/O CC	148	Quintile 5
151	PERITONEAL ADHESIOLYSIS W/O CC	150	Quintile 5
153	MINOR SMALL & LARGE BOWEL PROCEDURES W/O CC	152	Quintile 5
155	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W/O CC	154	Quintile 5
156	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE 0-17	154	Quintile 5
158	ANAL & STOMAL PROCEDURES W/O CC	157	Quintile 4
160	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W/O CC	159	Quintile 3
162	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W/O CC	178	Quintile 1
163	HERNIA PROCEDURES AGE 0-17	178	Quintile 1
164	APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W CC	148	Quintile 5
165	APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W/O CC	148	Quintile 5
166	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W CC	148	Quintile 5
167	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W/O CC	148	Quintile 5
169	MOUTH PROCEDURES W/O CC	185	Quintile 3
184	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE 0-17	183	Quintile 2
186	DENTAL & ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AGE 0-17	185	Quintile 3
187	DENTAL EXTRACTIONS & RESTORATIONS	185	Quintile 3
190	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE 0-17	189	Quintile 3

LTC-DRG	Description	Cross-Walked LTC-DRG	Low-Volume Quintile Assigned
192	PANCREAS, LIVER & SHUNT PROCEDURES W/O CC	191	Quintile 5
194	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W/O CC	193	Quintile 1
195	CHOLECYSTECTOMY W C.D.E. W CC	197	Quintile 5
196	CHOLECYSTECTOMY W C.D.E. W/O CC	197	Quintile 5
198	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W/O CC	197	Quintile 5
199	HEPATOBIILIARY DIAGNOSTIC PROCEDURE FOR MALIGNANCY	200	Quintile 3
211	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W/O CC	210	Quintile 5
212	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE 0-17	210	Quintile 5
219	LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE >17 W/O CC	218	Quintile 4
220	LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE 0-17	218	Quintile 4
223	MAJOR SHOULDER/ELBOW PROC, OR OTHER UPPER EXTREMITY PROC W CC	233	Quintile 4
224	SHOULDER, ELBOW OR FOREARM PROC, EXC MAJOR JOINT PROC, W/O CC	227	Quintile 2
232	ARTHROSCOPY	234	Quintile 3
252	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE 0-17	234	Quintile 3
255	FX, SPRN, STRN & DISL OF UPARM, LOWLEG EX FOOT AGE 0-17	234	Quintile 3
257	TOTAL MASTECTOMY FOR MALIGNANCY W CC	275	Quintile 1
258	TOTAL MASTECTOMY FOR MALIGNANCY W/O CC	275	Quintile 1
259	SUBTOTAL MASTECTOMY FOR MALIGNANCY W CC	275	Quintile 1
279	CELLULITIS AGE 0-17	273	Quintile 1
282	TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE 0-17	281	Quintile 3
286	ADRENAL & PITUITARY PROCEDURES	292	Quintile 4
289	PARATHYROID PROCEDURES	63	Quintile 4
290	THYROID PROCEDURES	63	Quintile 4
291	THYROID GLOSSAL PROCEDURES	63	Quintile 4
293	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W/O CC	292	Quintile 4
298	NUTRITIONAL & MISC METABOLIC DISORDERS AGE 0-17	297	Quintile 2
309	MINOR BLADDER PROCEDURES W/O CC	308	Quintile 4
311	TRANSURETHRAL PROCEDURES W/O CC	310	Quintile 3
313	URETHRAL PROCEDURES, AGE >17 W/O CC	312	Quintile 4
314	URETHRAL PROCEDURES, AGE 0-17	305	Quintile 2
322	KIDNEY & URINARY TRACT INFECTIONS AGE 0-17	326	Quintile 1
327	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE 0-17	326	Quintile 1
329	URETHRAL STRICTURE AGE >17 W/O CC	305	Quintile 2

LTC-DRG	Description	Cross-Walked LTC-DRG	Low-Volume Quintile Assigned
330	URETHRAL STRICTURE AGE 0-17	305	Quintile 2
333	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE 0-17	332	Quintile 2
334	MAJOR MALE PELVIC PROCEDURES W CC	345	Quintile 5
335	MAJOR MALE PELVIC PROCEDURES W/O CC	345	Quintile 5
337	TRANSURETHRAL PROSTATECTOMY W/O CC	306	Quintile 4
340	TESTES PROCEDURES, NON-MALIGNANCY AGE 0-17	339	Quintile 1
342	CIRCUMCISION AGE >17	339	Quintile 1
343	CIRCUMCISION AGE 0-17	339	Quintile 1
351	STERILIZATION, MALE	339	Quintile 1
353	PELVIC EVISCERATION, RADICAL HYSTERECTOMY & RADICAL VULVECTOMY	365	Quintile 5
354	UTERINE,ADNEXA PROC FOR NON-OVARIAN/ADNEXAL MALIGN W CC	365	Quintile 5
355	UTERINE,ADNEXA PROC FOR NON-OVARIAN/ADNEXAL MALIGN W/O CC	365	Quintile 5
356	FEMALE REPRODUCTIVE SYSTEM RECONSTRUCTIVE PROCEDURES	303	Quintile 4
357	UTERINE & ADNEXA PROC FOR OVARIAN OR ADNEXAL MALIGNANCY	303	Quintile 4
358	UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W CC	303	Quintile 4
359	UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W/O CC	303	Quintile 4
360	VAGINA, CERVIX & VULVA PROCEDURES	303	Quintile 4
361	LAPAROSCOPY & INCISIONAL TUBAL INTERRUPTION	149	Quintile 1
362	ENDOSCOPIC TUBAL INTERRUPTION	149	Quintile 1
363	D&C, CONIZATION & RADIO-IMPLANT, FOR MALIGNANCY	367	Quintile 1
364	D&C, CONIZATION EXCEPT FOR MALIGNANCY	367	Quintile 1
370	CESAREAN SECTION W CC	369	Quintile 3
371	CESAREAN SECTION W/O CC	367	Quintile 1
372	VAGINAL DELIVERY W COMPLICATING DIAGNOSES	367	Quintile 1
373	VAGINAL DELIVERY W/O COMPLICATING DIAGNOSES	367	Quintile 1
374	VAGINAL DELIVERY W STERILIZATION &/OR D&C	367	Quintile 1
375	VAGINAL DELIVERY W O.R. PROC EXCEPT STERIL &/OR D&C	367	Quintile 1
376	POSTPARTUM & POST ABORTION DIAGNOSES W/O O.R. PROCEDURE	367	Quintile 1
377	POSTPARTUM & POST ABORTION DIAGNOSES W O.R. PROCEDURE	367	Quintile 1
378	ECTOPIC PREGNANCY	369	Quintile 3
379	THREATENED ABORTION	367	Quintile 1
380	ABORTION W/O D&C	367	Quintile 1
381	ABORTION W D&C, ASPIRATION CURETTAGE OR HYSTEROTOMY	367	Quintile 1

LTC-DRG	Description	Cross-Walked LTC-DRG	Low-Volume Quintile Assigned
382	FALSE LABOR	367	Quintile 1
383	OTHER ANTEPARTUM DIAGNOSES W MEDICAL COMPLICATIONS	367	Quintile 1
384	OTHER ANTEPARTUM DIAGNOSES W/O MEDICAL COMPLICATIONS	367	Quintile 1
385	NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY	367	Quintile 1
386	EXTREME IMMATURETY OR RESPIRATORY DISTRESS SYNDROME, NEONATE	367	Quintile 1
387	PREMATURITY W MAJOR PROBLEMS	367	Quintile 1
388	PREMATURITY W/O MAJOR PROBLEMS	367	Quintile 1
389	FULL TERM NEONATE W MAJOR PROBLEMS	367	Quintile 1
390	NEONATE W OTHER SIGNIFICANT PROBLEMS	367	Quintile 1
391	NORMAL NEWBORN	367	Quintile 1
392	SPLENECTOMY AGE >17	197	Quintile 5
393	SPLENECTOMY AGE 0-17	197	Quintile 5
396	RED BLOOD CELL DISORDERS AGE 0-17	399	Quintile 2
402	LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W/O CC	395	Quintile 3
405	ACUTE LEUKEMIA W/O MAJOR O.R. PROCEDURE AGE 0-17	404	Quintile 1
407	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R.PROC W/O CC	408	Quintile 4
411	HISTORY OF MALIGNANCY W/O ENDOSCOPY	367	Quintile 1
412	HISTORY OF MALIGNANCY W ENDOSCOPY	367	Quintile 1
417	SEPTICEMIA AGE 0-17	416	Quintile 3
422	VIRAL ILLNESS & FEVER OF UNKNOWN ORIGIN AGE 0-17	426	Quintile 2
432	OTHER MENTAL DISORDER DIAGNOSES	427	Quintile 1
446	TRAUMATIC INJURY AGE 0-17	445	Quintile 3
448	ALLERGIC REACTIONS AGE 0-17	447	Quintile 3
451	POISONING & TOXIC EFFECTS OF DRUGS AGE 0-17	455	Quintile 2
471	BILATERAL OR MULTIPLE MAJOR JOINT PROCS OF LOWER EXTREMITY	236	Quintile 3
481	BONE MARROW TRANSPLANT	394	Quintile 4
482	TRACHEOSTOMY FOR FACE, MOUTH & NECK DIAGNOSES	63	Quintile 4
484	CRANIOTOMY FOR MULTIPLE SIGNIFICANT TRAUMA	1	Quintile 4
491	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF UPPER EXTREMITY	209	Quintile 5
492	CHEMOTHERAPY W ACUTE LEUKEMIA OR W USE OF HI DOSE CHEMOAGENT	410	Quintile 4
494	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W/O CC	493	Quintile 4
498	SPINAL FUSION EXCEPT CERVICAL W/O CC	497	Quintile 3
504	EXTENSIVE BURNS OF FULL THICKNESS BURNS WITH MECH VENT 96+HRS WITH SKIN GRAFT	468	Quintile 5

LTC-DRG	Description	Cross-Walked LTC-DRG	Low-Volume Quintile Assigned
507	FULL THICKNESS BURN W SKIN GRFT OR INHAL INJ W/O CC OR SIG TRAUMA	508	Quintile 3
516	PERCUTANEOUS CARDIOVASC PROC W AMI	518	Quintile 2
520	CERVICAL SPINAL FUSION W/O CC	497	Quintile 3
525	OTHER HEART ASSIST SYSTEM IMPLANT	468	Quintile 5
526	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG ELUTING STENT W AMI	517	Quintile 3
527	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG ELUTING STENT W/O AMI	517	Quintile 3
528	INTRACRANIAL VASCULAR PROC W PDX HEMORRHAGE	1	Quintile 4
530	VENTRICULAR SHUNT PROCEDURES W/O CC	529	Quintile 4
534	EXTRACRANIAL PROCEDURES W/O CC	500	Quintile 1
540	LYMPHOMA & LEUKEMIA W MAJOR OR PROCEDURE W/O CC	399	Quintile 2

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To illustrate this methodology for determining the relative weights for the

171 LTC-DRGs with no LTCH cases, we are providing the following examples, which refer to the no volume LTC-DRGs

crosswalk information for FY 2005 provided above in Table 2:

Example 1: There were no cases in the FY 2003 MedPAR file used for this final rule for LTC-DRG 163 (Hernia Procedures Age 0-17). Since the procedure is similar in resource use and the length and complexity of the procedures and the length of stay are similar, we determined that LTC-DRG 178 (Uncomplicated Peptic Ulcer Without CC), which is assigned to low-volume quintile 1 for the purpose of determining the FY 2005 relative weights, would display similar clinical and resource use. Therefore, we assign the same relative weight of LTC-DRG 178 of 0.4586 (Quintile 1) for FY 2005 (Table 11 in the Addendum to this final rule) to LTC-DRG 163.

Example 2: There were no LTCH cases in the FY 2003 MedPAR file used in this final rule for LTC-DRG 91 (Simple Pneumonia and Pleurisy Age 0-17). Since the severity of illness in patients with bronchitis and asthma is similar in patients regardless of age, we determined that LTC-DRG 90 (Simple Pneumonia and Pleurisy Age >17 Without CC) would display similar clinical and resource use characteristics and have a similar length of stay to LTC-DRG 91. There were over 25 cases in LTC-DRG 90. Therefore, it would not be assigned to a low-volume quintile for the purpose of determining the LTC-DRG relative weights. However, under our established methodology, LTC-DRG 91, with no LTCH cases, would need to be grouped to a low-volume quintile. We identified that the low-volume quintile with the closest weight to LTC-DRG 90 (0.7494; see Table 11 in the Addendum to this final rule) would be low-volume quintile 2 (0.8508; see Table 11 in the Addendum to this final rule). Therefore, we assign LTC-DRG 91 a relative weight of 0.8508 for FY 2005.

Furthermore, we are providing LTC-DRG relative weights of 0.0000 for heart, kidney, liver, lung, pancreas, and simultaneous pancreas/kidney transplants (LTC-DRGs 103, 302, 480, 495, 512, and 513, respectively) for FY 2005 because Medicare will only cover these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified.

Based on our research, we found that most LTCHs only perform minor surgeries, such as minor small and large bowel procedures, to the extent any surgeries are performed at all. Given the extensive criteria that must be met to become certified as a transplant center for Medicare, we believe it is unlikely that any LTCHs would become certified as a transplant center. In fact, in the nearly 20 years since the implementation of the IPPS, there has never been a LTCH that even expressed an interest in becoming a transplant center.

However, if in the future a LTCH applies for certification as a Medicare-approved transplant center, we believe that the application and approval

procedure would allow sufficient time for us to determine appropriate weights for the LTC-DRGs affected. At the present time, we are only including these six transplant LTC-DRGs in the GROUPER program for administrative purposes. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these LTC-DRGs would be administratively burdensome.

Again, we note that as this system is dynamic, it is entirely possible that the number of LTC-DRGs with a zero volume of LTCH cases based on the system will vary in the future. We used the best most recent available claims data in the MedPAR file to identify zero volume LTC-DRGs and to determine the relative weights in this final rule.

Table 11 in the Addendum to this final rule lists the LTC-DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (to assist in the determination of short-stay outlier payments under § 412.529) for FY 2005.

Comment: A few commenters believe that the budget neutrality requirement found in section 123 of the Public Law 106-113 requires CMS to adjust the LTC-DRG relative weights to ensure that total payments to LTCHs are budget neutral for the proposed changes to the LTC-DRG classifications and relative weights. Alternatively, the commenters suggested that we make an adjustment to the LTCH PPS Federal rate to account for the estimated \$55 million reduction in LTCH PPS payments which resulted from the proposed changes in the LTC-DRG classifications and relative weights.

Response: In the May 18, 2004 proposed rule (69 FR 28806), we estimated a \$55 million aggregate decrease in LTCH PPS payments as a result of the proposed changes in the LTC-DRG relative weights and proposed version 22.0 GROUPER for FY 2005. We note that we incorrectly estimated the impact of the change in the proposed LTC-DRGs for FY 2005 in the proposed rule because we failed to account for the change in DRG classifications and the change in the geometric average length of stay for each LTC-DRG. As discussed in section VII.B. of Appendix A to this final rule, we are estimating that the impact of the change in LTC-DRGs for FY 2005 (including changes in the DRG classifications, relative weights and geometric average length of stay) will result in approximately a \$14.9 million decrease in LTCH PPS payments. In that same proposed rule, we explained that we found that based on an analysis of

the LTCH claims in the FY 2003 MedPAR files, the average LTC-DRG relative weight across all LTC-DRGs has increased due to an increase in the number of cases being assigned to higher weighted LTC-DRGs. As a result, including cases with relatively lower charges into LTC-DRGs that have a relatively higher relative weight in the GROUPER version 21.0 (FY 2004) decreases the average relative weight in the proposed GROUPER version 22.0 (FY 2005).

As we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 55960), which implemented the LTCH PPS, section 123 of Public Law 106-113 requires that the LTCH PPS, among other things, shall include an adequate patient classification system that is based on DRGs and that reflects the differences in patient resource use and costs, and shall maintain budget neutrality. With respect to budget neutrality, we interpreted section 123(a)(1) of Public Law 106-113 to require that total payments under the LTCH PPS during FY 2003 will be projected to equal estimated payments that would have been made for LTCHs' operating and capital-related inpatient hospital costs had the LTCH PPS not have been implemented. Consistent with this requirement, under § 412.523(d)(2) an adjustment is made in determining the standard Federal rate for FY 2003 so that aggregate payments under the LTCH PPS are estimated to equal the amount that would have been paid to LTCHs under the reasonable cost-based (TEFRA) payment system if the LTCH PPS were not implemented. Therefore, in that same final rule (67 FR 56027 through 56037), in order to maintain budget neutrality, we adjusted the LTCH PPS Federal rate for FY 2003 so that aggregate payments under the LTCH PPS are estimated to equal the amount that would have been paid to LTCHs under the reasonable cost-based (TERFA) payment system had the LTCH PPS had not been implemented.

In addition, when we implemented the LTCH PPS in the August 30, 2002 LTCH PPS final rule, we provided subpart O of the regulations at 42 CFR, including § 412.517, for an annual adjustment to the LTC-DRG classifications and weighting factors to reflect changes in treatment patterns, technology, number of discharges, and other factors affecting the relative use of hospital resources. We do not believe that section 123 of the Pub. L. 106-113 requires that the annual update to the LTC-DRG classifications and relative weights maintain budget neutrality. We believe we have satisfied the budget neutrality requirement of section 123 of

the Pub. L. 106–113 by establishing the LTCH PPS Federal rate for FY 2003 under § 412.523(d)(2) so that aggregate payment under the LTCH PPS are projected equal to estimated aggregate payments under the reasonable cost-based payment system if the LTCH PPS were not implemented. Therefore, we disagree with the commenters that an adjustment to the FY 2005 LTC–DRG relative weights or to the LTCH PPS Federal rate is required as a result of the annual update to the LTC–DRGs under § 412.517 for FY 2005. Accordingly, we have updated the LTC–DRG classifications and relative weights for FY 2005 (as shown in Table 11 of Addendum to this final rule) without an adjustment for budget neutrality. We note that this is our policy regardless of whether the annual update to the LTC–DRG classifications and relative weights results in higher or lower estimated aggregate payments. For instance we estimate that the annual update to the LTC–DRG classifications and relative weights from FY 2003 to FY 2004 resulted in an estimated increase in LTCH PPS payments, yet the update to the LTC–DRGs in the August 1, 2003 final rule for FY 2004 were not adjusted to maintain budget neutrality. In either case, at this time we do not make an adjustment to maintain budget neutrality for the effects of changes in the LTC–DRG classifications and relative weights. Accordingly, in developing the FY 2005 LTC–DRGs and relative weights shown in Table 11 of this final rule, we have not applied an adjustment for budget neutrality nor are we adjusting the 2005 LTCH PPS rate year Federal rate established in the May 7, 2004, LTCH PPS final rule (69 FR 25674) to account for the estimated change in LTCH PPS payments which result from the annual update to the LTC–DRG classifications and relative weights for FY 2005.

The commenter raises the issue that it may be appropriate for certain aspects of the LTCH PPS to maintain budget neutrality when they are updated annually as they are in other PPSs, such as the annual update to the DRGs and wage index. Under section 123 of Public Law 106–113 and section 307 of Public Law 106–554, the Secretary generally has broad authority in developing the LTCH PPS, including whether and how to make adjustments to LTCH PPS payments. Specifically, section 307(b)(1) of Public Law 106–554 provides that “the Secretary shall examine and may provide for appropriate adjustments to the long-term hospital payment system, including adjustments to DRG weights, area wage adjustments, geographic

classification, outliers, updates, and a disproportionate share adjustment [* * *].” We will consider whether it is appropriate for use to propose a future revision to the LTCH PPS regulations at subpart O of 42 CFR to maintain budget neutrality in the annual update of some aspects of the LTCH PPS under our broad discretionary authority under the statute to provide “appropriate adjustments to the long-term hospital payment system.” Any changes to the LTCH PPS regulations would be made in accordance with Administrative Procedures Act guidelines.

5. Out of Scope Comments Relating to the LTCH PPS Payment Rates

Comment: A few commenters submitted comments that addressed aspects of the existing LTCH PPS, including the standard Federal rate and outlier methodology, which are not relevant to the LTCH policy proposals set forth in the May 18, 2004 IPPS proposed rule.

Response: Because those comments pertain to specific aspects of the existing LTCH PPS rather than to any specific proposed changes to the LTCH PPS presented in the May 18, 2004 IPPS proposed rule, we are unable to respond to those comments at this time. Rather, we believe it is more appropriate to address those issues in the annual LTCH PPS proposed and final rules, and we will consider the issues raised in those comments in the context of future rulemaking for the LTCH PPS.

E. Add-On Payments for New Services and Technologies

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that the process must apply to a new medical service or technology if, “based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.”

The regulations implementing this provision establish three criteria for special treatment. First, § 412.87(b)(2) defines when a specific medical service or technology will be considered new for purposes of new medical service or

technology add-on payments. The statutory provision contemplated the special payment treatment for new medical services or technologies until such time as data are available to reflect the cost of the technology in the DRG weights through recalibration. There is a lag of 2 to 3 years from the point a new medical service or technology is first introduced on the market and when data reflecting the use of the medical service or technology are used to calculate the DRG weights. For example, data from discharges occurring during FY 2003 are used to calculate the FY 2005 DRG weights in this final rule. Section 412.87(b)(2) provides that a “medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new medical service or technology (depending on when a new code is assigned and data on the new medical service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ‘new’ under the criterion for this section.”

In the May 18, 2004, proposed rule (69 FR 28237), we stated that the 2-year to 3-year period of newness for a technology or medical service would ordinarily begin with FDA approval, unless there was some documented delay in bringing the product onto the market after that approval (for instance, component production or drug production had been postponed until FDA approval due to shelf life concerns or manufacturing issues). After the DRGs have been recalibrated to reflect the costs of an otherwise new medical service or technology, the special add-on payment for new medical services or technology ceases (§ 412.87(b)(2)). For example, an approved new technology that received FDA approval in October 2003 and entered the market at that time may be eligible to receive add-on payments as a new technology until FY 2006 (discharges occurring before October 1, 2005), when data reflecting the costs of the technology would be used to recalibrate the DRG weights. Because the FY 2006 DRG weights will be calculated using FY 2004 MedPAR data, the costs of such a new technology would likely be reflected in the FY 2006 DRG weights.

Section 412.87(b)(3) further provides that, to receive special payment treatment, new medical services or technologies must be inadequately paid otherwise under the DRG system. To

assess whether technologies would be inadequately paid under the DRGs, we establish thresholds to evaluate applicants for new technology add-on payments. In the August 1, 2003, final rule (68 FR 45385), we established the threshold at the geometric mean standardized charge for all cases in the DRG plus 75 percent of 1 standard deviation above the geometric mean standardized charge (based on the logarithmic values of the charges and transformed back to charges) for all cases in the DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant DRGs, if the new medical service or technology occurs in many different DRGs). Table 10 in the Addendum to the August 1, 2003, final rule (68 FR 45648) listed the qualifying threshold by DRG, based on the discharge data that we used to calculate the FY 2004 DRG weights.

However, section 503(b)(1) of Public Law 108-173 amended section 1886(d)(5)(K)(ii)(I) of the Act to provide for "applying a threshold * * * that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved." The provisions of section 503(b)(1) apply to classification for fiscal years beginning with FY 2005. We updated Table 10 from the October 6, 2003, **Federal Register** correction document, which contains the thresholds that we used to evaluate applications for new service or technology add-on payments for FY 2005, using the section 503(b)(1) measures stated above, and posted these new thresholds on our Web site at: <http://www.cms.hhs.gov/providers/hipps/newtech.asp>. In the May 18, 2004, proposed rule, we included preliminary thresholds for evaluating applicants for new technology add-on payments for FY 2006. Table 10 of this final rule contains the final thresholds that will be used to evaluate applicants for new technology add-on payments for FY 2006. (Refer to section IV.D. of this preamble for a discussion of a revision of the regulations to incorporate the change made by section 503(b)(1) of Public Law 108-173.)

Section 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, a new technology represents a substantial

clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits or reduces recovery time compared to the technologies previously available. (See the September 7, 2001 final rule (66 FR 46902) for a complete discussion of this criterion.)

The new medical service or technology add-on payment policy provides additional payments for cases with high costs involving eligible new medical services or technologies while preserving some of the incentives under the average-based payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. Under § 412.88, Medicare pays a marginal cost factor of 50 percent for the costs of a new medical service or technology in excess of the full DRG payment. If the actual costs of a new medical service or technology case exceed the DRG payment by more than the 50-percent marginal cost factor of the new medical service or technology, Medicare payment is limited to the DRG payment plus 50 percent of the estimated costs of the new technology.

The report language accompanying section 533 of Public Law 106-554 indicated Congressional intent that the Secretary implement the new mechanism on a budget neutral basis (H.R. Conf. Rep. No. 106-1033, 106th Cong., 2nd Sess. at 897 (2000)). Section 1886(d)(4)(C)(iii) of the Act requires that the adjustments to annual DRG classifications and relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. Therefore, in the past, we accounted for projected payments under the new medical service and technology provision during the upcoming fiscal year at the same time we estimated the payment effect of changes to the DRG classifications and recalibration. The impact of additional payments under this provision was then included in the budget neutrality factor, which was applied to the standardized amounts and the hospital-specific amounts.

Section 503(d)(2) of Public Law 108-173 amended section 1886(d)(5)(K)(ii)(III) of the Act to provide that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, add-on payments for new medical services or technologies for FY 2005 and later years will not be budget neutral. We discuss the regulation change necessary to implement this provision in section IV.H. of this final rule.

Applicants for add-on payments for new medical services or technologies for FY 2006 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate the medical service or technology meets the high-cost threshold, no later than early October 2004. Applicants must submit a complete database no later than mid-December 2004. Complete application information, along with final deadlines for submitting a full application, will be available at our Web site after publication of this FY 2005 final rule at: <http://www.cms.hhs.gov/providers/hipps/default.asp>. To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2006, the Web site will also list the tracking forms completed by each applicant.

2. Other Provisions of Section 503 of Public Law 108-173

Section 503(b)(2) of Public Law 108-173 amended section 1886(d)(5)(K) of the Act by adding a new clause (viii) to provide for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial improvement or advancement. The revised process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries.
- Make public and periodically update a list of the services and technologies for which an application for add-on payments is pending.
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial improvement.
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new service or technology represents a substantial

clinical improvement to the clinical staff of CMS.

In order to satisfy the requirements of this last provision, we published a notice in the **Federal Register** on February 27, 2004, and held a town meeting at the CMS Headquarters Office in Baltimore, MD, on March 15, 2004. In the announcement notice for the meeting, we stated that the opinions and alternatives provided during the meeting would assist us in our evaluations of applications by allowing public discussions of the substantial clinical improvement criteria for each of the FY 2005 new medical service and technology add-on payment applications before the publication of the FY 2005 IPPS proposed rule.

Approximately 70 participants registered and attended in person, while additional participants listened over an open telephone line. The participants focused on presenting data on the substantial clinical improvement aspect of their products, as well as the need for additional payments to ensure access to Medicare beneficiaries. In addition, we also received many written comments regarding the substantial clinical improvement criterion for the applicants. As indicated in the May 18, 2004, proposed rule, we considered these comments in our evaluation of each new application for FY 2005 in the proposed rule. In the proposed rule, we summarized these comments or, if applicable, indicated that no comments were received, at the end of the discussion of the individual applications.

Section 503(c) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a new clause (ix) requiring that before establishing any add-on payment for a new medical service or technology, that the Secretary shall seek to identify one or more DRGs associated with the new technology, based on similar clinical or anatomical characteristics and the costs of the technology and assign the new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology. No add-on payment shall be made with respect to such a new technology.

At the time an application is submitted, the DRGs associated with the new technology are identified. We only determine that a new technology add-on payment is appropriate when the reimbursement under these DRGs is not adequate for this new technology. The criterion for this determination is the cost threshold, which we discuss below. We discuss the assignments of several new technologies within the DRG

payment system in section II.B. of this final rule. The comment regarding the DRG assignment of the treatment for AIP is addressed in section II.B.16.i. of this final rule.

Comment: We received several letters from commenters stating that we should address the inequities in the DRG system with respect to several drugs and technologies that appeared to go unnoticed by us, according to the commenters. Specifically, payments for the treatment of acute intermittent porphyria (AIP) were brought to our attention. We received additional comments from physicians and a company concerning new procedure code 00.16 (Pressurized treatment of venous bypass graft (conduit) with pharmaceutical substance). The commenters requested that we evaluate potential reimbursement scenarios for these new procedures.

Response: We discuss the method for applying for consideration for the new technology add-on payment in section II.E.1. of this preamble. The Medicare program pays for thousands of medical services, drugs and technologies and may not necessarily be aware of all new technologies that come to the market. We have implemented the new technology add-on payment provision by providing a process by which applicants can present these technologies to us for add-on payment consideration. Commenters should also consider the application process for obtaining new ICD–9–CM codes to further aid in obtaining specifically identifying procedure codes in an effort to seek new technology add-on payments. We discuss the DRG assignment of procedure code 00.16 in section II.B.16.c. of this final rule. The comment regarding the DRG assignment of the treatment for AIP is addressed in section II.B.16.i. of this final rule.

Comment: Some commenters objected to the application of the newness criterion in the proposed rule. These commenters asserted that CMS's description of the criterion requiring a technology to be new was inconsistent with the statute and the September 7, 2001 final rule. Specifically, the commenters maintained that defining the period of new as during the 2-year to 3-year period after FDA market approval would "represent a significant shift, retroactively changing the conditions under which companies have been developing innovative technologies and filing new technology applications." These commenters further stated that this makes the regulatory process unpredictable, "potentially having an adverse effect on patient access to breakthrough medical

technologies." The commenters urged us to "reaffirm" our September 7, 2001, policy and reevaluate the applications that CMS proposed to deny on the newness issue.

Response: The intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. Generally, we use the FDA approval as the indicator of the time when a technology begins to become available on the market and data reflecting the costs of the technology begin to become available for recalibration of the DRGs. In some specific circumstances, we have recognized a date later than the FDA approval as the appropriate starting point for the 2-year to 3-year period. For example, we have recognized a later date where an applicant could prove a delay in actual availability of a product after FDA approval. The costs of the new medical service or technology, once paid for by Medicare for this 2-year to 3-year period, are accounted for in the MedPAR data that are used to recalibrate the DRG weights on an annual basis. Therefore, it is appropriate to limit the add-on payment window for those technologies that have passed this 2-to 3-year timeframe.

We disagree that our statement of the policy in the proposed rule is inconsistent with policy that was implemented in previous rules. In the first year that new technology applications were considered in the IPPS (that is, during calendar year 2002), we discussed several applications and determined whether they could be considered new on the basis of when FDA approval was granted to the technologies. Again in our August 1, 2003 final rule for FY 2004, we denied applicants on the basis that the technologies had gained FDA approval prior to FY 2001; and thus, were not eligible for new technology add-on payments. In these instances, we employed the actual date of FDA market approval, not the date a separate ICD–9–CM code became available, since data reflecting the costs associated with those technologies had already been included in the DRG weights prior to the adoption of a separate ICD–9–CM code.

Using the ICD–9–CM code alone is not an appropriate test of newness because technologies that are new to the market are automatically placed into the closest ICD–9–CM category when they first come on the market, unless the

manufacturer requests the assignment of a new ICD-9-CM code because existing codes do not adequately reflect or describe the medical service or device. The services and technologies that have been placed into existing ICD-9-CM codes have been paid for using those descriptors. Therefore, while it may be impossible to actually identify when a particular product was used because there is no unique code to identify it amongst other products in the category, the product is nonetheless used and paid for. In addition, hospital charges reflect the services provided to patients receiving the new service or device whether or not a specific code is assigned. Therefore, data containing payments for these new technologies are already in our MedPAR database and when DRG recalibration occurs these costs are accounted for. Furthermore, assignment of new codes can occur for many reasons other than the introduction of new procedures and technologies. For example, new codes can simply reflect more refined and discriminating descriptions of existing procedures and technologies.

If we were strictly to use the ICD-9-CM coding system for the purposes of identifying what technologies are new, there would be an incentive for nearly every product, service and surgical technique to apply for a new, unique ICD-9-CM code. The ICD-9-CM system could not absorb all these potential new codes. It would also be inappropriate to pay more, in the form of new technology add-on payments, for most of the codes, as the technology may have been in use prior to the assignment of the new code for several years, or several decades in some cases. For example, there is currently no procedural distinction between a patient receiving a kidney transplant from a living or cadaver donor. It is conceivable that this kidney transplant could be broken out into several procedures, identifying the source of the kidney (from living/deceased, relative/stranger, etc.), and each would be a "new" procedure if we were to adopt the commenters' approach. These procedures have been in use for up to half a century; and therefore, clearly should not qualify as a new medical service or technology simply because a new ICD-9-CM code has been assigned. Another example that further exemplifies the limitations of this ICD-9-CM-based approach is the esophageal permanent tube, which is a stent implanted in a patient who cannot be medically treated and is unable to swallow. If we create a new code, and use it to determine if the esophageal permanent tube should qualify for new

technology payment under the commenters' approach, the technology could qualify as new, although the procedure has been used for the last 20 years.

We also note that our existing interpretation does not hamper the ability of patients to receive technologies that do not qualify for new technology add-on payments. The IPPS will continue to pay for existing and new medical services and technologies through the regular payment mechanism established by the DRG payment methodology. Therefore, patient access to these technologies is not adversely affected by this interpretation, and this interpretation is not inconsistent with the framework used to review new technology applications in previous years.

Comment: One commenter stated, "we believe that the 2-to 3-year clock should not start until a technology receives final approval by the Food and Drug Administration." The commenter also submitted an additional comment that stated that the "date of ICD-9 code assignment should start the add-on payment eligibility time clock, not the date of FDA approval."

Response: We note that the commenter's comments were somewhat contradictory on the issue of newness. The timeframe that a new technology can be eligible to receive new technology add-on payments begins when data become available. Section 412.87(b)(2) clearly states that "a medical service or technology may be considered new within the 2 to 3 year after the point at which data begins to become available reflecting the ICD-9-CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration)." Section 412.87(b)(2) also states "***[a]fter CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion of this section." Therefore, regardless of whether a technology can be individually identified by a separate ICD-9-CM code, if the costs of the technology are included in the charge data, and the DRGs have been recalibrated using that data, then the device can no longer be considered new for the purposes of this provision.

Comment: A commenter suggested that CMS adopt a different strategy for defining the newness criterion. The commenter believes that the decision of whether a technology is new should

involve consideration of both the FDA approval date and the date of issuance of an ICD-9-CM code. The commenter explained that if an ICD-9-CM code is issued within 12 months of FDA approval, the 2-to 3-year period of a technology being considered new should begin from the date of issuance of the ICD-9-CM code. If a code is issued more than 12 months after FDA approval, the 2-to 3-year period should begin from the FDA approval date. The commenter noted that adoption of this interpretation would strike a balance between the FDA approval date and the procedure code effective date and is consistent with the preamble of the September 7, 2001 **Federal Register** (66 FR 46914) and the text of the regulation (42 CFR 412.87(b)(2)).

Response: We note that the time period does not necessarily start with the approval date for the medical service or technology and does not necessarily start with the issuance of a distinct code. Instead, it begins with availability of the product on the market, which is when data become available. We have consistently applied this standard, and believe that it is most consistent with the purpose of new technology add-on payments.

Comment: MedPAC recommended that we use a different approach to DRG recalibration. In these instances, MedPAC recommends that we exclude those cases involving a new technology from our DRG recalibration method. Doing so "would avoid overpaying for the technology by including its costs in the base payment while also providing an add-on payment" during the overlapping 2-to 3-year period in question. MedPAC further stipulates that this approach "should be used for all cases where the new technology can be tracked" with an ICD-9-CM code or where cases can be identified by other characteristics in our MedPAR data. They also stressed the importance of maintaining a conservative approach when CMS evaluates technologies for add-on payments. In addition, they noted that paying indiscriminately for too many technologies "can be seen as unbundling of the DRG system" which would threaten the "incentives for hospitals to be efficient and weigh the benefits of new technologies against their costs." Moreover, they noted that section 503(b)(1) of Public Law 108-173 changed the cost criteria by lowering the threshold to qualify for add-on payments. As such, MedPAC believes that the number of technologies that could potentially be eligible to qualify will likely increase expenditures to the program since these payments are no longer budget neutral.

Response: We appreciate MedPAC's recommendations and will consider its suggestion regarding excluding the costs of cases involving new technologies from DRG recalibration calculations in the future. We also believe that we have consistently applied an appropriately high standard of clinical improvement to restrict these types of payments to relatively few technologies that are truly new. We will continue to apply this high standard in our review of applications for new technology add-on payments in the future.

Comment: A commenter noted that if "CMS believes that it erred in developing the payment period policy published in the September 7, 2001 final rule, then it should propose a policy change applying to all applications for new technology add-on payments." The commenter also stated, that "the implementation of such a policy change should affect only the applications received thereafter, and should not apply to any applications currently under consideration."

Response: We believe that the commenter, the manufacturer of InFUSE™ Bone Graft, wanted to ensure that if we made a change in the policy, that change would be done through notice and comment rulemaking and that the change would not be applied retroactively to applicants that are currently under consideration. However, we note that we have not made any changes to the policies implemented in the September 7, 2001 final rule.

Comment: Several commenters urged us to be as clear as possible in implementing section 503 of Public Law 108-173. The commenters stated that transparency is necessary, particularly for "small companies doing a disproportionate amount of the medical device research and development." Many commenters urged us to clearly state and adopt an approach to the provision so there is "a clear path to follow and a reliable set of requirements to meet." Several commenters also noted that, despite how we have been applying the definition of new, many of the companies that have applied or could apply for new technology add-on payments do not neatly fall into a standard definition because different manufacturers follow different pathways. These commenters stated, "many device manufacturers, especially small device entrepreneurs, lack the nationwide marketing, distribution, and reputation of the larger companies in the industry. These small companies are most affected by the so-called 'payment lag' during which new products are under-reimbursed.***" In addition,

commenters stated, despite or because of these problems of distribution, the rates of adoption and utilization of new products should be accounted for before we decide technologies are no longer new. In addition, commenters call for CMS to "clarify what the bar is for a device to represent a substantial [clinical] improvement." Commenters stated that determinations of what represents a substantial clinical improvement have been largely subjective, but that, "for future generations of add-on applicants, an elaborated definition would be helpful."

Response: As stated previously, we have used as our uniform standard, the date of FDA approval in combination with market availability to evaluate new technology applications. We also note that in our evaluation of previous new technology applications, we have stated whether or not the applicants have met the substantial clinical improvement criterion as part of the basis for our approval or disapproval of the application. We follow the guidelines, as listed in the September 7, 2001 final rule, to make these determinations as they apply to improving the quality of care for the elderly Medicare population. However, as discussed in response to several of the other comments, we may need to consider revising our policies in the future to make the process more streamlined as more technologies apply for the new technology add-on payments. We will also consider the commenter's views concerning the payment lag for new products as we continue to develop policy in this area. However, at this time we believe that the 2-to 3-years timeframe remains an appropriate standard for determining when the costs of new technologies have been incorporated into the DRG weights.

Comment: Several commenters urged CMS to adopt a uniform standard for reviewing new technology add-on payment applications that is consistent between both the IPPS and the OPFS. Additionally, one commenter believes that CMS is inconsistent in its use of external data for verifying or amending payment rates. The commenter recommended that CMS should acknowledge that different types of data are appropriate for different uses such as revisions to APCs in the outpatient setting and adjustment of DRG relative weights in the inpatient setting. The commenter added that data requirements for determining eligibility for a new technology add-on payment should not be the same as for adjusting DRG relative weights. The commenter also recommended that external data provided for DRG assignments or

payments for new technologies may be appropriately proprietary in these cases and the commenter believes CMS should release such data in a summary format agreed to by the companies and should not make the data available for public inspection without the companies' consent. The commenter also suggested that CMS should not require identification of a hospital by its Medicare provider number in cases where there may be a confidentiality agreement between the manufacturer or data vendor and the hospital submitting the data. The commenter recommended that CMS use pseudo-identifiers as an alternative to actual provider numbers. The commenter also proposed that CMS allow the use of external data from recent timeframes without corresponding MedPAR data, particularly for procedures involving new technologies and codes. The commenter explained that external data from private vendors has only a 60-90 day time lag compared to MedPAR, which has a lengthier time lag. The commenter further recommended that when determining the price of a drug or device CMS should accept the disclosure of discounts and rebates at the estimated aggregate level since the company may not know the final price paid by the hospital for a given product. Finally, the commenter recommended that CMS should request that medical technology companies offer the HCPCS codes and ICD-9-CM codes that seem most clinically appropriate to the procedure since this information would be most helpful to CMS and allow companies to target their resources in providing external data. Another commenter expressed that companies will not make the best data available "unless CMS agrees to hold it confidential."

Another commenter encouraged CMS to expand its acceptance of external data in order to ease the process of establishing adequate initial inpatient payment for new technology procedures at or as close as possible to the time of FDA approval. The commenter also urged CMS to accept external data as part of the recalibration of the DRG weights. The commenter also recommended that CMS apply reasonable standards that take into account the limited amount of data that may be available for new technologies and the difficulties involved in collecting such data in determining whether external data provides an acceptable basis for making a new DRG assignment or adjustment of the DRG weights.

One commenter, a company that gathers data on hospital services, noted

that its data could be used to project national trends and establish Medicare policies. The commenter also noted that there are instances where its data are more detailed than MedPAR. The commenter believes CMS should work with the industry to develop criteria for making use of external data. The commenter was also concerned about the difficulty of obtaining MedPAR data. The commenter explained that CMS no longer makes available quarterly updates to the MedPAR and that the MedPAR data used to develop the FY 2005 proposed rule were not made available in a timely manner.

Response: We note that we have followed many of these examples when reviewing previous technologies. In the case of Xigris®, we worked very closely with the applicant to review the applicant's data in order to identify a cohort of cases that would be appropriate candidates to receive the new drug. For FY 2005, we have also worked very closely with the applicants to help them identify what data requirements needed to be met and to help them to determine the best strategies to meet these requirements. We note, however, that applicants should weigh the advantages of submitting additional data in support of an application for new technology add-on payments with the need to preserve the confidentiality of certain proprietary data. We thank the commenters for their other comments and recommendations regarding accepting non-MedPAR data. We intend to take these comments into consideration and review the feasibility of adopting one or more of these approaches at some time in the future. Because we did not make any proposals regarding the use of external data in the May 18, 2004 proposed rule, we are not making any changes at this time. However, we will consider the comments in developing future proposals.

We also note that we offer two annual updates of the MedPAR data used for determining the rates in FY 2005. One update is based on the data used for the proposed rule. This update is usually issued in May. The second update is based on the data used in the final rule and is usually issued in September. Information on purchasing the MedPAR data used in determining the rates for FY 2005 can be found on our Web site at <http://www.cms.hhs.gov/data/order/default.asp>. Finally, we note, that in the interests of providing the most accurate and complete data files and due to time and work constraints, we are no longer able to issue quarterly updates of the MedPAR to the public.

Comment: Commenters in general contended that they “cannot meet the public's demands to adopt new technologies * * * because their ability to access capital is deteriorating”. Commenters stated that since very few new technologies have qualified for this add-on payment, hospitals continue to underutilize and potentially limit use of clinically important new technologies in the absence of these higher payments. Commenters again urged CMS to increase the payment for new technology add-on payments from 50 percent of the cost of the device to 80 percent of the costs. They stated that to do so would be in line with the Conference Committee Agreement accompanying Public Law 108–173 which states, “the Secretary should consider increasing the percent of payment associated with the add-on payments up to the marginal rate used for the inpatient outlier.” (108 Cong., 2d Sess., 212(2003)). Commenters further stated that CMS “apparently believes that this outlier payment level strikes the appropriate balance between ensuring that providers are not unduly at financial risk for expensive cases * * *”, yet has offered no explanation for why this payment level would not be appropriate for the new technology add-on payment as well.

Response: We note that we have made substantial changes to the application threshold in the last year, reducing the cost threshold to qualify for new technology add-on payments twice. In addition, we have eliminated the budget neutrality provision, thus increasing the total moneys spent to pay for deserving, new technologies. While the conference report to the MMA recommended that the Secretary should consider changing the payment factor, we will not make such a change this year. Rather, we will analyze the impacts of the other MMA changes, especially the reduction in the cost threshold and the elimination of the budget neutrality of the add-on payments, before we consider making changes in the payment percentage. We will continue to consider the conference report's recommendation and will determine whether to proceed with a change in the light of our continuing analysis.

Comment: Commenters urged CMS to adopt an approach to the public meetings required by the MMA in a manner that is similar to the ICD–9 Coordination and Maintenance Committee meetings. Commenters noted that a specific agenda and preliminary opinions are released to the public prior to these meetings and urged CMS to present preliminary opinions on

substantial clinical improvement prior to the public meeting on this topic.

Response: We have traditionally not provided our opinion on substantial clinical improvement of applicants for new technology add-on payments until the final rule. We note that if all the criteria are met prior to the publication of the proposed rule, we would prefer to make our preliminary determinations available at that time. However, to date we have not been able to make a sound determination regarding substantial clinical improvement until after the publication of the proposed rule.

Section 503(b)(2) of Public Law 108–173 requires CMS to consider public comments regarding whether an applicant for new technology payments meets the substantial clinical improvement criterion. Comments must be received and considered prior to the publication of the proposed rule for the annual IPPS update. This requirement, which was implemented for the first time through the new technology town hall meeting held in March of this year, and the subsequent comment period is further evidence that we do take the issue of substantial clinical improvement into account prior to the publication of the proposed rule. However, the MMA provision does not require the type of procedure recommended by the commenter, but merely the opportunity for presentation of comments, recommendations, and data to CMS.

We designed the town hall-styled meeting this spring to provide a forum for public comment on the applicants. This format appeared to be received well by most of the attendees. We accepted comments and topics from attendees and presenters at the meeting, as well as accepting comments on substantial clinical improvement of the applicants after the meeting. If presenters would like a more detailed agenda to be published prior to the rule, we welcome them to register to attend the annual meeting and provide the information requested in the **Federal Register** notice announcing the meeting (this includes personal information for registration purposes as well as topics to be presented at the meeting). If we have this information well in advance of the meeting, the agenda will reflect all issues that have been raised regarding the assessment of the substantial clinical improvement criterion for each applicant. We welcome further input on how to better incorporate input prior to the announcement of the next town hall meeting on this topic.

In the May 18, 2004 proposed rule (69 FR 28236), we also evaluated whether new technology add-on payments will

continue in FY 2005 for the two technologies that currently receive such payments. In accordance with section 503(e)(2) of Public Law 108-173, we also reconsidered one application for new technology add-on payments that was denied last year. Finally, we presented our evaluations of 10 new applications for add-on payments in FY 2005.

3. FY 2005 Status of Technology Approved for FY 2004 Add-On Payments

a. Drotrecogin Alfa (Activated)—Xigris®

Xigris®, a biotechnology product that is a recombinant version of naturally occurring Activated Protein C (APC), was approved by the FDA on November 21, 2001. In the August 1, 2002, IPPS final rule (67 FR 50013), we determined that cases involving the administration of Xigris®, (as identified by the presence of code 00.11 (Infusion of drotrecogin alfa (activated))) were eligible for additional payments in FY 2003. (The August 1, 2002, final rule contains a detailed discussion of this technology.)

In the August 1, 2003, final IPPS rule (68 FR 45387), we indicated that, for FY 2004, we would continue to make add-on payments for cases involving the administration of Xigris® as identified by the presence of code 00.11. This was because we determined that Xigris® was still within the 2-year to 3-year period before the costs of this new technology would be reflected in the DRG weights.

Xigris® became available on the market at the time of its FDA licensure on November 21, 2001. Early in FY 2005, Xigris® will be beyond the 2-year to 3-year period during which a technology can be considered new. Therefore, in the May 18, 2004 proposed rule, we proposed that Xigris® would not continue to receive new technology add-on payments in FY 2005. During the period of 2 years and 8 months since it came onto the market, Xigris® has been used frequently in the appropriate DRGs. For FY 2005, we analyzed the number of cases involving this technology in the FY 2003 MedPAR file. We found 4,243 cases that received Xigris®, the majority of which fell appropriately into DRGs 415, 416, 475, and 483, with by far the most cases in DRG 416 (Septicemia Age >17). Accordingly, the costs of Xigris® are now well represented in those DRGs. Therefore, we proposed that FY 2004 would be the final year for Xigris® to receive add-on payments.

Prior to the publication of the May 18, 2004, proposed rule, we received no public comments regarding the

continuation of add-on payments for Xigris®. During the 60-day comment period for the proposed rule, we received 3 comments on this application.

Comment: The manufacturer submitted comments that were highly critical of CMS' proposal to discontinue add-on payments for Xigris®. The commenter brought up several points, which it believes, show that CMS is in violation of the statutory provisions. First, the manufacturer expressed opposition to the proposal to terminate the new technology add-on payments. It agreed that it was important to consider when a product comes on the market, but stated, "[w]hether a technology is 'new' is not salient in determining whether a third year of add-on payments should continue." It stated that the costs of the drug had not been adequately accounted for as required by statute and that the period during which it was eligible to receive add-on payments should continue another year, until 3 full years of add-on payments had been made. It stated, that "the fact that costs of a new technology or service may be included in the Medicare hospital discharge database (MedPAR) starting at the time an item or service is introduced into the marketplace is irrelevant. What matters is the ability to examine 2 years of cost data for cases coded as having used the new technology or service." Further, it argued, "these cost data cannot be identified and collected until the ICD code is assigned and used in the coding of cases." It also stated that, since this 3-year maximum period had not yet ended, the costs of the cases could not have adequately been accounted for in our DRG recalibration using only data from FY 2003. It further stated that we should wait to remove them from add-on payment status until data from the FY 2004 MedPAR are available to recalibrate the DRGs. The manufacturer also stated that "the point of the legislative changes was to improve the old way of doing business * * *. It is unfortunate that CMS proposes to take the path of least resistance because it is the Medicare beneficiaries who will ultimately suffer."

Another commenter stated that our proposal to deny additional add-on payments in FY 2005 will deny Medicare beneficiaries the access to Xigris®. An additional commenter noted that, particularly because CMS was unable to implement the systems changes necessary to pay the new technology add-on payment for Xigris® until 8 months after the new code and higher payment were allowed, many hospitals were unclear as to the

significance of correctly coding the new ICD-9-CM code identifying Xigris®, and therefore, the data for the first year of add-on payments do not adequately reflect the actual use of the drug.

Response: As stated previously, when we determine the newness criterion for new technology add-on applications, we use the date of FDA approval to determine that data including the technology are being incorporated into DRG recalibration, except in those rare cases where evidence can be presented that demonstrates that the product could not be marketed immediately after FDA approval. We have used this method of determining newness since we began reviewing new technology applications. While there was no clearly distinguishable code assigned to Xigris® prior to the implementation of the new ICD-9-CM code 00.11 on October 1, 2002, treatment with Xigris® was identified prior to that time by procedure code 99.19. While this may not suit the applicant in terms of the ability to track specific cases that involved the use of Xigris®, the drug was being used for more than 10 months prior to the assignment of code 00.11 and the costs associated with the drug were, therefore, clearly included in the FY 2003 MedPAR update. Additionally, we note that the manufacturer itself was able to identify patients that would or could use Xigris(r), as discussed in the May 9, 2002 proposed rule. There we stated, "Lilly also submitted detailed ICD-9-CM diagnosis and procedure codes for a subset of * * * patients with billing data. * * *" (67 FR 31428). Because the manufacturer was able to identify a subset of patients without billing data at that time, we have met the criteria set forth by the manufacturer itself in being able to identify "2 years of cost data for cases coded as having used the new technology. * * *" The data we have captured since including the data used for the FY 2003 proposed rule analysis, have adequately accounted for costs associated with these cases. Including the 2 subsequent years during which Xigris® was eligible to receive new technology add-on payments, this makes a total of 3 years of data that CMS has used to incorporate the costs associated with the drug into the weights of the DRGs into which these cases fall.

In the FY 2004 annual update, we estimated that there would be 3,000 cases involving Xigris® in the relevant DRGs and we note that there are now 4,313 cases involving the drug in the March update of the FY 2003 MedPAR. We have conducted an analysis of the FY 2002 MedPAR to determine the frequency of these cases in the DRGs in

which Xigris® has been used. We have identified 593 cases using procedure code 99.19 in these 5 DRGs, which is significantly lower than the most recent 2 years of data. Additionally, we recognize that this code included other drugs and that not all 593 cases reporting this code in these 5 DRGs necessarily involved Xigris®. However, this low number of cases is consistent with what we would expect, given that the initial ICD-9-CM code did not drive DRG placement or payments. It is also consistent with the reasoning behind our approval of Xigris® for new technology add-on payments, since it was clearly a new technology that provided great potential benefit to Medicare beneficiaries and met the other criteria as defined by the statute. It is also reasonable to expect that, once the new ICD-9-CM code went into effect, with a payment incentive to encourage its rapid adoption and use, the number of cases including this code rose dramatically. While the figure of 593 cases using procedure code 99.19 in the relevant cases in FY 2002 is not very high, we note that in the August 1, 2002 final rule we stated that, based on the sales figures from the company at that time, there was already “\$35 million in sales reported by Lilly through February 2002 (since the drug was approved in November 2001). (At \$6,800 per patient, \$35 million in sales equates to just over 5,000 cases for the first 4 months since FDA approval.)” (67 FR 50015). Therefore, we are confident that we have adequate data reflecting the use of Xigris® over the past 3 years. If we were to continue add-on payments beyond FY 2004, the technology would be beyond its 2-3 year maximum as allowed by the statute. We have used these data to recalibrate the DRGs into which these cases most frequently fall, so the costs of the technology have already been accounted for in those DRG weights. Similarly, although we regret that systems changes delayed the processing of add-on payments for Xigris® in FY 2003, hospitals received add-on payments for all cases reporting the ICD-9-CM code for Xigris®. Furthermore, the costs of the new technology are nonetheless represented in the 2003 MedPAR data, whether hospitals used the new ICD-9-CM code for Xigris® (00.11) or the earlier procedure code (99.19). We do not agree with the assertion that Medicare beneficiaries will no longer have access to this important drug once the new technology add-on payments associated with it are terminated. To the contrary, we will continue to pay for the drug through DRG payment, and as noted

above, the costs associated with the drug have been included in the weights of the relevant DRGs through the DRG recalibration.

Comment: The manufacturer also noted that section 1886(d)(5)(K)(ii)(IV) of the Act requires, “that discharges involving such a service or technology that occur after the close of the period [of add-on payments] will be classified within a new or existing diagnosis-related group with a weighting factor * * * that is derived from the cost data collected with respect to discharges occurring during such period.” The commenter argues that there is no room for interpretation of the statute and that, since the average costs of cases involving the technology are very high, they should be assigned either to a new DRG or remapped to higher-weighted DRGs to reflect the cost of the cases. Another commenter asked that, if CMS refused to continue add-on payments for the entirety of FY 2005, such payments should be “maintained at least until the agency has analyzed the available data and has classified cases in which Xigris® is administered into an appropriate DRG.”

Response: We do not agree with the implications the commenter draws from the statutory language. We have assigned cases involving the use of Xigris® to clinically coherent DRGs, and the weights of these DRGs have been recalibrated to reflect the costs of these technology. We have also analyzed the costs of these cases and determined that, although the average standardized charge for these cases is higher than the average charges for the DRGs into which the cases involving Xigris® fall, there appears to be no justification to warrant creation of a new DRG or re-assignment of cases involving Xigris® into higher-weighted DRGs. We do not believe that it is necessary to assign cases involving Xigris® to a separate unique DRG, as requested by the manufacturer, in order to satisfy the statutory requirement. Indeed, we note that the commenter’s own comment stated, “Xigris® is administered to only a small proportion of the severe sepsis population and is not representative of the comprehensive incidence of the disease.” Therefore, by the manufacturer’s own statements, we cannot use cases involving the code for Xigris® as the standard by which to assign severe sepsis cases. We discuss the DRG assignment of Xigris® in section II B.16.c. of this final rule.

Comment: One national hospital association agreed with our proposal to discontinue add-on payments for this technology. The commenter noted that the termination of the add-on payments falls outside the timeframe in which a

technology is new for add-on payment purposes. The association strongly encouraged CMS to continue monitoring the use of Xigris® and associated conditions of severe sepsis to determine if future revisions to the current DRGs will be necessary. Another commenter urged us to continue to monitor the use and diffusion of all new technologies that qualify or have previously qualified for this provision. Commenters urged CMS to require that all hospitals continue to code for the use of the new technologies, even after the period of add-on payment for the technologies has ended, thus ensuring adequate tracking of diffusion of the new technologies as they continue to be used.

Response: We appreciate the commenter’s support for our decision to remove this technology from add-on payment status. We note that we review new technology add-on payment recipients annually to determine whether they continue to meet the criteria to receive add-on payments. In the case of Xigris®, this review led us to find that it no longer meets the newness criterion. While we encourage hospitals to continue to code for the drug, even though there is no longer a payment incentive to do so, we cannot require hospitals to code for the use of the drug.

We are finalizing our proposal to remove Xigris® from new technology status and will no longer pay new technology add-on payments for this technology, starting October 1, 2004. The manufacturer also asked us to consider creating a DRG specifically for severe sepsis. We discuss this request in section II.B.16.c. of the preamble to this final rule.

b. InFUSE™ (Bone Morphogenetic Proteins (BMPs) for Spinal Fusions)

InFUSE™ was approved by FDA for use on July 2, 2002, and became available on the market immediately thereafter. In the August 1, 2003 IPPS final rule (68 FR 45388), we approved InFUSE™ for add-on payments under § 412.88, effective for FY 2004. This approval was on the basis of using InFUSE™ for single-level, lumbar spinal fusion, consistent with the FDA’s approval and the data presented to us by the applicant. Therefore, we limited the add-on payment to cases using this technology for anterior lumbar fusions in DRGs 497 (Spinal Fusion Except Cervical With CC) and 498 (Spinal Fusion Except Cervical Without CC). Cases involving InFUSE™ that are eligible for the new technology add-on payment are identified by assignment to DRGs 497 and 498 as a lumbar spinal fusion, with the combination of ICD-9-

CM procedure codes 84.51 (Insertion of interbody spinal fusion device) and 84.52 (Insertion of recombinant bone morphogenetic protein).

Because InFUSE™ was approved by the FDA for use on July 2, 2003, it is still within the 2-year to 3-year period during which a technology can be considered new under the regulations. Therefore, in the May 18, 2004 proposed rule, we proposed to continue add-on payments for FY 2005 for cases receiving InFUSE™ for spinal fusions in DRGs 497 (Spinal Fusion Except Cervical With CC) and 498 (Spinal Fusion Except Cervical Without CC). We also proposed to continue limiting the add-on payment for cases receiving InFUSE™, to those cases identified by the presence of procedure codes 84.51 and 84.52. However, we proposed to eliminate add-on payment for the interbody fusion device that is used in combination with this recombinant human bone morphogenetic protein (rhBMP) product (procedure code 84.52). We note that currently add-on payments for InFUSE™ include costs for the interbody fusion device (the LT Cage, identified by procedure code 84.51), used in the spinal fusion procedure with the InFUSE™ product. Because this device is not a new technology, but in fact has been in use for 9 years for spinal fusions, we believe that it is inappropriate to pay for this device in conjunction with the genuinely new rhBMP technology. Therefore, we proposed no longer to pay for the interbody fusion device as bundled in the current maximum add-on payment amount of \$4,450 for cases that qualify for additional payment. The proposal would reduce the add-on payment to account for no longer including the costs of the LT Cage in computing the add-on payment amount. This would reduce the cost of this new technology by \$4,990, which results in a total cost of \$3,910 for InFUSE™. Therefore, we proposed a maximum add-on amount of \$1,955 for cases that qualify for additional payment. Although we proposed to eliminate payment for the LT Cage, we would still require the presence of procedure code 84.51 (in combination with procedure code 84.52) when making new technology add-on payments for InFUSE™. This is due to the fact that the LT Cage is still required by the FDA when InFUSE™ is used for single level spinal fusions.

Prior to the publication of the May 18, 2004 proposed rule, we received public comments in accordance with section 503(b)(2) of Public Law 108-173 regarding the continuation of add-on payments for this technology.

Commenters expressed support for the continuation of new technology add-on payments for this technology in FY 2005.

We are finalizing that proposal in this final rule.

We received the following comments in response to the May 18, 2004 proposed rule.

Comment: Several commenters supported our proposal to no longer pay for the LT Cage as a bundled add-on payment with InFUSE™. They noted that it was not appropriate to pay for the LT Cage as part of the InFUSE™ add-on since the technology has been available for several years.

Response: When we initially reviewed the application, the applicant indicated to us that the FDA approval was for a pre-packaged product that included the LT Cage, the InFUSE™ biotechnology product, and an absorbable collagen sponge to carry the rhBMP. While the FDA label required the product to be used with the LT Cage, we were initially under the impression that these devices were provided to hospitals in the same package. It later was brought to our attention that the product was not marketed this way and that in fact the rhBMP product is supplied to hospitals in several different sized "kits" that have differing amounts of InFUSE™ in them, and that the LT Cage is purchased separately. As such, it is not only easy to see why the add-on payment should be unbundled, but also easy to do so.

Comment: Some commenters, including the manufacturer, were opposed to our proposal to discontinue bundled payment for InFUSE™ in combination with the LT Cage. They argue that to remove the payment for the LT Cage would result in even further restricting the use of this much needed technology that eliminates a painful second surgery and extensive blood loss for the patients who must otherwise undergo spinal fusions via conventional, autogeneous bone-harvesting methods. Other commenters were very concerned that the lower add-on payment amount would result in hospitals using cages other than the FDA-approved LT Cage with this technology. These commenters stated that to encourage this off-label use by not continuing the higher payments is contrary to our statement in last year's final rule requiring that a product qualify for add-on payments based upon usage consistent with its FDA labeling.

Response: In this clear case where a new technology is being used in conjunction with an old technology, we do not believe it is appropriate to continue to pay an add-on payment for the old device, as this device has

already been in use for 9 years and has been accounted for in DRG payments. We are finalizing our proposal to approve InFUSE™ for spinal fusion for an additional year of new technology add-on payments, through the end of FY 2005. We note that in order to receive new technology add-on payment for InFUSE™, we are continuing to require both the procedure code for InFUSE™ (84.52) and the code for the LT Cage (84.51) due to the FDA label that requires the LT Cage to be used in conjunction with the InFUSE™ product. While the procedure code for the LT Cage (84.51) does include other brands and types of cages for spinal fusion, we expect that doctors will maintain the best clinical standard for their patients and will continue to use the LT Cage with the InFUSE™ product. We are therefore finalizing our proposal to unbundle the new technology add-on payments for this device for FY 2005 by removing payment for the LT Cage from the add-on payment for cases involving InFUSE™. We are also finalizing the maximum add-on payment amount of \$1955 for cases that are eligible to receive the add-on payment.

Comment: Other commenters were pleased about our proposal to discontinue bundled payments that include the LT Cage for spinal fusions because this bundled payment precluded payment for similar technologies that are used in spinal fusion surgery but that do not require use of the LT Cage. One commenter noted that another BMP product was just awarded FDA approval for spinal fusion involving posterolateral approach. This commenter requested that the other devices of this nature be included in any approval of rhBMPs for new technology add-on payments or an unfair economic advantage would be created.

Response: As we discussed in the September 7, 2001, final rule (66 FR 46915), an approval of a new technology for special payment should extend to all technologies that are substantially similar. Otherwise, our payment policy would bestow an advantage to the first applicant to receive approval for a particular new technology. The new product, called OP-1 Putty, manufactured by Stryker Biotech, utilizes a similar mechanism to promote natural bone growth by using a closely related bone morphogenetic protein called rhBMP-7 (InFUSE™ is rhBMP-2). Because the OP-1 Putty is now available on the market (it received FDA approval for spinal fusions in May of this year) for similar spinal fusion procedures and also eliminates the need

for the autograft bone surgery, we are extending new technology add-on payments to this technology as well, for FY 2005. Because the new product does not require the LT Cage to be used simultaneously, we are requiring that providers use different codes when the different products are used.

Cases using InFUSE™ should be identified by the combination of procedure codes 84.51 and 84.52, as described above and as required in the previous year of new technology add-on payments for this technology. For cases using the OP-1 Putty, the procedure code 84.52 (Insertion of recombinant bone morphogenetic protein) must be coded in combination with procedure codes identifying posterolateral spinal fusions, as is consistent with the FDA approval for this device. Therefore, procedure code 84.52 must be coded with any of the following procedure codes: 81.08 (Lumbar/lumbosac fusion posterior technique), 81.38 (refusion of lumbar posterior approach), 81.05 (Dorsal and dorsolumbar fusion, posterior technique), or 81.35 (Refusion of dorsal and dorsolumbar spine, posterior technique) in order to receive add-on payments under this provision. Both of these devices have FDA approval that is consistent with cases that would be assigned to DRGs 497 or 498. Because Stryker Biotech did not submit a new technology add-on payment application, we were unable to do a complete analysis of the cost of the device. However, we have been able to determine that the costs associated with the OP-1 Implant are similar to those associated with InFUSE™. Therefore, we believe that the same payment amount for new technology add-on payments is appropriate for both devices. Accordingly, cases containing one of the above combinations of procedure codes and that fall into DRGs 497 or 498 will be eligible to receive the add-on payment, with a maximum of \$1,955 for FY 2005.

4. Reevaluation of FY 2004 Applications That Were Not Approved

Section 503(e)(2) of Public Law 108-173 requires us to reconsider all applications for new medical service or technology add-on payments that were denied for FY 2004. We received two applications for new technologies to be designated eligible for add-on payments for new technology for FY 2004. We approved InFUSE™ for use in spinal fusions for new technology add-on payments in FY 2004. We denied the application for new technology add-on payments for the GLIADEL® wafer.

GLIADEL® Wafer

Glioblastoma Multiforme (GBM) is a very aggressive primary brain tumor. Standard care for patients diagnosed with GBM includes surgical resection followed by radiation and, in some cases, systemic chemotherapy. According to the manufacturer, the GLIADEL® wafer is indicated for use at the time of surgery in order to prolong survival in patients with GBM. Implanted directly into the cavity that is created when a brain tumor is surgically removed, the GLIADEL® wafer delivers chemotherapy directly to the site where the tumor is most likely to recur.

The FDA gave initial approval for the GLIADEL® wafer on September 23, 1996, for use as an adjunct to surgery to prolong survival in patients with recurrent GBM for whom surgical resection is indicated. In 2003, Guilford Pharmaceuticals submitted an application for approval of the GLIADEL® wafer for add-on payments and stated that the technology should still be considered new for FY 2004, despite its approval by the FDA on September 23, 1996. The manufacturer stated that the technology was still new because it had not been possible to specifically identify cases involving use of the GLIADEL® wafer in the MedPAR data prior to the adoption of a new ICD-9-CM code 00.10 (Implantation of a chemotherapeutic agent) on October 1, 2002. However, as discussed in the September 7, 2001 final rule (66 FR 46914), the determination concerning whether a technology meets this criterion depends on the date of its availability for use in the Medicare population rather than the date a specific code may be assigned. A technology can be considered new for 2 or 3 years after data reflecting the costs of the technology begin to become available. Data on the costs of this technology began to become available in September 1996. As a result, the costs of this technology are currently reflected in the DRG weights. As discussed in the final rule for FY 2004 (68 FR 45391), on February 26, 2003, the FDA approved the GLIADEL® wafer for use in newly diagnosed patients with high-grade malignant glioma as an adjunct to surgery and radiation. However, our understanding is that many newly diagnosed patients were already receiving this therapy. To the extent that this is true, the charges associated with this use of the GLIADEL® wafer were also reflected in the DRG relative weights. Therefore, the GLIADEL® wafer did not meet this criterion for FY 2004.

Section 503(e)(2) of Public Law 108-173 required us to reconsider this

application, but did not revise the criterion for determining whether a medical service or technology is new. As stated above, the FDA originally approved the GLIADEL® wafer on September 23, 1996. Therefore, this technology is beyond the period in which it can be considered new. Accordingly, in the May 18, 2004, proposed rule, we proposed to deny this application for new technology add-on payments for FY 2005.

Prior to the publication of the May 18, 2004, proposed rule, we received no public comments regarding our reconsideration of this application for add-on payments. During the 60-day comment period for the May 18, 2004, proposed rule, we received the following public comments regarding our reconsideration of the application.

Comment: One commenter stated, “[a]s a country that prides itself on being a leader in cancer research, it is disheartening that patients must battle to gain access to the benefits that this research has provided.”

Response: We continue to pay for technologies that do not meet the criteria to receive new technology add-on payments through the regular payment mechanism established by the DRG payment methodology. Therefore, patient access to these technologies should not be adversely affected by a determination that a technology does not qualify to receive add-on payments.

Comment: One commenter believes that the GLIADEL® chemotherapy wafer merits a separate DRG, which the applicant contends would be similar to our treatment of the establishment of new DRGs for drug-eluting stents. The commenter acknowledges that DRGs are “not normally created to recognize the presence or absence of new technology.” Nevertheless, the commenter argues that CMS’ recognition of the “unique circumstances surrounding the potential breakthrough nature” of drug-eluting stents should also be applied to GLIADEL® wafer.

Response: Guilford asked us to consider reclassifying this device into another DRG. We discuss issues relating to the DRG assignment of the GLIADEL® wafer in section II.B.16.c. of this final rule. In that discussion, we announce our decision to create a new DRG 543 (Craniotomy with implantation of chemotherapeutic agent or acute complex central nervous system principle diagnosis) to which Gliadel cases will be assigned. The cases assigned to this new DRG have similar resource utilization and comparable charges to cases involving the GLIADEL® wafer. As a result, we

believe this DRG assignment will result in appropriate payments for these cases. In this rule we are finalizing our denial of new technology add-on payments for this technology.

5. FY 2005 Applicants for New Technology Add-On Payments

a. InFUSE™ Bone Graft (Bone Morphogenetic Proteins (BMPs) for Tibia Fractures)

Bone Morphogenetic Proteins (BMPs) have been shown to have the capacity to induce new bone formation and, therefore, to enhance healing. Using recombinant techniques, some BMPs (referred to as rhBMPs) can be produced in large quantities. This has cleared the way for their potential use in a variety of clinical applications such as in delayed unions and nonunions of fractured bones and spinal fusions. One such product, rhBMP-2, is developed for use instead of a bone graft with spinal fusions.

Medtronic Sofamor Danek submitted an application for the InFUSE™ Bone Graft for use in tibia fractures for approval as a new technology eligible for add-on payments in FY 2005. Medtronic submitted a similar application for new technology add-on payments in FY 2004 for InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. As discussed above, we approved this application for FY 2004, and will continue to make new technology payments for FY 2005 for InFUSE™ when used in spinal fusions (refer to section III.E.3.b. of this preamble).

In cases of open tibia fractures, InFUSE™ is applied using an absorbable collagen sponge, which is then applied to the fractured bone in order to promote new bone formation. The manufacturer contends that this use is severely limited due to the greatly increased costs for treating these cases with InFUSE™ at the time of wound debridement and closure. The manufacturer has conducted a clinical trial and FDA approval for the use of InFUSE™ for open tibia fractures was awarded on April 30, 2004. The application for add-on payments for the use of InFUSE™ for open tibia fractures proposes that such payment would encourage the use of InFUSE™ for treatment of these fractures of grade II or higher (up to and including grade III, which often must be amputated due to the severity of injury). The additional payment, according to the applicant, would encourage more hospitals to use the technology at the time of initial wound closure and would result in reduced rates of infection and nonunion

currently associated with the treatment of these injuries.

The manufacturer submitted data on 315 cases using InFUSE™ for open tibia fractures in the FY 2002 MedPAR file, as identified by procedure code 79.36 (Reduction, fracture, open, internal fixation, tibia and fibula) and diagnosis codes of either 823.30 (Fracture of tibia alone, shaft, open) or 823.32 (Fracture of fibula and tibia, shaft, open). The applicant also noted that the patients in their clinical trials as well as patients that would be likely candidates to receive InFUSE™ for tibia fractures would include those cases that had malunion of their fractures (diagnosis code 733.81) or nonunion of fractures (diagnosis code 733.82). The applicant also submitted data for a hospital sample that included 63 cases using the same identifying codes. Based on the data submitted by the applicant, InFUSE™ would be used in four different DRGs: 217 (Wound Debridement and Skin Graft Except Hand, for Musculoskeletal and Connective Tissue Disorders), 218 and 219 (Lower Extremity and Humerus Procedures Except Hip, Foot, Femur Age > 17, With and Without CCs, respectively) and 486 (Other O.R. Procedures for Multiple Significant Trauma). The analysis performed by the applicant resulted in a case-weighted cost threshold of \$27,111 for these four DRGs. The average case-weighted standardized charge for cases using InFUSE™ in these four DRGs would be \$46,468. Therefore, the applicant maintains that InFUSE™ for open tibia fractures meets the cost criterion.

Further discussions with the applicant revealed that the more appropriate DRGs to which this device should be limited are DRGs 218 and 219 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur Age > 17, With and Without CC). The manufacturer projects that there would be approximately 550 cases (based on the number of open tibia fractures that would have qualified for InFUSE™ in the FY 2002 MedPAR) in FY 2005. Since FDA approval for use of InFUSE™ for open tibia fractures, we have performed an analysis to determine the number of cases that may have already received InFUSE™ for treatment of open tibia fractures. We identified 3,788 cases in DRGs 218 and 219 (Lower Extremity & Humerus Procedures except hip, foot, femur, age >17, with and without CCs) that also had procedure code 79.36 (Reduction, fracture, open, internal fixation, tibia and fibula) and any of the following diagnosis codes: 823.30 (Fracture of tibia alone, shaft, open), 823.32

(Fracture of fibula with tibia, shaft, open), 733.81 (Malunion of fracture), or 733.82 (Nonunion of fracture). We identified 38 cases in DRGs 218 and 219 that contained a code identifying a BMP product (identified by the presence of procedure code 84.52) in the FY 2003 MedPAR.

In the May 18, 2004, proposed rule, we noted that as part of its application, the applicant submitted evidence on the substantial clinical improvement criterion. The applicant cited data from a prospective, controlled study published on December 12, 2002 in *The Journal of Bone and Joint Surgery* (Govender, S., Crismona, C., Genant, H.K., Valentin-Opran, V., "Recombinant Human Bone Morphogenetic Protein-2 for Treatment of Open Tibia Fractures," Vol. 84-A, No. 12, p. 2123). The study, also known as BESTT study group, involved 49 trauma centers in 11 countries. The study enrolled 450 patients who had sustained an open tibia shaft fracture that normally would be treated by intramedullary nail fixation and soft tissue management. The patients were randomly and blindly assigned to one of three groups: The standard of care as stated above, the standard of care plus implantation of an absorbable collagen sponge soaked with .75 mg/ml of rhBmP-2, or the standard of care plus implantation of an absorbable collagen sponge soaked with 1.50 mg/ml of rhBMP-2. The study followed up with 421 (94 percent) of all patients. The applicant stated that the study found that patients who received the standard of care plus an absorbable collagen sponge soaked with 1.50 mg/ml of rhBMP-2 achieved the following results compared to the standard of care without the rhBMP: a 44-percent reduction in the rate of secondary surgery, an average of 39 days reduction in time of clinical healing and lower infection rates. As a result, the applicant maintains that InFUSE™ in tibia fractures represents a substantial clinical improvement over previously available technologies.

In the May 18, 2004, proposed rule, we did not present a full analysis of this application under the substantial clinical improvement criterion because the technology had not yet received FDA approval for this use in time for consideration in the proposed rule. However, we noted that, although the cited study provides some evidence of clinical efficacy, we had some concerns about whether the study conclusively demonstrates substantial clinical improvement over previously available technologies because of its design. (It is important to note, as we stated in the August 1, 2002, **Federal Register** (67 FR

50015), that we do not employ FDA guidelines to determine what drugs, devices, or technologies qualify for new technology add-on payments under Medicare. Our criteria do not depend on the standard of safety and efficacy that the FDA sets for general use, but on a demonstration of substantial clinical improvement in the Medicare population, particularly patients over age 65.) We indicated that we would present our full analysis of the evidence regarding clinical improvement in the final rule.

Since the publication of the proposed rule, the manufacturer has provided additional information regarding substantial clinical improvement. The applicant provided research indicating both the efficacy of the rhBMP product in the elderly, Medicare population as well as satisfactorily answering any remaining questions our physicians had regarding the clinical trials for this use of InFUSE™.

In the proposed rule, we indicated that we determined that this technology still qualifies as new in the context of extending new technology add-on payments for InFUSE™ for single-level spinal fusions (refer to InFUSE™ for spinal fusion in section 3(b) above). We noted that, in the September 7, 2001 final rule (66 FR 46915), we stated that if an existing technology was assigned to different DRGs than those in which the technology was initially used, the new use may be considered for new technology add-on payments if it also meets the substantial clinical improvement and inadequacy of payment criteria. Under the policy suggested in that rule, approval of InFUSE™ for tibia fractures would start a new period of add-on payments for the new use of this technology. However, we stated that we had some reservations about whether this result would be appropriate. We stated that it might be possible, under the policy described in the September 7, 2001 final rule, for a technology to receive new technology add-on payments for many years after it is introduced, provided that use of the technology is continually expanded to treatment of new conditions (in this case, every time the product is used to treat a new bone injury). We invited comment on whether it would be more appropriate merely to extend the existing approval of InFUSE™ for spinal fusions to cases where InFUSE™ is used for open tibia fractures, without extending the time period during which the technology will qualify for add-on payments. We also invited comments on whether use of InFUSE™ for open tibia fractures should qualify for add-on

payments under the cost and substantial clinical improvement criteria.

Comment: One commenter wrote “to bring to Medicare’s immediate attention that there is more than one BMP manufacturer with approved indications for long bone fractures * * *”. The commenter went on to note that “Stryker[Biotech]’s * * * OP–1 Implant for recalcitrant long bone non-unions received FDA clearance in October, 2001.” The commenter urged Medicare that “the decision for add-on payment should be for the BMP, not the manufacturer.”

Response: We agree with the commenter that determinations concerning new technology add-on payments should not make distinctions between different manufacturers of the same technology. As we stated in the proposed rule on May 18, 2004: “an approval of a new technology for special payment should extend to all technologies that are substantially similar. Otherwise, our payment policy would bestow an advantage to the first applicant to receive approval for a particular new technology.” (69 FR 28242). In this case, we had received no information concerning the existence of the OP–1 Implant for long bone fusion, created by Stryker Biotech, prior to this comment. Since the OP–1 Implant received FDA clearance in October, 2001, it has been necessary to reevaluate whether InFUSE™ for open tibia fractures can still be considered new in the light of this new information. This determination turns on two considerations: whether these products are substantially similar, and whether the indications for the two products lead to the assignment of cases involving the use of the two products to the same DRGs. The crucial consideration in determining whether a technology is new from a payment policy perspective is whether data reflecting the costs of the technology have been incorporated into setting the DRG weights. A technology can be considered new for 2 to 3 years after the point at which charge data begin to become available.

We have been able to determine that the OP–1 Implant created by Stryker Biotech in fact was approved by the FDA under Humanitarian Device Exemption (HDE) on October 17, 2001, for the indication of “use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed.” It came onto the market shortly after approval. The trials where the OP–1 Implant was used demonstrated the safety and efficacy of OP–1 Implant for patients with

complicated fractures of the tibia.³ These cases and the study protocol are similar to those described in the clinical trials involving InFUSE™ for open tibia fractures. In fact, many of the cases that were brought for review during the application process for InFUSE™ were patients that had already experienced non-union, were not candidates for autograft (due to already having autograft surgery and there not being enough material left in the hip to acquire more, or poor quality of the bone, etc.), or had fractures in long bones other than the tibia (many cases were femur fractures). Therefore, we believe the technology involving use of rhBMP to treat severe long bone fractures, including open tibial fractures, and recalcitrant long bone fractures has been in use for more than 3 years. In addition, cases involving use of the OP–1 Implant for long bone nonunions and open tibia fractures are assigned to the same DRGs (218 and 219, Lower extremity procedures with and without complication or comorbidity, respectively). Therefore, data reflecting the costs associated with this technology began to become available in the relevant DRGs in 2001, and are now reflected in the DRG weights. We therefore find that the use of rhBMPs for these indications is not a new technology for the purposes of the new technology add-on payment. In addition, if we were to approve InFUSE™ for open tibia fractures for the new technology add-on payment there would be no way to distinguish the claims getting InFUSE™ BMP and those cases receiving the OP–1 Implant BMP, because they are indistinguishable by patient characteristics or ICD–9 code.

Accordingly, we are denying the application for add-on payments for InFUSE™ for open tibia fractures because this device is not a substantial clinical improvement over existing technologies, and therefore is not a new technology for purposes of new technology add-on payments. We acknowledge, however, that products may evolve that are very closely related but that have very different clinical efficacies, and we are committed to continuing to refine and share our methodology for deciding what should or should not be considered a new and innovative technology. In this context, we would note that MedPAC has encouraged us “to be conservative in [evaluating] * * * technologies for add-

³ Friedlaender, GE, et al. “Osteogenic Protein–1 (Bone Morphogenetic Protein–7) in the Treatment of Tibial Nonunions: A Prospective, Randomize Clinical Trial Comparing rhOP–1 with Fresh Bone Autograft.” *Journal of Bone & Joint Surgery*. 2001;83A(S1): 151–158.

on payments, ensuring that technologies are substantially different from predecessor technologies, costly, and with clinical benefit.”

Comment: Several commenters stated their concerns regarding a number of issues raised in our discussion in the proposed rule. They do not think that it would be appropriate to deny add-on payments for InFUSE™ for tibia fractures regardless of the existing status of the device for use in other surgeries. They stated that CMS should not indiscriminately impose our policy criteria without considering the clinical opinions of experts involved in these cases and as a result deny patients access to the latest breakthrough medical technologies. Several other commenters wrote to encourage CMS to make add-on payments for the InFUSE™ bone graft for treatment of “compound fractures of the tibia.” The manufacturer commented that it would go against CMS precedent not to consider the new indication for InFUSE™ as qualifying for its own determination of substantial clinical improvement since we had made a similar analysis in FY 2004 for GLIADEL® wafer. One commenter also supported the review and approval of new technology add-on payments where the new technology is being used for a different medical procedure than the original use and will group to separate DRGs.

Response: As stated previously, we do not believe that patient access to breakthrough technologies is being denied. Because another device using rhBMPs for these indications has been in use for 3 years and the costs for this technology have been included in the weights for the DRGs where cases involving InFUSE™ for open tibia fractures have been assigned, this technology is not a substantial clinical improvement over existing technologies and can no longer be considered “new.” We further note that because we determined that the GLIADEL® wafer did not meet the newness criterion, we did not conduct an analysis on the substantial clinical improvement criterion in FY 2004.

b. Norian Skeletal Repair System (SRS)® Bone Void Filler

Brigham and Women’s Hospital submitted an application for approval of the Norian Skeletal Repair System (SRS)® Bone Void Filler (Norian SRS® Cement), manufactured by Synthes for new technology add-on payments for FY 2005. Synthes has been assisting the applicant with supplemental information and data to help the applicant with the application process.

According to the manufacturer, Norian SRS® Cement is an injectable, fast-setting carbonated apatite cement used to fill defects in areas of compromised cancellous bone during restoration or augmentation of the skeleton. The product provides a bone-void filler that resorbs and is replaced with bone during the healing process.

On December 23, 1998, the FDA approved Norian SRS® for use as an adjunct for fracture stabilization in the treatment of low impact, unstable, metaphyseal distal radius fractures, in cases where early mobilization is indicated. On December 20, 2001, the FDA approved Norian SRS® Cement for use in bony voids or defects that are not intrinsic to the stability of the bony structure. Norian SRS® Cement is intended to be placed or injected into bony voids or gaps in the skeletal system. These defects may be surgically created osseous defects or osseous defects caused by traumatic injury to the bone.

Despite the time that has elapsed since FDA approval, the manufacturer contends that Norian SRS® Cement should still be considered new for several reasons. First, until April 2002, Norian SRS® Cement was hand mixed using a mortar and pestle. Once Norian SRS® Cement was approved by the FDA in December 2001 (for the indication of use in bony voids or defects that are not intrinsic to the stability of the bony structure), the manufacturer issued a new pneumatic mixer. According to the manufacturer, this new pneumatic mixer allows for better preparation, reliability, and ease of use. In addition, a new injection syringe mechanism was developed and made available in May 2002 and replaced the “Norian Delivery Device”. The manufacturer believes these new procedures for mixing and delivery of the product to the patient should be considered new services as stated in section 1886(d)(5)(k)(ii) of the Act and § 412.87(b)(1) of the regulations. Second, the manufacturer contends that the cement should still be considered new because there is no ICD-9-CM code to uniquely identify Norian SRS® Cement within the DRGs.

In the May 18, 2004, proposed rule, we indicated that, although there have been changes in the way Norian SRS® Cement is mixed and delivered to the patient, we do not believe these changes are significant enough to regard the technology as new. While these changes may enhance the ease with which the technology is used, the product remains substantially the same as when it was initially developed. As we have indicated previously, technology can be considered new only for 2 to 3 years

after data reflecting the costs of the technology begin to become available. Data on the costs of this technology began to become available after FDA approval in 1998, and these costs are currently reflected in the DRG weights. As we discussed in the September 7, 2001, final rule (66 FR 46914), the determination concerning whether a technology meets this criterion depends on the date of its availability for use in the Medicare population rather than the date a specific code may be assigned. Therefore, we proposed that Norian SRS® Cement does not meet the newness criterion.

Although we proposed to deny add-on payments because the technology does not meet the newness criterion, we noted that the manufacturer submitted information on the cost criterion and the substantial clinical improvement criterion. The manufacturer submitted 52 Medicare and non-Medicare cases using Norian SRS® Cement. There are currently no ICD-9-CM codes that can distinctly identify Norian SRS® Cement within the MedPAR data; therefore, we cannot track this technology with our own analysis of MedPAR data. Based on the data submitted by the manufacturer, cases using Norian SRS® Cement were found in 12 DRGs, with 71.1 percent of the cases in DRGs 210, 218, 219, and 225. Based on the 52 cases submitted by the applicant, the case-weighted threshold across all DRGs was \$22,493. The average case-weighted standardized charge was \$29,032. As a result, the applicant and manufacturer maintained that Norian SRS® Cement meets the cost criterion.

According to the manufacturer, Norian SRS® Cement represents a substantial clinical improvement for the following reasons: It enhances short-term and long-term structural support, improves the rate and durability of healing, decreases donor site morbidity, decreases risk of infection at graft site, lowers the risk of operative complications from shorter operative procedures, lowers the rate of post-treatment hospitalizations and physician visits, and finally, reduces pain.

In the May 18, 2004, proposed rule, we did not present a full evaluation of the application for add-on payments for Norian SRS® Cement under these criteria because the technology did not meet the newness criterion. Therefore, we proposed to deny add-on payments for this technology.

In the proposed rule we indicated that prior to publication of the proposed rule, we had received no public comments on this application for add-on payments. During the 60-day

comment period for the proposed rule, we received the following public comments on this application.

Comment: One commenter, the manufacturer, noted that Norian SRS® Cement should still be considered "new" since there is sufficient information on the record, including sales data, to prove that Norian SRS® Cement could not have been included in the DRGs until the middle of 2002. The commenter also noted that public comments were indeed submitted prior to the proposed rule supporting a new technology add-on payment for Norian SRS® Cement. Another commenter also explained that Norian SRS® Cement should be considered new since it was not generally distributed to the public for use because of technical difficulties in mixing the product even though the product had been produced and released for quite some time.

Response: As stated previously and as we discussed in the September 7, 2001 final rule (66 FR 46914), the determination concerning whether a technology is new depends on the date of its availability for use in the Medicare population, rather than the date a specific code may be assigned. Data on the costs of this technology began to become available after FDA approval in 1998, and these costs are currently reflected in the DRG weights. Therefore we do not consider Norian SRS® cement to meet the newness criterion. As a result we are denying add-on payments for this technology in FY 2005.

As a final note, the February 27, 2004, **Federal Register** notice specified the method of submitting comments on the town hall meeting. Our statement in the proposed rule that we did not receive comments regarding this application referred to not having received any comments using that method. We are glad to receive the information now. We did, however, consider this comment as part of our discussion to deny add-on payments for this technology in FY 2005.

Comment: One commenter noted that the Norian SRS® Cement is an outstanding product that allows the stabilization of fractures that would normally develop postoperative deformity and problems after surgery. The commenter added that allograft or autogenic bone graft that uses a bone void filler would often deform and cause settling of the joint while the Norian SRS® cement seems to glue all of the small fracture fragments together and can hold together very tenuous reductions extremely well. The commenter also noted that it only began to use the Norian SRS® Cement once the new mixer system became available.

Another commenter also noted that the clinical benefits of Norian SRS® cement allow for earlier removal of external fixators and pins without risk of collapse of the fracture site and allow permanent internal fixation to load share with the Norian SRS® cement. This results in earlier range of motion in a safe manner, which ultimately results in earlier return to a functional and productive lifestyle for patients.

Response: We thank the commenters for providing information on the clinical benefits of Norian SRS® cement. However, as stated above, we do not consider Norian SRS® cement to meet the newness criterion and are denying add-on payments for this technology in FY 2005.

Comment: Some commenters supported the creation of procedure code 84.55 (insertion of bone filler) but requested the title of the code be revised to injection of bone void filler cement from insertion of bone filler in order to capture cases of bone void filler cements that require mixing and are applied via injection. One commenter requested we review the data upon implementation of this code to see how these devices affect the DRG weights.

Response: A new code was created for bone void filler which will be implemented on October 1, 2004. The code is as follows: 84.55 Insertion of bone void filler. Various options for this new code were discussed at the April 1–2, 2004, ICD–9–CM Coordination and Maintenance Committee. A summary of this meeting can be found at: <http://www.cms.hhs.gov/paymentsystems/icd9>.

Public comments received at the meeting and later submitted in writing were mixed. The manufacturer and some physicians supported new codes that differentiated between bone void fillers that were pre-mixed and required little or no mixing prior to insertion versus those that required more extensive pre-mixing. The manufacturer suggested a new code for the injection of bone void filler and another new code for insertion of bone void filler. Representatives of hospital and coder organizations were opposed to such a differentiation and recommended the creation of a single new code to capture this technology: 84.55, Insertion of bone void filler. The hospital and coding organizations stated that hospital coders would have difficulty differentiating between the insertion versus the injection of bone void filler. They stated that this would be especially true in cases where it would be necessary to determine the amount of mixing of the product that was necessary. These organizations did not believe that the

medical records would provide this type of documentation.

The American Hospital Association will be providing education to hospital coders on the use of this and other new codes. We will review data on claims submitted using this new code to determine if DRG modifications are necessary.

We are finalizing our proposal not to approve this technology for new technology add-on payments.

c. InSync® Defibrillator System (Cardiac Resynchronization Therapy with Defibrillation (CRT–D))

Cardiac Resynchronization Therapy (CRT), also known as bi-ventricular pacing, is a therapy for chronic heart failure. A CRT implantable system provides electrical stimulation to the right atrium, right ventricle, and left ventricle to re-coordinate or resynchronize ventricular contractions and improve the oxygenated blood flow to the body (cardiac output).

Medtronic submitted an application for approval of the InSync® Defibrillator System, a cardiac resynchronization therapy with defibrillation system (CRT–D), for new technology add-on payments for FY 2005. This technology combines resynchronization therapy with defibrillation for patients with chronic, moderate-to-severe heart failure who meet the criteria for an implantable cardiac defibrillator. Unlike conventional implantable cardiac defibrillators, which treat only arrhythmias, CRT–D devices have a dual therapeutic nature intended to treat two aspects of a patient's heart disease concurrently: (1) The symptoms of moderate to severe heart failure (that is, the ventricular dysynchrony); and (2) high risk of ventricular arrhythmias, as documented by a electrophysiologic testing or clinical history or both, which would cause sudden cardiac death.

InSync® Defibrillation System received FDA approval on June 26, 2002. However, another manufacturer, Guidant, received FDA approval for its CRT–D device on May 2, 2002. Guidant, and another competitor that has yet to receive FDA approval for its CRT–D device, have requested that their devices be included in any approval of CRT–D for new technology add-on payments. As we discussed in the September 7, 2001 final rule (66 FR 46915), an approval of a new technology for special payment should extend to all technologies that are substantially similar. Otherwise, our payment policy would bestow an advantage to the first applicant to receive approval for a particular new technology.

The applicant contends that, despite the approval of a similar device in May

2002, the InSync® Defibrillator System should still be considered new for several reasons: First, an ICD-9-CM code was only issued in FY 2003, which falls within the 2-year to 3-year range provided in the regulations. Second, the utilization of CRT-Ds is still growing and has not reached full utilization and, therefore, CRT-Ds remain underreported within the FY 2003 MedPAR data that are being used to recalibrate the DRG weights for FY 2005. Finally, the applicant believes reporting of CRT-Ds may be insufficient to accurately recalibrate the DRGs because the new ICD-9-CM codes for CRT-Ds are unlikely to be used consistently and accurately by hospitals in the first year.

We have discussed the relationship between existence of a specific ICD-9-CM code for a technology and our determination of its status as a new technology. As discussed in the September 7, 2001 final rule (66 FR 46914), the determination of whether a technology is new depends on the date of its availability for use in the Medicare population, rather than the date a specific code may be assigned. Because CRT-Ds were available upon the initial FDA approval in May 2002, we consider the technology to be new from this date and not the date a code was assigned.

Using the March 2004 update file to the FY 2003 MedPAR file, we have identified 11,004 cases using CRT-D in the FY 2003 MedPAR database. Of these, 10,750 cases were reported in DRGs 514 and 515 (then Cardiac Defibrillator Implant With and Without Cardiac Catheter, respectively). In DRG 515, we found 3,960 cases with procedure code 00.51 (Implantation of cardiac resynchronization defibrillator, total system (CRT-D)) and 6,790 cases in DRG 514. DRG 514 is no longer valid, effective in FY 2004. In FY 2004, we assigned new cases of defibrillator implants with cardiac catheters from DRG 514 to new DRGs 535 (Cardiac Defibrillator Implant with Cardiac Catheter With Acute Myocardial Infarction (AMI) Heart Failure/Shock) and 536 (Cardiac Defibrillator Implant with Cardiac Catheter Without Acute Myocardial Infarction (AMI) Heart Failure/Shock). Using the 6,790 cases from the FY 2003 MedPAR found in DRG 514, we examined the primary diagnosis codes necessary for assignment to DRG 535 along with procedure code 00.51 and found 3,413 cases of CRT-D for DRG 535. The remaining 3,377 CRT-D cases found in DRG 514 using procedure code 00.51 fall into DRG 536. For FY 2003, the total number of cases of CRT-D found in the FY 2003 MedPAR data for DRGs 514

and 515 were 48,700. Cases reporting CRT-Ds thus represent 22 percent of all cases for these DRGs.

A medical service or technology can no longer be considered new after 2 to 3 years, when data reflecting the costs of the technology begin to become available. Data on the costs of this technology began to become available in May 2002. Our analysis of data from the FY 2003 MedPAR file also shows that the costs of CRT-D are represented by a substantial number of cases within the DRGs. However, as discussed above, the technology still remains within the 2-year to 3-year period during which it can be considered new. Therefore, we indicated in the proposed rule that we were considering whether the CRT-D technology still meets the newness criterion. We stated that we would welcome comments on this issue as we analyzed whether to approve this technology in the final rule.

Comment: Two commenters, the applicant and another manufacturer of CRT-D devices, commented that the utilization of CRT-D is still growing and has not reached full utilization. One of the commenters further noted that industry estimates forecast that CRT-D will ultimately account for over 50 percent of the defibrillator market by 2006 (or double the amount seen in FY 2003). As a result, additional time and utilization is necessary with CRT-D before the DRGs can be recalculated to reflect the full costs of CRT-D in the DRG weights. Some commenters, including the applicant, also explained that the volume of cases in the FY 2003 MedPAR is indicative of the breakthrough nature of the technology and the benefit it confers to heart failure patients. The fact that some hospitals were willing to absorb the costs of the technology and make CRT-D available to their patients should have no effect if the technology remains new and eligible for new technology add-on payments. In light of the above, the applicant believes the technology should be considered new under the timeframe of newness and that the existing MedPAR data are insufficient to update the DRG weights for FY 2005. Another commenter noted that over the last 12 months, the volume of patients receiving the CRT-D in the commenter's hospital has risen by 28 percent. The commenter added that for the coming year the volume of patients receiving the CRT-D is expected to rise an additional 30 percent.

MedPAC questioned if this technology still meets the newness criterion. MedPAC noted that the technology could diffuse further and represent an even greater share of cases.

However, MedPAC believes it is clear that costs of the technology are already reflected in the data used to set the DRG weights. MedPAC recommended that one way to deal with this issue would be to exclude cases of the technology when it can be tracked from the calculation of the mean charges from the DRG during recalibration of the relative weights. This would avoid overpaying for the technology by including its costs in the base payment while also providing an add-on payment.

One commenter, the applicant, was concerned that MedPAC's recommendation might lead to the lowering of payment for implantable cardioverter defibrillators (ICDs). The commenter recommended that CMS not take any action that would lower payment for a technology that already experiences inadequate payment.

Response: Although we have a large amount of cases of CRT-D reflected within the DRGs, as stated by the commenter, the potential population that can receive the CRT-D could be much larger as time elapses. While the regulations state that a technology is no longer new when data begin to become available reflecting the new technology in the DRGs, the commenter has argued that the CRT-D is not fully reflected in the DRGs since it has not reached its full market utilization. In the proposed rule, we expressed concerns regarding the extent of the data already reflected in the DRGs, which suggests that CRT-D should no longer be considered "new". However, at this point we cannot make a definite determination that the CRT-D is fully reflected within the DRGs; and therefore, we have concluded that CRT-D should be considered to meet the newness criterion.

We have responded to MedPAC's recommendation on excluding a new technology from recalibration of the relevant weight above. We will consider this recommendation as we continue to develop policy in this area.

Comment: Some commenters believed that the date of issuance of an ICD-9-CM code should start the 2- to 3-year period of a technology being new instead of the FDA approval date. The commenters explained that considering a technology new from the FDA approval date is inconsistent with the regulations in 42 CFR § 412.87(b)(2). One commenter further noted that distinct hospital charge data for CRT-D only became available after the issuance of a ICD-9-CM code and CRT-D charge data did not become publicly available until May 2004. As a result the commenter maintains that the CRT-D is still within the 2-3 year period of being considered "new". Another commenter

added that even though CRT-D was approved in May of 2002, it is uncertain if hospitals adjusted their charges at that time in order to reflect the higher costs of CRT-D procedures, especially given the lack of a unique ICD-9-CM code. Furthermore, it was not possible to uniquely identify CRT-D in the data until a unique ICD-9-CM code was issued. Therefore, the commenter believes it does not seem appropriate to consider the CRT-D new from the FDA approval date of May 2002. One commenter was concerned that continued inadequate payment for the CRT-D has the potential to limit patient access to this new technology. Therefore, the commenter encouraged CMS to consider the CRT-D to meet the newness criterion.

One commenter, the applicant, added that prior to the MMA, CRT-D did not meet the cost threshold and therefore the applicant did not apply for new technology add-on payments. The commenter noted that had Congress acted earlier an application would have been submitted earlier as well. The applicant believes that finding the CRT-D to meet the newness criterion and approval of add-on payments for CRT-D is consistent with Congress' intent to ensure more new technologies qualify for add-on payments.

Response: As stated previously, we have determined that CRT-D meets the newness criterion. For a further discussion on the newness criterion regarding FDA approval dates and the issuance of ICD-9-CM codes, please see section II.E.2. of the preamble to this final rule.

We note that the applicant submitted information on the cost and substantial clinical improvement criteria. The applicant commissioned Navigant Consulting, Inc. to collect charge data on CRT-D. Navigant found 354 Medicare cases among 30 hospitals. Cases were identified using ICD-9-CM procedure code 00.51. Of these 354 cases, 44.1 percent were reported in DRG 515, 23.7 percent were reported in DRG 535, and 32.2 percent were reported in DRG 536. These DRGs result in a case-weighted threshold of \$78,674. The average case-weighted standardized charge for the 354 cases mentioned above was \$79,163. Based on these data, the manufacturer contends that InSync® Defibrillator System would meet the cost criterion.

In the September 7, 2001 final rule, we stated that the data submitted must be of a sufficient sample size to demonstrate a significant likelihood that the sample mean approximates the true mean across all cases likely to receive the new technology. Using a standard

statistical methodology for determining the needed (random) sample size based on the standard deviations of the DRGs identified by the applicant as likely to include cases receiving a CRT-D, we have determined that a random sample size of 354 cases can be reasonably expected to produce an estimate within \$3,500 of the true mean.⁴ Of course, the data submitted, which include Medicare data from 30 hospitals, do not represent a random sample of all cases in these DRGs across all hospitals.

The manufacturer also contends that the added capability of the InSync® Defibrillator System device provides significant benefits over and above a conventional defibrillator. The InSync® Defibrillator System device treats both the comorbid conditions of ventricular arrhythmias and moderate to severe heart failure, and takes the place of the existing treatment of drug therapy for heart failure plus a conventional implantable cardiac defibrillator for ventricular arrhythmia. The applicant states this CRT-D is a substantial clinical improvement for patients who remain symptomatic despite drug therapy and who are also at high risk for ventricular arrhythmias. According to the applicant, some of the improved outcomes that result from using a CRT-D device instead of existing treatments include: improved quality of life, improved exercise tolerance, improved hemodynamic performance, and reduced hospitalizations and mortality due to chronic heart failure.

We welcomed comments on whether this technology meets the new technology criterion, but especially about whether it meets the newness criterion in the light of the extent to which it is represented cases within the relevant DRGs. We indicated that we would determine whether to approve this technology in the light of any comments that we received and our continuing analysis.

Prior to the publication of the May 18, 2004, proposed rule, we received public comments in accordance with section 503(b)(2) of Public Law 108-173 regarding this application for add-on payments. Commenters noted that CRT-D has had positive clinical outcomes by reversing remodeling of the heart and improving the heart's ability to pump more efficiently. One commenter added that CRT-D has helped decrease hospitalizations and length of stay.

⁴ The formula is $n = 4\sigma/B^2$, where σ is the standard deviation of the population, and B is the bound on the error of the estimate (the range within which the sample means can reliably predict the population mean). See *Statistics for Management and Economics*, Fifth Edition, by Mendenhall, W., Reinmuth, J., Beaver, R., and Duhan, D.

During the 60-day comment period for the May 18, 2004, proposed rule, we received the following public comments on this application.

Comment: The applicant submitted additional data aside from the data discussed in the proposed rule showing that CRT-D meets the cost criterion. The applicant searched the FY 2003 MedPAR for cases with procedure code 00.51 and found 3,947 cases in DRG 515, 3,396 cases in DRG 535 and 3,351 cases in DRG 536. The average standardized charge for these DRGs were \$81,950 for DRG 515, \$104,092 for DRG 535 and \$97,250 for DRG 536. This resulted in a case weighted average standardized charge of \$93,776. The case weighted threshold using the threshold amounts from table 10 was \$81,161. Based on this analysis, the applicant maintains that CRT-D meets the cost criterion since the case weighted average standardized charge is greater than the case weighted threshold. One commenter believes that the average costs of the CRT-D meet or exceed the cost threshold. The commenter added that CRT-D procedures are more complex and take longer than conventional ICD implantations. One commenter added that the DRGs do not provide adequate reimbursement for cases with a CRT-D.

Response: We also searched the latest update to the FY 2003 MedPAR and found 3960 cases in DRG 515 with an average standardized charge of \$82,520, 3,413 cases in DRG 535 with an average standardized charge of \$104,755 and 3,377 cases in DRG 536 with an average standardized charge of \$98,329. This resulted in a case weighted average standardized charge of \$94,546. Using the thresholds from table 10, the case weighted threshold for DRGs 515, 535 and 536 was \$81,169. As a result, the average standardized charge is greater than the case weighted threshold and therefore the CRT-D meets the cost criterion for new technology add-on payments.

Comment: The applicant also submitted the following comments on the substantial clinical improvement criterion. The commenter first noted that CRT-D meets the definition of substantial clinical improvement described in 42 CFR 412.87(b)(1) because prior to May 2, 2002 there was no device available that provided cardiac resynchronization therapy in combination with an implantable cardiac defibrillator, and that the introduction of the CRT-D device enabled the treatment of patients with symptomatic heart failure despite maximal medical therapy in addition to providing a potentially life saving

defibrillator in those patients who are at high risk for ventricular arrhythmias. Another commenter agreed with the applicant that the CRT-D represents a substantial clinical improvement because it provides treatment for a new and different patient population (those with heart failure and high risk for ventricular arrhythmias). Two commenters further noted multiple studies that demonstrated objective and subjective clinical improvement in patients with moderate to severe heart failure when treated with CRT or CRT-D as quantified by such measures as New York Heart Association Class, 6 minute walk distance, peak oxygen uptake, left ventricular ejection fraction, and area of regurgitant mitral jet. It was also noted by the applicant that CRT-D was shown in the COMPANION study to significantly reduce all cause of mortality. One of the commenters also noted that CRT-D reduced symptoms and improved quality of life. Another commenter added that the CRT-D provides dual therapy for patients with dual indications, and that it is not simply a combination of two existing devices. One commenter believed that there is some potential benefit from reduced hospital readmissions and cost savings to both the hospital and Medicare program when using the CRT-D.

Response: We agree that CRT-D provides a valuable treatment to Medicare beneficiaries who have refractory, symptomatic congestive heart failure despite optimal medical management and who are also at significant risk for potentially fatal ventricular arrhythmias. We recognize that prior to the advent of CRT-D patients could not have had access to the benefits of both cardiac resynchronization therapy and an implantable defibrillator. For these reasons CMS believes the CRT-D device represents a substantial clinical improvement for the purposes of a new technology add-on payment.

Comment: The applicant commented that the FDA's view of CRT-P and CRT-D devices further supports the distinction between the two technologies. The commenter explained that the FDA did not allow for the pooling of data for the Miracle trial (study of a CRT-P) and MIRACLE ICD trial (study of a CRT-D) as the studies and devices addressed different patient populations and indications. The FDA required that the safety and efficacy of the devices be proven separately as a result of the differences between the devices and because biventricular pacing was a new technology. The commenter explained that the FDA

believed that the two types of CRT therapy would affect two different populations (indications for an ICD and CRT-D versus indications for a CRT-P with no arrhythmia). The commenter finally noted that the FDA listed the CRT-D as one of ten "Advances in Patient Care" in its Fiscal Year 2002 Office of Device Evaluation Annual Report. In reference to CRT-D the report stated "[t]he device, the first of its kind, can be used to treat symptoms of advanced heart failure in certain people who already need an ICD." The commenter emphasized the FDA's language describing the device as the "first of its kind."

Response: We again agree that the CRT-D device represents a substantial clinical improvement because it is capable of treating patients with the two distinct conditions of congestive heart failure and "at high risk for sudden cardiac death," who prior to its availability could not have received the benefits of both cardiac resynchronization therapy and immediate defibrillation in the event of sustained ventricular arrhythmia. We have therefore determined that this device meets the substantial clinical improvement criterion.

Comment: The applicant submitted three different scenarios on the potential add-on payment amount for the new technology. The device consists of a defibrillator, right atrial and right ventricular leads, left ventricular lead, lead delivery system and a balloon catheter. The first scenario would pay for the device and all the leads associated with implanting the device. The second approach, which was supported by the applicant, excluded the costs of the right atrial and right ventricular leads because these items are used in ICDs whose costs are already reflected in DRGs 515, 535 and 536. The last scenario excluded all costs associated with the ICD since the DRGs have already captured all costs of an ICD in the CRT-D.

Response: After reviewing all the criteria, we have determined that CRT-D is eligible for add-on payments in FY 2005. Cases involving CRT-D that are eligible for new technology add-on payments are identified by either one of the following two ICD-9-CM procedure codes: 00.51 (Implantation of Cardiac Resynchronization Defibrillator, Total System (CRT-D)) or 00.54 (Implantation or Replacement of Pulse Generator Device Only (CRT-D)). We agree with the commenter that option number two is the best approach to determine the costs of the CRT-D for the purpose of new technology add-on payments. Using this approach, the total costs for

the device are \$32,525. Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the costs of the technology or 50 percent of the costs in excess of the DRG payment for the case. As a result, the maximum add-on payment for a case involving the CRT-D is \$16,262.50.

Comment: One commenter recommended that CRT-D add-on payments should expire in May of FY 2005. The commenter explained that the newness criterion should be extended to the full 2-3 year period from the FDA approval date.

Response: Predictability is an important aspect of the prospective payment system methodology. Accordingly, we believe that it is appropriate to apply a consistent payment methodology for new technologies throughout the fiscal year. Furthermore, we note that the CRT-D will still be within the 2 to 3 year period in which it can be considered new for most of FY 2005. As a result, we will make add-on payments for cases involving CRT-D for the entire FY 2005.

d. GliaSite® Radiation Therapy System (RTS)

The Pinnacle Health Group submitted an application for approval of GliaSite® Radiation Therapy System (RTS) for new technology add-on payments. GliaSite® RTS was approved by the FDA for use on April 25, 2001. The system involves several components, including a drug called Iotrex and a GliaSite® catheter. Iotrex is an organically bound liquid form of Iodine¹²⁵ used in intracavitary brachytherapy with GliaSite® RTS. Iotrex is a single nonencapsulated (liquid) radioactive source. The liquid is a solution of sodium ³⁻⁽¹²⁵⁾iodo-4-hydroxybenzenesulfonate and is used to deliver brachytherapy for treatment of brain cancer.

The delivery system for Iotrex is the GliaSite® RTS catheter. Iotrex is administered via injection through a self-sealing port into the primary lumen of the barium-impregnated catheter that leads to the balloon reservoir. After a malignant brain tumor has been resected, the balloon catheter (GliaSite®) is implanted temporarily inside the cavity. The patient is released from the hospital. After a period of 3 days to 3 weeks, the patient is readmitted. During the second admission, the appropriate dose (200 to 600 millicuries) of radiation is then administered. Iotrex is infused into the GliaSite® catheter and intracavitary radiation is delivered to the target area. The gamma radiation emitted by Iotrex is delivered directly to

the margins of the tumor bed. After 3 to 7 days, the Iotrex is removed.

GliaSite® RTS was approved by the FDA for use on April 25, 2001. Technology is no longer considered new 2 to 3 years after data reflecting the costs of the technology begin to become available. Because data regarding this technology began to become available in 2001, we determined that GliaSite® RTS does not meet the criterion that a medical service or technology be considered new. Therefore, in the May 18, 2004 proposed rule, we proposed to deny approval of GliaSite® RTS for new technology add-on payments.

Although we proposed not to approve this application because GliaSite® RTS does not meet the newness criterion, we noted that the applicant submitted information on the cost criterion and substantial clinical improvement criterion. The applicant stated that the number of cases in DRG 7 for FY 2004 was projected to be 14,782, and estimated that 10 percent (or about 1,478) of those patients would be candidates for GliaSite® RTS. The applicant estimated that the standardized charge for all cases using the technology in DRG 7 was \$49,406. Based on this calculation, the manufacturer stated in its application that this figure is greater than the cost threshold of \$32,115 for DRG 7. Therefore, according to the manufacturer, it appears that GliaSite® RTS would meet the cost criterion.

The applicant also claims this way of delivering brachytherapy to the brain is significantly more patient friendly. The use of a single intracavitary applicator positioned inside the resection cavity during the initial surgery in place of an interstitial-seed implant removes the need for additional invasive procedures and the need for multiple puncture sites (up to 20). In addition, the manufacturer claims that the approach used in the GliaSite® RTS system improves dose-delivery and provides a more practical means of delivering the brachytherapy.

However, as discussed above, because GliaSite® RTS did not meet the newness criterion, we proposed to deny add-on payments for this technology in FY 2005.

Prior to the publication of the May 18, 2004 proposed rule, we received no public comments on this application for add-on payments. During the 60-day comment period for the proposed rule, we received the following public comments on this application.

Comment: Many commenters objected to the proposed denial of new technology status for Iotrex (the chemotherapy agent in the GliaSite® RTS). They stated that it represents a

substantial improvement over conventional brachytherapy treatment for brain tumors by reducing the number of radioactive seeds implanted into the patient's brain (via up to 20 catheters). Commenters also stated that this therapy reduces the problems associated with conventional therapy by providing a more "conformal therapy with no target tissue underdosing, less target tissue overdosing and no healthy tissue 'hot spots.'"

Commenters also noted that this therapy is more widely available at over 140 centers starting in 2003 (whereas brachytherapy treatment is only offered at 5 centers nationwide). While more widely spread, commenters nonetheless stated that prior to 2003, when the treatment was accepted at the 140 centers noted above, "significantly fewer hospitals offered this therapy" due to a combination of licensing and safety requirements that must be met in order for providers to purchase and use this radioisotope. Commenters stated that meeting these requirements of the Nuclear Regulatory Commission or applicable State authorities governing the distribution and use of Iotrex was time-consuming, taking on average 6 to 8 months or more per hospital, and caused a significant delay in the adoption and use of this therapy, despite the FDA approval date. Commenters also stated that by denying GliaSite® RTS new technology status, CMS is not permitting appropriate payment for the device and is "likely restricting access to this therapy."

Response: The regulations clearly state that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). Notably, the regulations continue, "[a]fter CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion of this section." This device received FDA approval in April of 2001. Information provided by the applicant demonstrates that despite the delays caused by licensing and safety requirements, the device was available on the market no later than fall of 2001 and data began to become available at that time. The applicant's own comments indicate that since that time, a relatively large number of hospitals have adopted this therapy, with 69

hospitals having the required license halfway through FY 2002, and 118 hospitals with the required license at the end of FY 2003. Therefore, the costs of the device have already been reflected in three cycles of DRG recalibrations using costs contained in the second half of FY 2001, and captured in the entirety of FYs 2002 and 2003 MedPAR data. Since the product has been on the market since 2001, and since many hospitals that treat this disease are currently using the device, and have since early in FY 2002, this device is now beyond the 2 to 3 year period in which it can still be considered new.

Comment: One commenter noted that the DRG for craniotomy (DRGs 1 and 2) does not adequately cover the cost of the catheter and isotope. The commenter stated that "some centers are readmitting the patients for reoperation to place the catheter" and "some are treating patients as outpatient to avoid losing money on the DRG."

Response: Since Medicare has paid for the device for the hospitals that have correctly coded the use of the product in the correct DRGs as well as in other DRGs and in other areas of our system (as disclosed by this commenter), the costs have nonetheless been accounted for in our data and the treatment cannot be considered new.

We therefore finalize the decision to deny new technology add-on status for the GliaSite® RTS (Iotrex) for FY 2005.

e. Natreacor®—Human B-Type Natriuretic Peptide (hBNP)

Scios, Inc. submitted an application for approval of Natreacor® for new technology add-on payments. Natreacor is a member of a new class of drugs, Human B-type Natriuretic Peptide (hBNP), and it is manufactured from *E. coli* with recombinant DNA technology. It binds to the particulate guanylate cyclase receptor of vascular smooth muscle endothelial cells, leading to increased intracellular concentrations of guanosine 3'5'-cyclic monophosphate, and therefore to enhanced smooth muscle cell relaxation, ultimately causing dilation of arteries and veins. The applicant states that Natreacor® is more potent and relieves symptoms of heart failure more rapidly, while also causing less hemodynamic instability than intravenous nitroglycerin, the most commonly used vasodilator for heart failure.

Natreacor® was approved by the FDA for the treatment of acute congestive heart failure on August 10, 2001. It is indicated for the intravenous treatment of patients with acutely decompensated congestive heart failure (dyspnea).

Congestive heart failure is the result of impaired pumping capacity of the heart. It causes a variety of clinical consequences, including water retention, sodium retention, pulmonary congestion, and diminished perfusion of blood to all parts of the body.

The applicant concedes that the FY 2003 MedPAR file includes hospital charge information for patients receiving Natrecor®. The manufacturer contends that Natrecor® should still be considered new for several reasons. The first reason is that these data will not provide an accurate representation of hospital utilization of this product nor an adequate reimbursement rate for hospitals treating acute congestive heart failure patients with Natrecor® in FY 2005. The FY 2003 MedPAR file represents the first full year in which the ICD-9-CM procedure code 00.13 (Injection or infusion of nesiritide) was in effect. Therefore, the manufacturer anticipates a slow increase in the accuracy of coding and billing in FY 2003. In addition, the manufacturer stated that market penetration for this product was 3 percent for FY 2003, but is expected to be significantly higher for FY 2005.

However, technology is no longer considered new 2 to 3 years after data reflecting its costs begin to become available. Because data reflecting the costs of Natrecor® began to become available in 2001, these costs are currently reflected in the DRG weights. In addition, as discussed in the September 7, 2001 final rule (66 FR 46914), the determination of whether a technology is new depends on the date of its availability for use in the Medicare population rather than the date a specific code was assigned. Because Natrecor® was available upon FDA approval, it does not meet the criterion that a medical service or technology be considered new.

Although we proposed not to approve this application because Natrecor® does not meet the newness criterion, in the proposed rule, we noted that the applicant submitted information on the cost criterion and substantial clinical improvement criterion. Scios commissioned Premier, Inc. to search its database of 196 hospitals for cases in FY 2003 that used Natrecor®. Premier identified 9,811 cases across many DRGs using National Drug Codes from pharmacy databases. The majority of cases (approximately 42 percent) were found in DRG 127 (Heart Failure and Shock), while the remaining cases were found in other DRGs that individually had a maximum of 8 percent of the 9,811 cases identified by Premier. The case-weighted threshold across all DRGs

for Natrecor®, using data provided by Premier, was \$26,509. (DRGs with less than 25 discharges were not included in this analysis.) The average charge for cases with Natrecor® was \$70,137. The average case-weighted standardized charge across all DRGs was \$43,422. Because the average standardized charge is greater than the case-weighted threshold, the applicant stated that Natrecor® meets the cost criterion.

The manufacturer stated that Natrecor® represents a substantial clinical improvement over existing treatments for decompensated congestive heart failure because it provides novel clinical effects, leads to fewer complications, and improves overall clinical outcomes. Specifically, Natrecor® reduces left ventricular preload, afterload, and pulmonary capillary wedge pressure without inducing tachyphylaxis, and it causes a balanced vasodilation of veins, arteries, and coronary arteries that increases cardiac output. It has also been shown to significantly reduce dyspnea, and it blocks the rennin-aldosterone-angiotensin system, thereby reducing sodium retention and enhancing diuresis and natriuresis. In addition, Natrecor® is not pro-arrhythmic; it does not increase cardiac work by causing tachycardia, and it does not cause electrolyte imbalances.

However, as discussed above, Natrecor® does not meet the newness criterion. Therefore, in the May 18, 2004 proposed rule, we proposed to deny add-on payments for this technology in FY 2005.

Prior to the publication of the proposed rule, we received no public comments on this application for add-on payments. During the 60-day comment period for the proposed rule, we received the following public comments on this application.

Comment: Some commenters, including the applicant, disagreed with CMS' position that Natrecor® is ineligible for an add-on payment since it is not "new". A commenter explained that in the proposed rule CMS stated that the 2-to-3 year period for collection of cost data begins when the drug or biological receives FDA approval and not when an ICD-9-CM code is issued. The commenter felt this contradicts the statutory language in section 1886(d)(5)(K)(ii)(II) and the regulatory text in 42 CFR 412.87(b)(2). The commenter stated that that based on the statutory and regulatory text, a technology should be considered new from the date a code is issued. As a result, since Natrecor® did not receive a unique code until October 1, 2002, it should still fall

within the 2-3 year period to be considered new.

The commenter further noted that heart failure patients who receive Natrecor® are more costly than patients who do not receive Natrecor®. Based on data the applicant submitted, the commenter explained that the average charge for a patient receiving Natrecor® is 47.5 percent higher than the case weighted average charge threshold of \$32,485. The commenter also added that based on data from the Premier database, even though 48 percent of all cases of Natrecor® map to DRG 127, Natrecor® has had a very small impact on DRG 127 since it represents only 1.8 percent of all charges in DRG 127 which is a result of the fact that only 8.4 percent of all patients assigned to DRG 127 received Natrecor®. As a result, the commenter disagreed with CMS' contention that charges for Natrecor® are adequately reflected in the relevant DRGs. The commenter concluded that limited Medicare reimbursement coupled with the high cost of a breakthrough biologic therapy have led to restrictions on the use of Natrecor®. Also, the number of patients that could receive Natrecor® in DRG 127 is much higher than the current figure of 8.4 percent.

Another commenter believed that CMS should provide its full evaluation of the cost and clinical data submitted by this applicant (and all other applicants) in order to provide for better insight into the agency's decision-making process. The commenter was concerned that during the comment period an application could satisfy the criterion upon which CMS had proposed to deny the application in the proposed rule, while in the final rule CMS could deny the application on a different criterion that had not been discussed in the proposed rule. As a result, the commenter recommended a full analysis of all the criteria in the proposed rule.

Response: As stated above, a technology is no longer considered new 2 to 3 years after data reflecting its costs begin to become available. Because data reflecting the costs of Natrecor® began to become available in 2001, these costs are currently reflected in the DRG weights. For a further discussion on the newness criterion regarding FDA approval dates and the issuance of ICD-9-CM codes, please see the preamble above.

We conduct sufficient analysis on each application in order to provide sufficient opportunity to comment. We do not believe that it is necessary to provide a full analysis of all the criteria in cases where, for example, we believe

that sufficient evidence is available to propose denying the application on the basis of the newness criterion. However, even in these cases we provide an account of any information submitted by the applicant in order to provide opportunity for comment.

Comment: One commenter believes that CMS should be more proactive when it comes to DRG reclassifications of new technologies. The commenter cited Natreacor® as an example of a new technology with over 10,000 cases in which the current reimbursement is inadequate. The commenter noted that after CMS denied the application for add-on payments, no consideration was given to the reclassification of the new technology. The commenter encouraged CMS to make strides to ensure that patient access to important, life threatening therapies is not threatened by inappropriate PPS payments.

Response: When reviewing new technology applications, we consider if the applicant has met all the criteria for new technology add-on payments. The applicant or anyone from the public is free to make a separate request for consideration of a new DRG assignment as we discuss in section II. B. of this final rule.

Because Natreacor® does not meet the newness criterion, we are finalizing our proposal not to approve add-on payments for this technology in FY 2005.

f. Kinetra® Implantable Neurostimulator for Deep Brain Stimulation

Medtronic, Inc. submitted an application for approval of the Kinetra® implantable neurostimulator device for new technology add-on payments. The Kinetra® device was approved by the FDA on December 16, 2003. The Kinetra® implantable neurostimulator is designed to deliver electrical stimulation to the subthalamic nucleus (STN) or internal globus pallidus (GPi) in order to ameliorate symptoms caused by abnormal neurotransmitter levels that lead to abnormal cell-to-cell electrical impulses in Parkinson's Disease and essential tremor. Before the development of Kinetra®, treating bilateral symptoms of patients with these disorders required the implantation of two neurostimulators (in the form of a product called Soletra™, also manufactured by Medtronic): one for the right side of the brain (to control symptoms on the left side of the body), the other for the left side of the brain (to control symptoms on the right side of the body). Additional procedures are required to create pockets in the chest cavity to place the two generators required to run

the individual leads. The Kinetra® neurostimulator generator, implanted in the pectoral area, is designed to eliminate the need for two devices by accommodating two leads that are placed in both the left and right sides of the brain to deliver the necessary impulses. The manufacturer argues that the development of a single neurostimulator that treats bilateral symptoms provides a less invasive treatment option for patients, and simpler implantation, follow up, and programming procedures for physicians.

In December 2003, the device was approved by the FDA. Therefore, it qualifies under the newness criterion because FDA approval was within the statutory timeframe of 2–3 years and its costs are therefore not yet reflected in the DRG weights. Because there are no data available to evaluate costs associated with Kinetra®, we conducted the cost analysis using Soletra™, the predecessor technology used to treat this condition, as a proxy for Kinetra®. The pre-existing technology provides the closest means to track cases that have actually used similar technology and serves to identify the need and use of the new device. The manufacturer informed us that the cost of the Kinetra® device is twice the price of a single Soletra™ device. Since most patients would receive two Soletra™ devices if the Kinetra® device is not implanted, data regarding the cost of Soletra™ give a good measure of the actual costs that will be incurred. Medtronic submitted data for 104 cases that involved the Soletra™ device (26 cases in DRG 1 (Craniotomy Age > 17 With CC), and 78 cases in DRG 2 (Craniotomy Age > 17 Without CC)). These cases were identified from the FY 2002 MedPAR file using procedure codes 02.93 (Implantation, intracranial neurostimulator) and 86.09 (Other incision of skin and subcutaneous tissue). In the analysis presented by the applicant, the mean standardized charges for cases involving Soletra™ in DRGs 1 and 2 were \$69,018 and \$44,779, respectively. The mean standardized charge for these Soletra™ cases according to Medtronic's data was \$50,839.

For the proposed rule, we used the same procedure codes to identify 187 cases involving the Soletra™ device in DRGs 1 and 2 in the FY 2003 MedPAR file. Similar to the Medtronic data, 53 of the cases were found in DRG 1, and 134 cases were found in DRG 2. The average standardized charges for these cases in DRGs 1 and 2 were \$51,163 and \$44,874, respectively. Therefore, the case-weighted average standardized charge for cases that included

implantation of the Soletra™ device was \$46,656. The new cost thresholds established under the revised criteria in Public Law 108–173 for DRGs 1 and 2 are \$43,245 and \$30,129, respectively. Accordingly, the case-weighted threshold to qualify for new technology add-on payment using the data we identified would be \$33,846. Under this analysis, Kinetra® would qualify for the cost threshold.

We note that an ICD–9–CM code was approved for dual array pulse generator devices, effective October 1, 2004, for IPPS tracking purposes. The new ICD–9–CM code that will be assigned to this device is 86.95 (Insertion or replacement of dual array neurostimulator pulse generator), which includes dual array and dual channel generators for intracranial, spinal, and peripheral neurostimulators. The code will not identify cases with this specific device and will only be used to distinguish single versus dual channel-pulse generator devices.

The manufacturer claims that Kinetra® provides a range of substantial improvements beyond previously available technology. These include a reduced rate of device-related complications and hospitalizations or physician visits and less surgical trauma because only one generator implantation procedure is required. Kinetra® has a reed switch disabling function that physicians can use to prevent inadvertent shutoff of the device, as occurs when accidentally tripped by electromagnetic interference (caused by common products such as metal detectors and garage door openers). Kinetra® also provides significant patient control, allowing patients to monitor whether the device is on or off, to monitor battery life, and to fine-tune the stimulation therapy within clinician-programmed parameters. While Kinetra® provides the ability for patients to better control their symptoms and reduce the complications associated with the existing technology, it does not eliminate the necessity for two surgeries. Because the patients who receive the device are often frail, the implantation generally occurs in two phases: the brain leads are implanted in one surgery, and the generator is implanted in another surgery, typically on another day. However, implanting Kinetra® does reduce the number of potential surgeries compared to its predecessor (which requires two surgeries to implant the two single-lead arrays to the brain and an additional surgery for implantation of the second generator). Therefore, the Kinetra® device reduces the number of surgeries from 3 to 2.

In the May 18, 2004, proposed rule, we indicated that, despite the improvement Kinetra® represents over its immediate predecessor, Solettra™, we had concerns about whether the device is significantly different in terms of how it achieves its desired clinical result. The stimulation mechanism by which it treats patient symptoms remains substantially the same as the predecessor device. The enhancements cited by the manufacturer are primarily to features such as control, power, monitoring, and reliability. Nevertheless, these improvements, along with the reduced number of surgeries required, may be sufficient to warrant a determination that the device represents a substantial clinical improvement. We welcomed further public comment on the issue of whether the device is sufficiently different from the previously used technology to qualify as a substantially improved treatment for the same patient symptoms.

In the proposed rule, we also invited comments concerning the cost of the device. If the new device, at twice the cost of the existing technology, merely replaces the costs of two of the previous devices, then the charges for Kinetra® are not substantially different from current charges resulting from the use of either device alone. Because the costs for the predecessor device meet the statutory cost criterion, the successor technology would meet the criterion as well, at least under the manufacturer's assumption that a single Kinetra® costs twice as much as each of the two Solettras™ required to perform the same function. However, since there should be less surgery involved, more patient control, less risk of complications, and fewer office visits as a result of using Kinetra®, we stated in the proposed rule that we would expect the costs for patients who receive the new device to drop. We stated that, for those reasons, it may not be appropriate to base the cost analysis for Kinetra® on the manufacturer's assumption that total costs for Solettra™ and Kinetra® are substantially the same.

In addition, in the proposed rule, we invited public comment concerning the approval of the device for add-on payment, given the uncertainty over the frequency with which the patients receiving the device have the generator implanted in a second hospital stay, and the frequency with which this implantation occurs in an outpatient setting. Any hospital performing the implantation in two separate patient stays, whether they are both inpatient or whether one is inpatient and the second is outpatient, would be paid double for

the single device. Therefore, we had some concern about the appropriateness of approving add-on payments for a device that may already receive payment at a nonbundled rate for a high percentage of patients who receive the device. We also investigated whether a second hospital stay is needed for implantation of Kinetra®.

Despite these issues, we indicated that we would continue to consider whether it was appropriate to approve add-on status for Kinetra® for FY 2005. If approved for add-on payments, the device would be reimbursed up to half of the costs for the device. Since the manufacturer has stated that the cost for Kinetra® would be \$16,570, the maximum add-on payment for the device would be \$8,285. We stated that we would make a final determination in the light of public comments that we received on the proposed rule and our continuing analysis.

Prior to publication of the proposed rule, we received no public comments on this application. During the 60-day comment period for the proposed rule, we received the following public comments on this application.

Comment: The applicant responded to our request for comments by providing further detail on the cost of the device, how it derived the higher cost for the device and recommendations on how we might proceed if we were to approve the device for add-on payments. It noted that the device has substantially higher manufacturing costs than the predecessor device, Solettra™, which has a smaller battery and much lower production cost. The applicant also stated that the device meets the substantial clinical improvement criterion due to the much improved user outcomes for patients that receive Kinetra® as opposed to those that receive the Solettra™. In addition to the factors listed above, it noted that not only does the device reduce invasiveness and risk of surgical complications to implant the device, but the shorter operating time needed to implant one device reduces the duration of anesthesia in one episode that these patients need for surgical placement. The time to reach the desired and improved therapeutic outcome is greatly reduced. The need for follow up care is substantially reduced and the intervals between battery replacement operations with the new device are significantly increased (anywhere from 15 months to 2 years longer, based on various comments received).

The applicant also provided data that satisfactorily answered our remaining questions with regard to the reasons for staged implantation of the device in

some patients. It noted that many patients simply cannot physically tolerate the long day of surgery, and particularly the general anesthesia required to implant the generator if the procedure is all done in one day or one hospital stay. In addition, due to the nature of the brain surgery involved to place the leads, care must be given to ensure that no hemorrhages are present before proceeding with implanting the rest of the device. Other physicians noted that patient medications must also be taken into account when planning the implantation of the device. One commenter, a physician using the device in his practice, also noted the improved mobility and function of patients receiving this device and the reduced interference in daily and leisure activities for patients receiving this device over the Solettra™ generators. Other physicians noted that patients actually spend less time in the hospital under the staged method for implanting the device and tolerate the procedures much better. Some nurses noted that there are additional educational requirements associated with the Kinetra® device due to the unique patient control, but this training and the additional time to set up the initial programming of the device result in reduced follow-up visits and re-programming, and allow the patients to monitor their symptoms in the stress-free environment of the home instead of the doctor's office.

Response: We believe that sufficient evidence has been provided by the applicant to demonstrate that this device satisfies the significant clinical improvement criterion and should receive new technology add-on payment for FY 2005. We have found that, based on the new evidence provided, Kinetra® does represent a substantial clinical improvement over the previous Solettra™ device. Specifically, the increased patient control, reduced surgery, fewer complications, and elimination of environmental interference significantly improve patient outcomes. Since we stated in the proposed rule that the device meets the newness criterion, and that the device meets the cost threshold in the DRGs to which it is assigned, this determination of substantial clinical improvement warrants the approval of Kinetra® for new technology add-on payments for FY 2005.

Comment: The applicant also recommended that, if approved for add-on payment, CMS should require both the procedure code that identifies the neurostimulator device for deep brain stimulation (02.93) in addition to the code that identifies the placement of the

generator in the chest cavity (86.95). In addition, it commented that any concern over double-payment if implantation occurs in a staged manner (that is, in separate inpatient admissions or in different settings that Medicare pays for) would be ameliorated if we require that both these two ICD-9-CM codes be required in a case that is mapped to either DRG 1 or 2 (Craniotomy with and without CC).

Response: We agree that this is the best approach to resolving both the reimbursement issue as well as concerns over the possibility of paying for the device twice if performed in different settings (that is, a staged implantation). We are approving new technology add-on payments for the Kinetra® device for FY 2005 in this final rule. Cases receiving Kinetra® for Parkinson's disease or essential tremor on or after October 1, 2004 will be eligible to receive an add-on payment of up to \$8,285, or half the cost of the device, which is approximately \$16,570. These cases will be identified by the presence of procedure codes 02.93 (Implantation or replacement of intracranial neurostimulator leads) and 86.95 (Insertion or replacement of dual array neurostimulator pulse generator). If a claim has only the procedure code identifying the implantation of the intracranial leads, or if the claim identifies only insertion of the generator, no add-on payment will be made.

Comment: Commenters expressed disappointment that we did not approve this device in our proposed rule. However, they remarked upon the complex issues that were raised by our concerns. Specifically, commenters urged that CMS adopt and maintain a uniform standard between the inpatient PPS and the outpatient PPS, urging CMS to make consistent decisions for devices that may be used appropriately in both settings. The commenters specifically referenced different sets of language defining substantial improvements from the OPSS rules, urging the IPPS to follow the guidance of the policies set forth in the OPSS.

Response: The commenters' specific reference to the language in the November 1, 2002 outpatient prospective payment system final rule (67 FR 66781 through 66783) that refers to determinations of substantial clinical improvement where factors such as "increased battery life" and "miniaturization, might so improve convenience, durability and ease of operation" was taken out of context. The November 1, 2002 final OPSS rule states, "[n]evertheless, there may be some improvements in the medical

technology itself that are so significant that we may wish to recognize them for separate payment * * * even though they do not directly result in substantial clinical improvements." To date, the OPSS has only applied these explicit substantial clinical improvement criteria to pass-through device category applications. We have not yet determined whether to apply this particular standard within IPPS. However, we are approving the Kinetra® device for new technology add-on payments for FY 2005, without reference to these considerations. We will continue to consider whether to employ specific factors such as those identified for the OPSS in the IPPS.

Comment: Several commenters noted the importance of the programmability of the device, especially for patients who live at a distance from their physician and would not be able to visit frequently to adjust the level of stimulation as would be necessary with the Soletra™ device. One commenter (a physician) noted that "the problem [with the Soletra™ device] has been so severe in some patients that [he has] had to loan them a regular physician programmer so that they could do the adjustments at home." He noted further that the Soletra™ programmer is not meant for patient use and encouraged CMS to approve add-on payment for Kinetra® so he can use it in his practice.

Response: We do not know the protocol for doctor-patient programming of the Soletra™ device, however, we are approving add-on payment for Kinetra® for FY 2005.

Comment: We received one comment that cited that "the use of Kinetra® in the VA system is preferred by an almost 3 to 1 ratio versus the previous technology" whereas the usage in Medicare was only approximately 1 to 4.

Response: We do not know where the commenter received the data in this comment, as we were not given this data by the applicant. However, we are approving Kinetra® for add-on payment for FY 2005.

g. Intramedullary Skeletal Kinetic Distractor (ISKD)

Orthofix, Inc. submitted an application for approval of the Intramedullary Skeletal Kinetic Distractor (ISKD) Internal Limb Lengthener for new technology add-on payments for FY 2005. The device received FDA marketing approval on May 2, 2001. The ISKD System is a "closed" lengthening system. There are no fixation pins exiting the skin, thus eliminating this portal for entry of infectious organisms. The device is

implanted in the intramedullary canal. This provides mechanical stability and support to the bone segments during the distraction, regeneration and consolidation phases, thus reducing the opportunity for misalignment.

In the May 18, 2004, proposed rule, we indicated that we had reviewed the application and technology, and we had determined that the device is not new and cannot be approved for new technology add-on payments because it came on the market on May 2, 2001. The costs of the device are thus reflected in the FY 2001 MedPAR file, as acknowledged by the manufacturer's data. As a result, the costs of the device are already reflected in the DRG weights.

The manufacturer submitted charge data for cases found in the FY 2001 MedPAR file, as well as data from several hospitals that have used the device. The manufacturer identified cases using ICD-9-CM codes 78.35 (Limb lengthening procedure, femur) and 78.37 (Limb lengthening, tibia/fibula). These procedure codes occur in four DRGs: DRGs 210 and 211 (Hip and Femur Procedures Except Major Joint Procedures Age > 17, With and Without CC, respectively) and DRGs 218 and 219 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur Age > 17, With and Without CC). The average charges for cases involving these procedure codes identified by the applicant were not standardized. The average charges provided for DRGs 210, 211, 218, and 219 were \$26,692, \$18,187, \$32,959 and \$20,228, respectively. The manufacturer then added the cost of the device, which the manufacturer states is \$6,750. The manufacturer projects that, in FY 2005, there will be 9 cases in DRG 210, 4 cases in DRG 211, 28 cases in DRG 218, and 19 cases in DRG 219, which results in a case-weighted threshold of \$22,347. Thus, according to the manufacturer's data, because the case-weighted average standardized charges of \$27,003 for the technology are greater than the cost threshold of \$22,347 for these projected 60 cases, the ISKD would qualify for new technology add-on payments.

The manufacturer also stated that the ISKD met the substantial clinical improvement criterion because, in addition to the improvements mentioned above (reduces infection rates and provides mechanical stability), lengthening with the ISKD occurs gradually and with no soft tissue impingement, reducing two factors commonly associated with pain during distraction. In addition, the manufacturer pointed out that with the ISKD, the lengthening procedure is

discreet because there are no external pins. There is no cumbersome external frame that may hinder the patient's activities of daily living, or draw further attention to the discrepant limb. In addition, the patient may have partial weight bearing during the lengthening process and resume some activities of normal living.

However, because the device is already captured in our DRG weights, in the May 18, 2004 proposed rule, we proposed to deny the application for the ISKD device for new technology add-on payments for FY 2005.

Prior to publication of the proposed rule, we received no public comments on this application. During the 60-day comment period for the proposed rule, we received the following public comments on this application.

Comment: The applicant noted that it was very disappointed with CMS' proposal to deny add-on payments for this device. It stated that, although the device may be paid for in the DRG system, so few cases have received the device that the costs related to the device are not accurately reflected in the data used to recalibrate the DRG weights. It argues that the low volume of cases that have received the device has been a direct result of underpayment for the device and that CMS is denying this treatment to beneficiaries by not paying more for this device. The applicant also stated that if we had asked for market data in the application, it would have provided that information to us sooner, and would have had the opportunity to present its argument that the device did, in fact, have a delay between FDA approval and coming to the market. It stated that the "delay between FDA approval and commercial availability was due to a halt in production while certain changes on the ISKD were validated." It also noted that the company "conducted a comprehensive review of its sales database" and has determined that the first commercial sales of the device were made in February 2002, and as such, the costs of the device were not included in the FY 2001 MedPAR.

Response: This device has been on the market for more than the 2- to 3-year period for which new technology add-on payments are allowed. Even though there may have been a delay in commercial availability of the device, the company stated that sales were made in February of 2002. We note that we are not using strictly the FY 2001 MedPAR as our basis for determining newness in FY 2005, but are denying add-on payments to those products that were on the market prior to midway into FY 2002. Products that were in use prior

to April of 2002 have data for more than half of FY 2002 so that the costs of the new technology were included in the DRG recalibration in subsequent years. We have been making payments for the ISKD device since it came on the market and data reflecting the cost of the device are therefore already reflected in the DRG weights. Therefore, we cannot find that the device is new and we are finalizing our proposal to deny this applicant new technology add-on payments.

h. Acticon™ Neosphincter

American Medical Systems submitted an application for approval of the Acticon™ Neosphincter for new technology add-on payments for FY 2005. The Acticon™ Neosphincter is a small, fluid-filled prosthesis that is completely implanted within the body. The Acticon™ Neosphincter prosthesis has been developed to treat severe fecal incontinence (the accidental loss of solid or liquid stool at least weekly). It is designed to mimic the natural process of bowel control and bowel movements. The prosthesis consists of three components: an occlusive cuff implanted around the anal canal, a pressure-regulating balloon implanted in the prevesical space, and a control pump with septum implanted in the scrotum. All components are connected with color-coded, kink-resistant tubing.

The FDA approved the Acticon Neosphincter for use on December 18, 2001. A technology can be considered new only 2 to 3 years after data reflecting the costs of the technology begin to become available. Data on the costs of this technology began to become available after the December 2001 FDA approval. As a result, the costs of this technology are currently reflected in the DRG weights. Therefore, in the proposed rule, we indicated that we had determined that Acticon™ Neosphincter does not meet this criterion.

Although we proposed not to approve this application because Acticon™ Neosphincter does not meet the newness criterion, we noted that the applicant submitted information on the cost criterion and substantial clinical improvement criterion. The applicant submitted 23 cases (that are indistinguishable as to whether they are Medicare or non-Medicare) using ICD-9-CM procedure codes 49.75 (Implantation or revision of artificial anal sphincter) and 49.76 (Removal of artificial anal sphincter) in order to identify cases where the Acticon™ Neosphincter was used. Of these cases, 9 were in DRG 157 (Anal and Stomal Procedures With CC), and 14 were in

DRG 158 (Anal and Stomal Procedures Without CC). The average standardized charge per case was \$16,758. The case-weighted threshold for DRGs 157 and 158 (39.1 percent of cases in DRG 157 and 60.1 percent of cases in DRG 158) for this technology is \$14,426. Therefore, according to the applicant, the Acticon™ Neosphincter meets the cost criterion.

The applicant states in its application that the Acticon™ Neosphincter represents a substantial clinical improvement for the following reasons: (1) There is no other existing device in the United States that can be used to treat severe fecal incontinence; and (2) self-treatment for severe fecal incontinence has proven to be largely unsuccessful and surgical options have historically been more limited, including sphincteroplasty or muscle transposition.

However, because Acticon™ Neosphincter does not meet the newness criterion, we proposed to deny add-on payments for this new technology. The applicant also requested a DRG reclassification for this technology. In section II.B.4 of the preamble of this final rule, we are finalizing our proposal to remove codes 49.75 and 49.76 from DRGs 157 and 158, and reassign them to DRGs 146 (Rectal Resection With CC) and 147 (Rectal Resection Without CC) in MDC 6 (Diseases and Disorders of the Digestive System) only. All other MDC and DRG assignments for codes 49.75 and 49.76 remain the same.

Prior to the publication of the May 18, 2004 proposed rule, we received public comments in accordance with section 50(b)(2) of Pub. L. 108-173 regarding this application for add-on payments.

One commenter noted that the implant of the Acticon™ Neosphincter avoids the life-altering and disfiguring consequences of a permanent stoma. Another commenter noted that the implant of the Acticon™ Neosphincter avoids the need for a colostomy, which limits a patient's ability to travel and work due to the fact they could have a fecal accident at any time. However, because we concluded that the Acticon™ Neosphincter is no longer new, we proposed that it is not eligible for add-on payments.

During the 60-day comment period for the May 18, 2004 proposed rule, we received the following public comments on this application.

Comment: One commenter, the applicant, commented that the Acticon™ Neosphincter should still be considered new under the newness criterion since the device received FDA approval on December 18, 2001 and

ICD-9-CM codes (49.75 and 49.76) became effective October 1, 2002. The commenter believes that only after the ICD-9-CM codes became available did data begin to reflect the costs of the technology in the DRGs. Based on the issuance of the codes, there is only 1½ years of data and this is the first year CMS is using data with the new ICD-9-CM codes that reflect the Acticon™ Neosphincter within the DRGs. As a result, the commenter maintains that the Acticon™ Neosphincter is still “new” under 42 CFR 412.87(b)(2).

The commenter also noted that the standardized charges per case of \$16,758 are actually the standardized costs per case. The correct average charge per case based on the data submitted is \$41,396.

Response: As stated above, a technology can be considered new only 2 to 3 years after data reflecting the costs of the technology begin to become available. Data on the costs of this technology began to become available after the December 2001 FDA approval and the costs of this technology are currently reflected in the DRG weights. As a result, the Acticon™ Neosphincter does not meet the newness criterion. For a further discussion regarding the effect of FDA approval dates and the issuance of ICD-9-CM codes upon our evaluation of the newness criterion, please see the preamble above.

Also, in reference to the cost data, we appreciate the commenter pointing out this error and agree that the average case weighted standardized charge is \$41,396. Because the average case weighted standardized charge is greater than the average case weighted threshold of \$14,426, the commenter maintains that the Acticon™ Neosphincter meets the cost criterion. However, because the Acticon™ Neosphincter does not meet the newness criterion, we are denying add-on payments for this technology in FY 2005.

We are finalizing our proposal not to approve this technology for add-on payments for FY 2005.

i. TandemHeart™ Percutaneous Left Ventricular Assist System

Brigham and Women's Hospital submitted an application for approval of the TandemHeart™ Percutaneous Ventricular Assist System (PVTA) manufactured by Cardiac Assists, Inc., for new technology add-on payments for FY 2005. Cardiac Assists, Inc. has been assisting the applicant with supplemental information and data to support the application process. According to the manufacturer, the device contains a controller, arterial and

venous cannulae, and the TandemHeart™ Percutaneous Ventricular Assist Device (pVAD) that works parallel with the left ventricle to provide left ventricular circulatory support. The device is intended for extracorporeal circulatory support using an extracorporeal bypass circuit. The duration of use approved by the FDA is for periods of up to 6 hours.

On November 11, 2000, FDA approved the AB-180 XC Blood Pump (also known as the TandemHeart™ pVAD) as a single use, disposable centrifugal blood pump designed to circulate blood through an extracorporeal circuit. On May 23, 2003, FDA approved the CardiacAssist Transseptal Cannula Set for transseptal catheterization of the left atrium via the femoral vein for the purpose of providing a means for temporary (6 hours or less) left ventricular bypass when connected to a suitable extracorporeal blood pump unit that returns blood to the patient via the femoral artery or other appropriate site. The manufacturer stated that, although the TandemHeart™ pVAD was approved in November 2000, this device should still be considered new because the device was not marketed and sold to hospitals until the CardiacAssist Transseptal Cannula Set was approved by FDA in May 2003. We have received confirmation from hospitals that the TandemHeart™ pVAD was indeed not marketed until FDA approved the CardiacAssist Transseptal Cannula Set. Also, only half of a year's worth of data containing the TandemHeart™ pVAD is reflected within the FY 2003 MedPAR file. The manufacturer stated that approximately 60 TandemHeart™ pVADs have been used since the FDA approved the Cardiac Arrest Transseptal Cannula Set in May 2003. Therefore, the costs of the TandemHeart™ pVAD are not adequately reflected within the DRGs. As a result, we consider the TandemHeart™ pVAD to be new under our criterion.

As stated above, according to the manufacturer, approximately 60 TandemHeart™ pVADs have been used since the FDA approved the Cardiac Assist Transseptal Cannula Set in May 2003 (not all of these have been used in Medicare beneficiaries). However, only two actual cases were submitted by the applicant with an ICD-9-CM code of 37.65 (Implant of an external pulsatile heart assist system) used to identify the device. As stated in the September 7, 2001, final rule (66 FR 46916), data submitted by the applicant must be of a sufficient sample size to demonstrate a significant likelihood that the true mean across all cases likely to receive

the technology will exceed the threshold established by CMS. We indicated in the proposed rule that, because we lack a significant sample of data reflecting the costs of this technology, we could not accurately determine the average charge per case for the TandemHeart™ pVAD. Neither could we determine whether this technology meets our cost criterion. We indicated that if we received sufficient data to complete our analysis in time for inclusion in the final rule, we would assess whether this technology meets the cost criterion.

In response to this request, the manufacturer and applicant submitted supplementary data on the TandemHeart™ pVAD. We received a total of 11 actual cases that used the Tandem Heart. Although these cases are approximately 18 percent of all TandemHeart™ pVAD cases, we cannot consider this a significant sample of cases to determine if the Tandem Heart meets the cost criterion. Of the 11 cases submitted, the variance in charges from the lowest charge per case to highest charge per case was close to 1 million dollars. Such a large variance in charges per case will require us to consider many more cases in excess of the 11 cases submitted and the 60 total cases that have used the device since its inception before we can determine if the TandemHeart™ pVAD meets the cost criterion. Also, because this is a small pool of cases, one unrepresentative case could skew the results of the data. As a result, because there are insufficient data for us to determine whether the TandemHeart™ pVAD meets the cost criterion, we are denying add-on payments for this technology in FY 2005.

Although we are not approving this application because we did not have sufficient data to determine whether TandemHeart™ pVAD meets the cost criterion, in the proposed rule we noted that the applicant submitted information on the substantial clinical improvement criterion. The applicant stated in its application that the TandemHeart™ pVAD represents a substantial clinical improvement because, at present, the only alternative to intra-aortic balloon pump support is the surgical implantation of a ventricular assist device. The TandemHeart™ pVAD is the only therapeutic intervention that is capable of achieving effective circulatory support to stabilize cardiogenic shock patients that could be placed via a percutaneous approach. In the proposed rule, we indicated that we would present a full analysis of this technology under the significant improvement

criterion if we received sufficient data in time for this final rule to evaluate whether the technology met the cost criterion. For this final rule, as we have determined above, the TandemHeart™ pVAD does not meet the cost criterion and therefore we are not presenting our full analysis of this technology under the substantial improvement criterion. However, we note, although the TandemHeart™ pVAD appears to be a promising new technology for providing circulatory support in profound, refractory left ventricular failure, our review of the submitted literature did not find that adequate clinical experience or clinical evidence exists to demonstrate substantial clinical improvement to the degree we feel is necessary to warrant a new technology special add-on payment. As a result of this and the fact that there are insufficient data to determine whether the TandemHeart™ pVAD meets the cost criterion, we are denying add-on payments in FY 2005 for this technology.

Nevertheless, we encourage the manufacturers of the TandemHeart™ pVAD device to continue their efforts to compile objective clinical data that demonstrate its clinical efficacy, particularly with regard to improved clinical outcomes in patients with this very serious, life threatening condition. Because the device only became available for use in May 2003, it could remain eligible for consideration for new technology add-on payments in FY 2006.

The applicant also requested an ICD-9-CM code for this technology. We discuss this request in section II.B.3. of the preamble of this final rule.

j. Aquadex™ System 100 Fluid Removal System (System 100)

CHF Solutions, Inc. submitted an application for the approval of the System 100 for new technology add-on payments for FY 2005. The System 100 is designed to remove excess fluid (primarily excess water) from patients suffering from severe fluid overload through the process of ultrafiltration. Fluid retention, sometimes to an extreme degree, is a common symptom of patients with chronic congestive heart failure. This technology removes excess fluid without causing hemodynamic instability. It also avoids the inherent nephrotoxicity and tachyphylaxis associated with aggressive diuretic therapy, the mainstay of current therapy for fluid overload in congestive heart failure.

The System 100 consists of: (1) A S-100 console; (2) a UF 500 blood circuit; (3) an extended length catheter (ELC);

and (4) a catheter extension tubing. The System 100 is designed to monitor the extracorporeal blood circuit and to alert the user to abnormal conditions. Vascular access is established via the peripheral venous system, and up to 4 liters of excess fluid can be removed in an 8-hour period.

On June 3, 2002, FDA approved the System 100 for use with peripheral venous access. On November 20, 2003, FDA approved the System 100 for expanded use with central venous access and catheter extension use for infusion or withdrawal circuit line with other commercially applicable venous catheters. According to the applicant, although the System 100 was first approved by FDA in June 2002, the System 100 was not used by hospitals until August 2002 because it took a substantial amount of time to market and sell the device to hospitals. As a result, the applicant believes that the System 100 should still be considered new. The applicant has presented data and evidence demonstrating that the System 100 was not marketed until August 2002. Therefore, we also believe August 1, 2002 is the relevant date for determining the availability of the System 100.

The applicant estimates that 308 patients (approximately 120 cases per year) have used the System 100 since its inception and the potential population for use of the device is 60,000 cases per year. These 308 cases represent a small percentage of the potential number of cases that can utilize the System 100. Therefore, the System 100 is not adequately reflected within the DRG weights (as discussed in the September 7, 2001 final rule (66 FR 46914)). In addition, the System 100 is within the 2 to 3 year period contemplated under § 412.87(b)(2) of the regulations. Therefore, the System 100 could be considered new. However, the ultrafiltration process that the System 100 employs can also be considered to be a type of hemodialysis, which is an old and well-established technology. In the proposed rule, we indicated that we have concerns about whether new technology add-on payments should be extended to a well-established technology, even when a new clinical application is developed for that technology. As discussed above, in the September 7, 2001 final rule (66 FR 46915), we noted that if an existing technology is used for treating patients not expected to be assigned to the same DRG as the patients already receiving the technology, it may be considered for approval if it also meets the other cost and clinical improvement criteria. In this case, the device does treat a

different patient population of congestive heart failure than the patient population for renal dialysis. Under the policy described in the September 7, 2001, final rule, this technology may be considered new for the purposes of determining whether it qualifies for add-on payments. However, in the proposed rule, we indicated that we have some concerns about whether this is an appropriate result, and about whether technologies that have been in use for many years, in some cases decades, should be able to qualify for add-on payments for new technologies. Therefore, we invited comments on whether this technology should be considered new, and on the general issue of whether existing technologies should be approved for add-on payments when new applications are developed for these technologies and whether special standards regarding, for example, clinical improvement, should be applied in such cases.

Comment: One commenter, the applicant, explained that the System 100 should still be considered new for numerous additional reasons. The commenter explained that System 100 has received numerous patents issued from the United States Patent Office for many aspects of the technology thus demonstrating its uniqueness and newness. The commenter also added that the technology should be considered new since the FDA recognized the features of the technology, such as proprietary design of the filter assembly and its unique low flow capability, as a different technology because the device can be used in a different patient population. The commenter further explained that no other technology operates in this low flow range using automatic pressure control algorithms and peripheral vascular access while delivering ease of use and patient safety.

Some commenters recommended that CMS maintain the criteria and definition established in the September 7, 2001, **Federal Register** (66 FR 46915) that if an existing technology is used for treating patients not expected to be assigned to the same DRG as the patients already receiving the technology, it may be considered for approval if it also meets the other cost and clinical improvement criterion. As a result, the commenters maintain that according to the September 7, 2001, final rule the System 100 meets these criteria and should be approved for new technology add-on payments.

Response: We appreciate the commenter's comments on the newness criterion. As noted above, we do not employ FDA guidelines to determine

what drugs, devices or technologies qualify for new technology add-on payments. We also do not consider patents issued by the United States Patent Office as an indicator of a new technology. For a more detailed discussion of the criteria for newness and substantial clinical improvement please see the September 7, 2001, **Federal Register** (66 FR 46914).

We will continue to review the policy stated in our September 7, 2001, rule. We invite further public comment on this issue in the interim.

The applicant submitted five sets of data to demonstrate that the System 100 meets the cost criterion. Of these five, three sets of data were flawed in the analysis of the cost criterion. Therefore, as in the proposed rule, we discuss only the data that are most accurate and relevant. It is important to note at the outset of the cost analysis that the console is reusable and is, therefore, a capital cost. Only the circuits and catheters are components that represent operating expenses. Section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act, which makes no mention of any add-on payments for a new medical service or technology. Therefore, it is not appropriate to include capital costs in the add-on payments for a new medical service or technology and these costs should also not be considered in evaluating whether a technology meets the cost criterion. The applicant has applied for add-on payments for only the circuits and catheter, which represent the operating expenses of the device. However, in the proposed rule we stated our belief that the catheters cannot be considered new technology in any sense. As a result, we considered only the UF 500 disposable blood circuit as relevant to the evaluation of the cost criterion.

The applicant commissioned Covance to search the FY 2002 MedPAR file. The applicant used a combination of diagnosis codes to determine which cases could potentially use the System 100. Covance found 27,589 cases with the following combination of ICD-9-CM diagnosis codes: 428.0 through 428.9 (Heart Failure), 402.91 (Unspecified with Heart Failure), or 402.11 (Hypertensive Heart Disease with Heart Failure), in combination with 276.6 (Fluid Overload) and 782.3 (Edema).

The 27,589 cases were found among 281 DRGs with 49.4 percent of cases mapped across DRGs 88, 89, 127, 277 and 316. The applicant eliminated those DRGs with less than 150 cases, which resulted in a total of 22,024 cases that could potentially use the System 100. The case-weighted average standardized charge across all DRGs was \$14,534. The case-weighted threshold across all DRGs was \$17,789. Although the case-weighted threshold is greater than the case-weighted standardized charge, it is necessary to include the standardized charge for the circuits used in each case. In order to establish the charge per circuit, the manufacturer submitted data regarding 51 actual cases that used the System 100. Based on these 51 cases, the standardized charge per circuit was \$2,209. The manufacturer also stated that an average of two circuits are used per case. Therefore, adding \$4,418 for the charge of the two circuits to the case-weighted average standardized charge of \$14,534 results in a total case-weighted standardized charge of \$18,952. This is greater than the case-weighted threshold of \$17,789. In the May 18, 2004 proposed rule, we welcomed comments from the public on the charge information submitted by the applicant for the circuits.

Comment: One commenter noted that we stated, “[c]atheters cannot be considered new technology in any sense.” The commenter stated that this language on catheters is unduly broad and it is possible that the introduction of a new catheter could represent a substantial clinical improvement. The commenter also noted that a catheter could be considered new under CMS policy specified in the September 7, 2001, **Federal Register** (66 FR 46915) that discusses if the new use of an existing technology is for treating patients not expected to be assigned to the same DRG, it may be considered for approval of new technology add-on payments.

Response: We thank the commenter for pointing this out and we agree that in a certain circumstance a catheter could be considered a new technology under our current policy. We also note that we are continuing to review our policy regarding whether a new use of an existing technology may be considered for approval of new technology add-on payments.

For the proposed rule, using the FY 2003 MedPAR file, we used the same combination of diagnosis codes to identify 28,660 cases across all DRGs. As in the applicant’s analysis, we eliminated those DRGs with less than 150 cases, which resulted in 22,395 cases. The case-weighted average

standardized charge for these cases is \$15,447. The case-weighted threshold to qualify for new technology add-on payments using the data we identified would then be \$18,029. Again, as in the applicant’s analysis, it was necessary to include in the charge of \$4,418 for the circuits. This results in a total case-weighted average standardized charge of \$19,865, which is also greater than the case-weighted threshold of \$18,029. Based on these two analyses, the System 100 meets the cost criterion.

The applicant contends that the System 100 represents a substantial clinical improvement for the following reasons: It removes excess fluid without the use of diuretics; it does not lead to electrolyte imbalance, hemodynamic instability or worsening renal function; it can restore diuretic responsiveness; it does not adversely affect the renin-angiotensin system; it reduces hospital length of stay for the treatment of congestive heart failure, and it requires only peripheral venous access. In the proposed rule we stated our belief that there was some basis for concluding that the System 100 represents a substantial clinical improvement over current standard treatment of fluid overload in congestive heart failure. However, in the May 18, 2004 proposed rule, we also invited comment on whether the data submitted are indeed adequate to demonstrate significant clinical improvement.

Prior to the publication of the May 18, 2004, proposed rule, we received public comments in accordance with section 503(b)(2) of Public Law 108-173 regarding this application for add-on payments. Several commenters noted that the System 100 provides physicians a new treatment option for patients with fluid overload who are unresponsive to diuretics and has been documented in clinical studies and other published articles to effectively treat fluid overload. Another commenter noted that patients who have been treated with the System 100 seem to have improved health versus those who have lingered on diuretic therapy or have been treated by hemodialysis. The commenter also noted that the System 100 reduces hospital stays. Other commenters noted that the System 100 is safer for those patients in terms of reduced electrolyte imbalance and renal dysfunction and is a major step forward in the treatment of decompensated heart failure.

We considered these comments in our evaluation in the proposed rule of whether the System 100 meets this substantial clinical improvement criterion. During the 60-day comment period for the proposed rule, we

received the following comments on this application.

Comment: One commenter, the applicant, illustrated that there remains a growing unmet clinical need for effective treatment of the congestive heart failure population. The need for new technologies to treat fluid overload is demonstrated through data from the ADHERE registry which states that the percentage of heart failure patients discharged but still symptomatic of fluid retention is 39 percent. The registry had other notable facts and concluded that chronic diuretic therapy is due to fluid overload seen in patients with and without renal insufficiency and is an independent predictor of poor clinical outcomes and higher resource utilization. The commenter concluded that the emerging knowledge of congestive heart failure patients suffering from fluid overload demonstrates the need for efficient and effective fluid removal such as the System 100.

Some commenters also commented that the System 100 meets the established criteria for new technology since it is clearly and distinctly new and different from any currently available technology and provides clinical services to patients who previously were ineligible for this kind of therapy, and treats a different patient population—heart failure versus renal failure. Furthermore, these commenters also noted that patients with fluid overload are treated in a different DRG than patients who have renal failure.

The applicant also noted that there are some clinical trials that have demonstrated the clinical safety and effectiveness as well as cost effectiveness of the System 100 in treating patients with fluid overload.

Response: We thank the commenters for their comments on this criterion. After careful review of all available information, we have determined that although we recognize the potential benefit of this new technology for Medicare beneficiaries (as stated by the commenter), we do not believe there is sufficient objective clinical evidence to determine that the System 100 meets the substantial clinical improvement criterion (such as a large prospective, randomized clinical trial), given the prevalence of congestive heart failure in the Medicare population. For example, a large prospective, randomized clinical trial that demonstrates improved outcomes, especially in morbidity and mortality, when compared to standard therapy for this sub-population of Medicare patients with congestive heart failure was not submitted. As a result,

we are denying add-on payments for this technology for FY 2005.

III. Changes to the Hospital Wage Index

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts “for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.” In accordance with the broad discretion conferred under the Act, we currently define hospital labor market areas based on the definitions of statistical areas established by the Office of Management and Budget (OMB). A detailed discussion of the FY 2005 hospital wage index based on the statistical areas, including OMB’s revised definitions of Metropolitan Areas, appears under section III.B of this preamble.

Beginning October 1, 1993, section 1886(d)(3)(E) of the Act requires that we update the wage index annually. Furthermore, this section provides that the Secretary base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. The survey should measure, to the extent feasible, the earnings and paid hours of employment by occupational category, and must exclude the wages and wage-related costs incurred in furnishing skilled nursing services. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The adjustment for FY 2005 is discussed in section II.B. of the Addendum to this final rule.

As discussed below in section III.G. of this preamble, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating the wage index. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The budget neutrality adjustment for FY 2005 is discussed in section II.B. of the Addendum to this final rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the initial collection of these data and the occupational mix adjustment that we are applying beginning October 1, 2004 (the FY 2005 wage index) appears under section III.C. of this preamble.

B. Revised OMB Definitions for Geographical Statistical Areas

1. Current Labor Market Areas Based on MSAs

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. In accordance with the broad discretion under section 1886(d)(3)(E) of the Act, we currently define hospital labor market areas based on the definitions of Metropolitan Statistical Areas (MSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs) issued by OMB. OMB also designates Consolidated MSAs (CMSAs). A CMSA is a metropolitan area with a population of one million or more, comprising two or more PMSAs (identified by their separate economic and social character). For purposes of the hospital wage index, we use the PMSAs rather than CMSAs because they allow a more precise breakdown of labor costs. If a metropolitan area is not designated as part of a PMSA, we use the applicable MSA.

These different designations use counties as the building blocks upon which they are based. Therefore, hospitals are assigned to either an MSA, PMSA, or NECMA based on whether the county in which the hospital is located is part of that area. For purposes of the IPPS wage index, we combine all of the counties in a State outside a designated MSA, PMSA, or NECMA together to calculate a statewide rural wage index.

2. Core-Based Statistical Areas

OMB reviews its Metropolitan Area (MA) definitions preceding each decennial census. In the fall of 1998, OMB chartered the Metropolitan Area Standards Review Committee to examine the MA standards and develop recommendations for possible changes to those standards. Three notices related to the review of the standards were published on the following dates in the **Federal Register**, providing an opportunity for public comment on the recommendations of the Committee: December 21, 1998 (63 FR 70526);

October 20, 1999 (64 FR 56628), and August 22, 2000 (65 FR 51060).

In the December 27, 2000, **Federal Register** (65 FR 82228 through 82238), OMB announced its new standards. According to that notice, OMB defines a Core-Based Statistical Area (CBSA), beginning in 2003, as “a geographic entity associated with at least one core of 10,000 or more population, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties. The standards designate and define two categories of CBSAs: Metropolitan Statistical Areas and Micropolitan Statistical Areas.” (65 FR 82235)

According to OMB, MSAs are based on urbanized areas of 50,000 or more population, and Micropolitan Statistical Areas (referred to in this discussion as Micropolitan Areas) are based on urban clusters of at least 10,000 population but less than 50,000 population. Counties that do not fall within CBSAs are deemed “Outside CBSAs.” In the past, OMB defined MSAs around areas with a minimum core population of 50,000, and smaller areas were “Outside MSAs.”

The general concept of the CBSAs is that of an area containing a recognized population nucleus and adjacent communities that have a high degree of integration with that nucleus. The purpose of the standards is to provide nationally consistent definitions for collecting, tabulating, and publishing Federal statistics for a set of geographic areas. CBSAs include adjacent counties that have a minimum of 25 percent commuting to the central counties of the area. This is an increase over the minimum commuting threshold for outlying counties applied in the previous MSA definition of 15 percent.

On June 6, 2003, OMB announced the new CBSAs, comprised of MSAs and the new Micropolitan Areas based on Census 2000 data. (A copy of the announcement may be obtained at the following Internet address: <http://www.whitehouse.gov/omb/bulletins/fy04/b04-03.html>.) The new definitions recognize 49 new MSAs and 565 new Micropolitan Areas, and extensively revise the composition of many of the existing MSAs. There are 1,090 counties in MSAs under these new definitions (previously, there were 848 counties in MSAs). Of these 1,090 counties, 737 are in the same MSA as they were prior to the changes, 65 are in a different MSA, and 288 were not previously designated to any MSA. There are 674 counties in Micropolitan Areas. Of these, 41 were previously in an MSA, while 633 were not previously designated to an MSA. There are five counties that previously

were designated to an MSA but are no longer designated to either an MSA or a new Micropolitan Area: Carter County, KY; St. James Parish, LA; Kane County, UT; Culpepper County, VA; and King George County, VA.

3. Revised Labor Market Areas

In its June 6, 2003 announcement, OMB cautioned that these new definitions “should not be used to develop and implement Federal, State, and local nonstatistical programs and policies without full consideration of the effects of using these definitions for such purposes. These areas should not serve as a general-purpose geographic framework for nonstatistical activities, and they may or may not be suitable for use in program funding formulas.”

We have previously examined alternatives to the use of MSAs for the purpose of establishing labor market areas for the Medicare wage index. In the May 27, 1994, proposed rule (59 FR 27724), we presented our latest research concerning possible future refinements to the labor market areas. Specifically, we discussed and solicited comment on the proposal by the Prospective Payment Assessment Commission (ProPAC, a predecessor organization to the Medicare Payment Advisory Commission (MedPAC)) for hospital-specific labor market areas based on each hospital’s nearest neighbors, and our research and analysis on alternative labor market areas. Even though we found that none of the alternative labor market areas that we studied provided a distinct improvement over the use of MSAs, we presented an option using the MSA-based wage index but generally giving a hospital’s own wages a higher weight than under the current system. We also described for comment a State labor market option, under which hospitals would be allowed to design labor market areas within their own State boundaries.

We described the comments we received in the June 2, 1995, proposed rule (60 FR 29219). There was no consensus among the commenters on the choice for new labor market areas. Many individual hospitals that commented expressed dissatisfaction with all of the proposals. However, several State hospital associations commented that the options merited further study. Therefore, we contacted the association representatives that participated in our November 1993 meeting on labor market issues in which we solicited ideas for additional types of labor market research to conduct. None of the individuals we contacted suggested any ideas for further research.

Consequently, we have continued to use MSAs to define labor market areas for purposes of the wage index. While we recognize MSAs are not designed specifically to define labor market areas, we believe they do represent a useful proxy for this purpose, and our analysis and discussion here are focused on issues related to adopting the new CBSAs to define labor market areas.

Comment: Many commenters recommended various revisions to the proposed labor market definitions. Many of these comments focused on specific situations, especially situations in which previously large MSAs were divided into smaller MSAs under the new definitions, and the converse situation in which MSAs expanded under the new definitions. One commenter, proposed an extensive reconfiguration of CMS’ labor market areas. Specifically, the commenter recommended that, instead of expanding certain MSAs, we create a system of overlapping markets, beginning with a core labor market, consisting of the original MSA and center city, and creating overlapping subdivisions, or “tiers,” out of the areas outside the core. Furthermore, the commenter cites a U.S. Government Accountability Office (GAO) report that called for CMS to refine its MSA-based wage index areas so that they might better represent actual hospital labor markets, which could potentially entail reducing the size of some large urban markets because of the large disparities between the wage levels in central cities, large towns, and outlying counties.

The proposal begins with all counties associated with the urban area, either under the old or new MSAs, which are then subdivided based upon PMSAs or Metropolitan Divisions. These areas would be ranked according to wage level, assigning the highest wage area as the “core.” Then overlapping labor markets would be formed as each subsequent ranked area is packaged with the center city, creating tiers of labor markets. A wage index would be developed for each tier, retaining a high wage value reflective of the center city, and successively lower wage levels for the surrounding areas. As the labor markets incorporate one another and build upon the central area, the system acknowledges the interaction between the given areas but fairly accounts for the wage level differences encompassed therein.

The commenter asserts that this system will adequately recognize the higher labor costs in the core area and moderate the funding differential between the central area and the

outlying communities, who are undoubtedly linked to the core area. It would also afford more reclassification opportunities for hospitals within the greater metropolitan area and prevent the 'orphanization' of hospitals whose provider neighbors are reclassified into higher wage areas while they retain their geographic wage index.

Other commenters objected to the division of certain MSAs, and advocated restoring the larger MSAs that existed under the previous definitions. These commenters contended that the smaller MSAs do not adequately capture the regional nature of markets for hospital labor.

Other commenters, especially those that would benefit from specific changes, supported the changes previously cited. Hospitals in a high wage area supported the proposal to split their area off from the lower wage areas around the fringe of the large MSA to which they had belonged under the old definitions. Hospitals that are included in a higher wage MSA under the new definitions also expressed strong support for the expansion of this MSA, and specifically requested that we make no changes in the proposal.

Response: We appreciate the detailed and substantive recommendations provided by these commenters. These recommendations merit further study and consideration. However, we do not believe that it would be prudent to proceed with any of these recommendations at this time, for several reasons. First, these recommendations are not entirely consistent, since some emphasize expanding existing MSAs or preserving large MSAs that existed under the old definitions, and others emphasize creating smaller units or at least distinguishing segments within larger MSAs. In addition, the range of comments on specific situations indicates the importance of taking into consideration all of the effects that these proposed revisions might have. Specifically, hospitals that stand to benefit from the new definitions might experience lesser gains from the proposed revisions. Finally, we believe that the 1-year transition that we have proposed will alleviate the concerns of many hospitals, by limiting the reductions that they might otherwise experience from the introduction of the new labor market areas. We will continue to study these issues.

Comment: Several commenters have suggested that the implementation of the new MSAs be delayed at least another year so that alternative solutions may be reviewed.

Response: The new MSA designations were released June 6, 2003. We stated in our August 1, 2003 final rule that CMS was unable to implement the new MSAs immediately but intended to evaluate the impact of the changes for the FY 2005 proposed rule. In essence, we have already delayed the implementation of the new Census information.

Comment: One commenter mentioned the need to closely monitor the population changes in the large Micropolitan areas, as crossing the threshold to 50,000 would create a new MSA. The commenter cited the case of Eagle Pass, TX, which, according to July 1, 2003 population estimates, now exceeds the 50,000 threshold. The commenter states that failure to recognize such areas will unnecessarily cripple growing areas.

Response: In the past, CMS has updated its MSA database annually before the publication of the proposed rule based on OMB's listing of MSAs. While an area may have an estimated population exceeding the threshold, we can only update once OMB recognizes this change. At this time, OMB still recognizes Eagle Pass, TX as a Micropolitan Area.

Comment: Many commenters believe that the large MSA should not be divided into the Metropolitan Divisions as outlined by the new OMB definitions.

Response: In previous years we have utilized PMSAs, a division of the larger CMSA. We believe the usage of Metropolitan Divisions represent the closest approximation to PMSAs, the building block of our current Labor Market Definitions. Therefore, we do not believe that we should abandon the use of these new definitions since they most accurately retain our current structuring of labor market areas. However, given the scope and drastic implications of these new boundaries and to buffer the subsequent negative impact on numerous hospitals, we have decided to provide, during FY 2005, a blend of wage indexes to those hospitals that would experience a drop in their wage indexes because of the adoption of the new labor market areas. Any hospital experiencing a decrease in their wage index relative to its FY 2005 wage index because of the labor market area changes will receive 50 percent of the wage index using the new labor market definitions and 50 percent of the wage index that the provider would have received under the old MSA standards. This blend will apply to any provider experiencing a decrease due to the new definitions, including providers who are reclassifying under MCGRB requirements, section 1886(d)(8)(B) of the Act or section 508 of Public Law

108-173. We describe the determination of this blend in detail below. It is important to note that this blend will not protect hospitals from the effects of a drop in wage index due to any reason other than the usage of the new MSAs. For example, the blend will not apply to changes due to the use of new wage data in calculating the FY 2005 wage index. In other words, the two wage indexes (one wage index reflecting the labor market definitions employed in FY 2004, the other wage index reflecting the new CBSA definitions) used in determining the blended wage index both reflect the new FY 2005 wage data. Both these wage indexes also reflect the 10 percent occupational mix adjustment that we discuss in section III.G of this final rule.

a. New England MSAs

As stated above, we currently use NECMAs to define labor market areas in New England, because these are county-based designations rather than the 1990 MSA definitions for New England, which used minor civil divisions such as cities and towns. Under the previous MSA definitions, NECMAs provided more consistency in labor market definitions for New England compared with the rest of the country, where MSAs are county-based. Under the new CBSAs, OMB has defined the MSAs and Micropolitan Areas in New England on the basis of counties. OMB also established New England City and Town Areas, which are similar to the previous New England MSAs. Therefore, to maintain consistency in the definition of labor market areas between New England and the rest of the country, in the May 18, 2004 proposed rule (69 FR 28250), we proposed to use the New England MSAs under the new CBSA definition.

Comment: Some commenters have expressed concern regarding the adoption of a county-based system for the New England MSAs. They believe that abandoning the city- and town-based areas will inaccurately reflect the labor market areas in New England.

Response: In order to create consistency among all labor market areas and facilitate the maintenance of these areas, we will use the county-based areas for all MSAs in the nation. Census has now defined the New England area around counties, creating a city- and town-based system as an alternative. We believe that adopting county-based labor market areas for the entire country provides consistency and stability in program payment, and minimizes programmatic complexity. In addition, we have consistently employed a county-based system for

New England for precisely that reason: to maintain consistency with the labor market definitions used throughout the country. Because we have never used cities and towns, employing a county-based system in New England maintains that consistent practice.

b. Metropolitan Divisions

A Metropolitan Division is a county or group of counties within a CBSA that contains a core population of at least 2.5 million, representing an employment center, plus adjacent counties associated with the main county or counties through commuting ties. A county qualifies as a main county if 65 percent or more of its employed residents work within the county and the ratio of the number of jobs located in the county to the number of employed residents is at least .75. A county qualifies as a secondary county if 50 percent or more, but less than 65 percent, of its employed residents work within the county and the ratio of the number of jobs located in the county to the number of employed residents is at least .75. After all the main and secondary counties are identified and grouped, each additional county that already has qualified for inclusion in the MSA falls within the Metropolitan Division associated with the main/secondary county or counties with which the county at issue has the highest employment interchange measure. Counties in a Metropolitan Division must be contiguous. (65 FR 82236)

As noted above, in the past, OMB designated CMSAs as Metropolitan Areas with a population of one million or more and comprising two or more PMSAs. We currently use the PMSAs rather than CMSAs to define labor market areas because they comprise a smaller geographic area with potentially varying labor costs due to different local economies. Similarly, in the May 18, 2004 proposed rule, we proposed to use the Metropolitan Divisions where applicable under the CBSA definitions.

Under the CBSA definitions, there are 11 MSAs containing Metropolitan Divisions: Boston; Chicago; Dallas; Detroit; Los Angeles; Miami; New York; Philadelphia; San Francisco; Seattle; and Washington, DC. Although these MSAs were also CMSAs under the prior definitions, in some cases their areas have been significantly altered. Under the prior definitions, Boston was a single NECMA. It is now comprised of 4 Divisions. Los Angeles went from 4 PMSAs to 2 Divisions because 2 MSAs became separate MSAs. The New York CMSA went from 15 PMSAs down to only 4 Divisions. Five PMSAs in Connecticut now become separate

MSAs, and the number of PMSAs in New Jersey goes from 5 to 2, with the consolidation of 2 New Jersey PMSAs (Bergen-Passaic and Jersey City) into the New York-Wayne-White Plains, NY-NJ Division. In San Francisco, only 2 Divisions remain where there were once 6 PMSAs, some of which are now separate MSAs.

Previously, Cincinnati, Cleveland, Denver, Houston, Milwaukee, Portland, Sacramento, and San Juan were all designated as CMSAs, but are not any longer. As noted previously, the population threshold to be designated a CMSA was one million. In most of these cases, counties formerly in a PMSA have become a separate, independent MSA, leaving only the MSA for the core area under the new CBSA definitions.

Comment: Many commenters have expressed their concern regarding the division of large MSAs of 2.5 million population or greater. They are concerned that this dividing of previously larger areas will result in dramatic disparities in wage indexes in what once was a congruous area. Additionally, many hospitals are concerned they did not have the opportunity to reclassify given the dramatic effect of this division of previously consolidated areas.

Response: As indicated above, Metropolitan Divisions represent the closest approximation to PMSAs, the building block of our current labor market definitions. Therefore, we do not believe that we should abandon the use of these new definitions since they most accurately retain our current structuring of labor market areas. However, given the scope and drastic implications of these new boundaries and to buffer the subsequent negative impact on numerous hospitals, we have decided to provide, during FY 2005, a blend of wage indexes to those hospitals that would experience a drop in their wage indexes because of the adoption of the new labor market areas. Any hospital experiencing a decrease in their wage index relative to its FY 2005 wage index because of the labor market area changes will receive 50 percent of the wage index using the new labor market definitions and 50 percent of the wage index that the provider would have received under the old MSA standards. This blend will apply to any provider experiencing a decrease due to the new definitions, including providers who are reclassifying under MCGRB requirements, section 1886(d)(8)(B) of the Act or section 508 of Public Law 108-173. We describe the determination of this blend in detail below. It is important to note that this blend will not protect hospitals from the effects of

a drop in wage index due to any reason other than the usage of the new MSAs. For example, the blend will not apply to changes due to the use of new wage data in calculating the FY 2005 wage index. In other words, the two wage indexes (one wage index reflecting the labor market definitions employed in FY 2004, the other wage index reflecting the new CBSA definitions) used in determining the blended wage index both reflect the new FY 2005 wage data.

c. Micropolitan Areas

One of the major issues with respect to the new definitions is whether to use Micropolitan Areas to define labor market areas for the purpose of the IPPS wage index. Because the new Micropolitan Areas are essentially a third area definition made up mostly of currently rural areas, but also some or all of current MSAs, how these areas are treated will have significant impacts on the calculation and application of the wage index. Treating Micropolitan Areas as separate and distinct labor market areas would affect both the wage indexes of the hospitals in the Micropolitan Areas and the hospitals in the labor market areas where those hospitals are currently located (both positively and negatively).

Because we currently use MSAs to define urban labor market areas and we group all the hospitals in counties within each State that are not assigned to an MSA together into a statewide rural labor market area, we have used the terms "urban" and "rural" wage indexes in the past for ease of reference. However, the introduction of Micropolitan Areas complicates this terminology because these areas include so many hospitals that are currently included in the statewide rural labor market areas. In order to facilitate the discussion below, we use the term "rural" hospitals to describe hospitals in counties that are not assigned to either an MSA or a Micropolitan Area. This should not be taken to indicate that hospitals in Micropolitan Areas are no longer "rural" hospitals. In fact, we proposed that hospitals in Micropolitan Areas are included in the statewide rural labor market areas, for the reasons outlined below. The reader is referred to section IV.B. of the preamble of this final rule for a more specific discussion of the implications of these changes for defining urban and rural areas under § 412.62(f).

Chart 1 below, which was included in the proposed rule, demonstrates the distributions of hospitals by their current and new designations. Approximately 50 percent of hospitals currently designated rural are now in

either Micropolitan Areas (691 hospitals) or MSAs (197 hospitals). The vast majority of hospitals currently in

MSAs remain in an MSA (2,478, although in some cases the MSAs have been reconfigured), while 2 are now in

rural areas and 65 are now in Micropolitan Areas.

Chart 1.--Distribution of Hospitals by Current and New Designation

2005 Statistical Area	Currently Rural (2004)	Currently MSA (2004)
Rural	861	2
Micropolitan	691	65
MSA	197	2,478
TOTALS	1,749	2,545

In order to evaluate the impact of these changes, we grouped hospitals based on the county where they are located according to the new MSA and Micropolitan areas using the definitions on the Census Bureau's Web site: <http://www.census.gov/population/www/estimates/metrodef.html>. We then compared the FY 2004 wage indexes (using data from hospitals' FY 2001 cost reports) calculated based on the current MSAs, without any effects of hospital geographic reclassifications. Consistent with current policy, we applied the rural floor in the case where the statewide rural wage index is greater than the wage index for a particular urban area. We excluded Indian Health Service hospitals from the analysis due to the special characteristics of the prospective payment system for these hospitals. Hospitals in Maryland were excluded from the analysis because they remain excluded from the IPPS under the waiver at section 1814(b)(3) of the Act. Our analysis also did not reflect any changes to the Puerto Rico-specific wage index, which is applicable only to the Puerto Rico standardized amounts (the analysis does include the national wage index values for Puerto Rico hospitals).

Chart 2 below, which was included in the proposed rule, shows the impact on hospitals' wage indexes of recalculating new wage indexes based on the new MSAs, and treating the new Micropolitan Areas as separate labor market areas. Specifically, the table

shows the impact of treating the new MSA and Micropolitan Areas as labor market areas and calculating a wage index for each one. The most dramatic impact of this change would be on hospitals that are currently classified as rural. Only 10 currently rural hospitals would experience no changes in their wage indexes after applying the new MSA definitions. Five of these hospitals are in Delaware and Connecticut (three and two hospitals respectively), where the only counties in the State currently considered rural are now part of Micropolitan Areas.

Approximately 62 percent (1,092 out of 1,749) of currently rural hospitals experience decreases in their wage indexes under this change. Among hospitals that remain rural after separately recognizing Micropolitan Areas (those hospitals in counties "outside CBSAs"), rural hospitals in six States (Arizona, Florida, Idaho, Indiana, Minnesota, and Missouri) experience a positive impact after applying the new MSA definitions. These hospitals benefit because the net effect on their wage index of other hospitals moving into Micropolitan Areas is positive. The majority of the currently rural hospitals (762 out of 1,092) that experience decreases in their wage indexes are hospitals that would remain rural under the new definitions. Moreover, among the 646 rural hospitals whose wage indexes would increase under the new definitions, 547 would now be in an MSA or Micropolitan Area.

Furthermore, in many cases, the magnitude of the changes is quite large. Nearly one-half of all rural hospitals would experience payment changes of at least 5.0 percent, either negatively or positively, if we were to adopt labor market areas based in part on the new Micropolitan Areas.

In contrast, there are 938 currently urban hospitals (37 percent) with wage indexes that are unaffected by the new MSA definitions. These hospitals are in MSAs or PMSAs that are either unchanged (for example, the Austin, Buffalo, Milwaukee, Oakland, Phoenix, San Diego, and Tampa-St. Petersburg MSAs are all unchanged) or include new counties without any hospitals in those counties that are now part of the existing MSA (for example, counties were added to the Atlanta, Denver, Little Rock, Omaha, Portland, Richmond, Toledo, Virginia Beach-Norfolk MSAs but hospitals were not added).

The most significant negative impact (more than a 20-percent decrease) among hospitals currently in an MSA is on those located in counties that become Micropolitan areas or rural areas. Among hospitals with the largest positive impacts (more than a 20-percent increase), the changes appear to be largely due to changes in the counties that are now included (under the CBSAs) in the MSA labor market area.

**Chart 2.--Impact on Wage Indexes of New MSA, Micropolitan Areas,
and Rural Labor Market Areas**

Percent Change in Area Wage Index	Number of Currently Rural Hospitals	Number of Currently MSA Hospitals	Total Number of Hospitals
Decrease Greater Than 10.0	99	36	135
Decrease Between 5.0 and 10.0	420	77	497
Decrease Between 2.0 and 5.0	238	95	333
Decrease Between 0 and 02.0	335	585	920
No Change	10	938	948
Increase Between 0 and 2.0	168	495	663
Increase Between 2.0 and 5.0	138	145	283
Increase Between 5.0 and 10.0	203	139	342
Increase Greater Than 10.0	138	35	173
Total	1,749	2,545	4,294

One of the reasons Micropolitan Areas have such a dramatic impact on the wage index is, because Micropolitan Areas encompass smaller populations than MSAs, they tend to include fewer hospitals per Micropolitan Area. Currently, there are only 25 MSAs with one hospital in the MSA. However, under the new definitions, there are 373 Micropolitan Areas with one hospital, and 49 MSAs with only one hospital.

This large number of labor market areas with only one hospital and the increased potential for dramatic shifts in the wage indexes from 1 year to the next is a problem for several reasons. First, it creates instability in the wage index from year to year for a large number of hospitals. Second, it reduces the averaging effect of the wage index, lessening some of the efficiency incentive inherent in a system based on the average hourly wages for a large number of hospitals. In labor market areas with a single hospital, high wage costs are passed directly into the wage index with no counterbalancing averaging with lower wages paid at nearby competing hospitals. Third, it creates an arguably inequitable system

when so many hospitals have wage indexes based solely on their own wages, while other hospitals' wage indexes are based on an average hourly wage across many hospitals.

For these reasons, in the May 18, 2004, proposed rule, we proposed not to adopt Micropolitan Areas as independent labor market areas. Although we considered alternative approaches that would aggregate Micropolitan Areas in order to reduce the number of one-hospital labor market areas, these approaches created geographically disconnected labor market areas, an undesirable outcome. Therefore, we proposed to maintain our current policy of defining labor market areas based on the new MSAs (and Divisions, where they exist) using OMB's new criteria and the 2000 Census data.

Chart 3, which was included in the proposed rule, displays the impacts of using this approach on hospital wage indexes. The most apparent difference comparing this chart to Chart 2 is the reduction in the numbers of currently rural hospitals impacted by more than 2.0 percent. Recognizing Micropolitan Areas as independent labor market areas

results in negative impacts of more than 2.0 percent for 757 currently rural hospitals, while the comparative number, when recognizing only MSAs, is 256. Conversely, the number of currently rural hospitals positively impacted by more than 2.0 percent declines from 479 to 154.

The greatest negative impacts among hospitals currently designated rural are in Idaho, where the statewide rural wage index falls 6.7 percent as a result of 6 formerly rural hospitals now being included in either new or redefined MSAs. The wage index for rural Utah hospitals declines by 5.7 percent, for similar reasons. Conversely, formerly rural hospitals that are not part of an MSA generally experience positive impacts.

Among hospitals that are currently in MSAs, the number of hospitals with decreases in their wage indexes of at least 10 percent increases from 36 to 45. These are primarily hospitals that are now located in Micropolitan Areas that are included in the statewide labor market area. There are 46 counties with 72 hospitals that are currently in an MSA that would be treated as rural.

Chart 3.--Impact on Wage Indexes of New MSA and Rural Labor Market Areas

Percent Change in Area Wage Index	Number of Currently Rural Hospitals	Number of Currently MSA Hospitals	Total Number of Hospitals
Decrease Greater Than 10.0	0	45	45
Decrease Between 5.0 and 10.0	122	60	182
Decrease Between 2.0 and 5.0	134	73	207
Decrease Between 0 and 2.0	588	615	1,203
No Change	160	1,015	1,175
Increase Between 0 and 2.0	591	574	1,165
Increase Between 2.0 and 5.0	32	103	135
Increase Between 5.0 and 10.0	64	25	89
Increase Greater Than 10.0	58	35	93
Total	1,749	2,545	4,294

Comment: Many commenters addressed the usage of Micropolitan Areas. Some commenters believe that we should adopt a policy recognizing each of the individual Micropolitan Areas. These commenters pointed out that some hospitals would benefit from the adoption of Micropolitan Areas as in the case of higher wage hospitals in currently rural areas that would receive a wage index more closely reflecting their own wage level. However, other commenters endorsed our proposal to treat Micropolitan Areas as part of the statewide rural areas. Many hospitals and several national hospital associations supported our decision not to employ Micropolitan Areas for the reasons that we presented. MedPAC also expressed support for the proposal to include Micropolitan Areas in the statewide rural areas.

Response: We continue to believe that the reasons we presented in the proposed rule for including Micropolitan Areas in the statewide rural areas are compelling. We are therefore finalizing our proposal to treat the Micropolitan Areas as "rural."

d. Transition Period

We have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. When we recently removed the

wage costs of teaching physicians and residents from the wage index data of teaching hospitals, we spread out the impact over 3 years by blending the hospitals' average hourly wages with and without the data. Similarly, the regulations at § 412.102 provide for a 3-year transition to the DSH adjustment payments to a hospital redesignated from urban to rural.

Given the significant payment impacts upon some hospitals because of these changes, we considered options to transition from the current MSAs to the new MSAs. As noted above, the most dramatic negative impacts are among hospitals currently located in an MSA but would become rural under the new definitions. Some negative impacts also occur among urban hospitals that remain in MSAs that have been reconfigured. However, these impacts are generally smaller than those among currently urban hospitals that would become rural. To help alleviate the decreased payments for currently urban hospitals that would become rural, in the May 18, 2004 proposed rule, we proposed to allow them to maintain their assignment to the MSA where they are currently located for the 3-year period FY 2005, FY 2006, and FY 2007. Specifically, we will assign these hospitals, as we did in the proposed rule, the prereclassified wage index of

the urban area to which they currently belong. (For purposes of wage index computation, the wage data of these hospitals will remain assigned to the statewide rural area in which they are located.) We are finalizing this policy in the final rule. We are using the wage data from these hospitals as part of setting the rural wage index. The higher wage indexes these hospitals are receiving is being taken into consideration in determining whether they qualify for the out-commuting adjustment and the amount of any adjustment. Beginning in FY 2008, these hospitals would receive their statewide rural wage index, although they will be eligible to apply for reclassification by the MGCRB, both during this transition period as well as subsequent years.

We also considered the option of allowing a transition to the new MSAs for all hospitals, such as a blend of wage indexes based on the old and new MSAs for some specified period of time. We noted that, although this would help some hospitals that are negatively impacted by the changes to the MSAs, it would dampen the payment increases for those hospitals that are positively impacted by the changes. Therefore, although we notified the public that a blended rate was a viable option, we did not propose this in the proposed rule. We also noted that OMB in the past has

announced MSA changes on an annual basis due to population changes, and we have not transitioned these changes.

Comment: Many commenters urged CMS to adopt broader protections for hospitals against changes in the wage index due to the adoption of the new labor market areas. Many of these commenters advocated extending hold harmless protection to other categories of providers beyond those that we provided for in the proposed rule. Commenters offered various recommendations about how to provide such protection. Most commenters advocated transition mechanisms such as hold harmless or blending only for those hospitals that would experience a wage index decrease from the effects of the labor market area changes. MedPAC recommended providing a transition to all hospitals that experience large decreases in their wage indexes due to these changes and phasing in the changes for these hospitals over three years. MedPAC also recommended that the threshold for large decreases be set so that the cost of this provision over the transition period would equal the cost of our proposal to implement the new market definitions with a hold harmless for urban hospitals that become rural under the new definitions.

Response: We recognize that many hospitals will experience decreases in wage index as a result of the labor market area changes. At the same time, significant numbers of hospitals will benefit from these changes. In addition, as of September 1, 2004, hospitals will be able to seek reclassification for FY 2006 using the new labor market areas, if they believe another area's wage index is more appropriate and if they meet the requirements for reclassification by the MGCRB. Therefore, we have decided to provide a 1-year transition blend for hospitals that, due solely to the changes in the labor market definitions, experience a decrease in their FY 2005 wage index compared to the wage index they would have received using the labor market areas included in calculating their FY 2004 wage index. Each hospital experiencing a decrease in its wage index due to the labor market changes will receive 50 percent of its wage index based upon the new CBSA configurations and 50 percent based upon FY 2004 MSA boundaries (in both cases using the FY 2001 wage data). This blend will not apply to any hospital that experiences a drop for any reason other than the new MSA definitions, nor will it apply to hospitals that benefit from a higher wage index due to the labor market definition changes.

Specifically, we will determine for each hospital a new wage index employing the FY 2001 wage index data and the old labor market definitions, and a wage index employing FY 2001 wage index data and the new labor market definitions. Any hospital experiencing a decrease in its wage index under the new labor market definitions will receive a blended wage index consisting of 50 percent of each of these wage indexes (that is, 50 percent of the wage index using the FY 2001 wage index data and the old labor market definitions, and 50 percent of the wage index using FY 2004 wage index data and the new labor market definitions). Both the comparison and the blending will employ post reclassification wage indexes; that is, wage indexes computed after applying the established rules for assigning the wage data for reclassifying hospitals to one or more wage areas.

As part of this transition, as we proposed in the proposed rule, we will also allow currently urban hospitals that become rural under the new definitions to maintain their assignment to the MSA where they are currently located for the 3-year period FY 2005, FY 2006, and FY 2007. Specifically, we will assign these hospitals, as we did in the proposed rule, the prereclassified wage index of the urban area to which they currently belong. (For purposes of wage index computation, the wage data of these hospitals will remain assigned to the statewide rural area in which they are located.) Beginning in FY 2008, these formerly urban hospitals will receive their statewide rural wage index, although they would be eligible to apply for reclassification by the MGCRB, both during this transition period as well as subsequent years. The hospitals receiving this transition will not be considered urban hospitals but rather they will maintain their status as rural hospitals. Thus, the hospital would not be eligible, for example, for a large urban add-on under capital PPS. Thus, it is the wage index, but not the urban or rural status, of these hospitals that is being affected by this transition.

Comment: One commenter asked us to clarify whether the special provisions of § 412.102 of the regulations apply to these hospitals, that is, hospitals that were classified as urban under the previous labor market definitions, but are rural under the new labor market definitions. The commenter pointed out that this section of the regulations provides special protections for hospitals against abrupt reductions in DSH payments resulting from transitions from urban to rural status.

Response: We agree with the commenter that the provisions of § 412.102 apply in this case. Specifically, as described in § 412.102, in the first year after a hospital loses urban status, the hospital will receive an additional payment that equals two thirds of the difference between the urban disproportionate share payments applicable to the hospital before its redesignation from urban to rural and the rural disproportionate share payments applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an additional payment that equals one third of the difference between the urban disproportionate share payments applicable to the hospital before its redesignation from urban to rural and the rural disproportionate share payments applicable to the hospital subsequent to its redesignation from urban to rural.

We decided not to provide for a longer transition, as recommended by MedPAC and other commenters, because we have already, in effect, provided one year at a higher wage index level for these hospitals by retaining the previous labor market definitions for one year after the new labor market definitions became available. However, we are still allowing a longer, 3-year hold-harmless transition for the group of hospitals that were previously urban, and are now rural under the new definitions. We are continuing to provide for a longer transition for these hospitals because, as a group they have experienced a steeper and more abrupt reduction in their wage index due to the labor market revisions.

We will apply this blended transition in a budget neutral manner. Specifically, we will make an adjustment to the rates to ensure that total payments, including the effects of the transition provisions, will equal what payments would have been if we had fully implemented the new labor market areas. We believe that doing so is most consistent with the requirement of section 1886(d)(3)(E) of the Act that any "adjustments or updates [to the adjustment for different area wage levels] * * * shall be made in a manner that assures that aggregate payments * * * are not greater or less than those that would have been made in the year without such adjustment." In addition, as a policy matter, it would not be feasible for us to allow for a transition only for hospitals that experience a decrease as a result of the new labor market definitions, were we not to implement such a transition in a budget

neutral manner. Because we have adopted a policy of allowing for a transition only when it would benefit the hospital, we believe it is appropriate to ensure that such a transition does not increase Medicare payments beyond the payments that would be made had we simply adopted the new labor market definitions without any transition provisions. We note that, consistent with past practice, we are not adopting the new labor market definitions themselves in a budget neutral manner. We do not believe that the revision to the labor market areas in and of itself constitutes an "adjustment or update" to the adjustment for area wage differences, as provided under section 1886(d)(3)(E) of the Act.

C. Occupational Mix Adjustment to FY 2005 Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Development of Data for the Occupational Mix Adjustment

In the September 19, 2003, **Federal Register** (68 FR 54905), we published a final notice of intent to collect occupational mix data from hospitals using the Medicare Wage Index Occupational Mix Survey, Form CMS-10079. (The survey and instructions may be accessed at the Web site: <http://cms.hhs.gov/providers/hipps/ippswage.asp>.) The survey requires hospitals to report the number of total paid hours for directly hired and contract employees in occupations that provide the following services: nursing, physical therapy, occupational therapy, respiratory therapy, medical and clinical laboratory, dietary, and pharmacy. These services each include several standard occupational classifications (SOCs), as defined by the Bureau of Labor Statistics (BLS) on its

Occupational Employment Statistics (OES) survey (http://www.bls.gov/oes/2001/oes_tec.htm), that may be used by hospitals in different mixes to provide specific aspects of patient care. CMS decided to use BLS's SOCs to categorize employees for the occupational mix survey in an effort to ease hospitals' reporting burden; most hospitals have had experience with collecting and reporting their employment data according to the SOC definitions. The survey includes a total of 19 SOCs that provide services for the above 7 categories and an "all other occupations" category. The hours collected on the survey would be used to determine the proportion of a general service category total that is attributable to each of the category's SOCs, that is, the category's occupational mix.

In order to accurately reflect a hospital's employment, we initially planned to require all hospitals to provide occupational mix data collected from a 1-year period. Several hospitals and their representatives advised us that a 1-year reporting period was feasible because salary and wage data are maintained quarterly for revenue and tax reporting purposes. However, several hospitals expressed concern that their payroll and other personnel accounting systems are typically not set up to collect data on hours for contract employees. The hospitals and their representatives advised us that the approximately 2-month timeframe (see dates below) for collecting and submitting the occupational mix data to the fiscal intermediaries would not allow hospitals enough time to develop a year's worth of hours data for contract workers. Therefore, given the short timeframe for collecting the occupational mix data, and to reduce hospitals' reporting burden associated with the initial collection of the data, we decided to allow hospitals the option of providing their hours data for the 19 SOCs either prospectively for a 4-week period beginning on or between December 28, 2003, and January 11, 2004, and ending no later than February 7, 2004, or retrospectively for a 12-month period, that is, calendar year 2003. Although we recognize that using data from only a 4-week period increases our risk of obtaining results that reflect seasonal rather than normal employment trends, we believe that the 4-week prospective reporting period should enable hospitals to plan and provide more accurate data according to our survey instructions and definitions. (See the discussion below on the verification and validity of our occupational mix survey results.)

An advance copy of the occupational mix survey was provided to hospitals in mid-December 2003 so that hospitals could begin gathering their data and documentation necessary to complete the survey. The official survey was published as a CMS One-Time Notification (Pub. 100-20, R47OTN) on January 23, 2004. We instructed our fiscal intermediaries to distribute and collect completed occupational mix surveys from any hospital that is subject to IPPS, or any hospital that would be subject to IPPS if not granted a waiver. If a hospital was not an IPPS provider during FY 2001 or, otherwise, did not submit a FY 2001 cost report, the hospital was not required to submit occupational mix data. Consistent with the wage data, CAHs were excluded from the occupational mix survey. In addition, the FY 2005 wage index does not include occupational mix data for hospitals that submitted FY 2001 wage data, but terminated participation in the Medicare program as IPPS providers before calendar year 2003. For such terminated hospitals, there would be no occupational mix data to collect for our survey period.

Hospitals had to submit their completed occupational mix surveys to their fiscal intermediaries by February 16, 2004. Our initial collection of these data was completed by March 1, 2004, the deadline for fiscal intermediaries to submit hospitals' survey data to CMS. We released a public use file containing the data on March 8, 2004 (through the Internet on our Web site at: <http://cms/hhs.gov/providers/hipps/ippswage.asp>). In a memorandum also dated March 8, 2004, we instructed all fiscal intermediaries to inform the IPPS hospitals they service of the availability of the occupational mix data file and the process and timeframe for requesting corrections and revisions. If a hospital wished to request a change to its data as shown in that file, the hospital had to submit the changes to its fiscal intermediary by March 22, 2004. In addition, as this was hospitals' first experience with the occupational mix survey, we provided hospitals another opportunity, if they missed the February 16 filing deadline, to submit their completed surveys. The deadline for this one-time, final opportunity to submit occupational mix data to fiscal intermediaries for the FY 2005 wage index was also March 22, 2004. The final deadline for fiscal intermediaries to submit hospitals' data to CMS was April 16, 2004. (From April 16 until the final rule is published, the process, criteria, and timetable for correcting occupational mix data was the same as

for Worksheet S-3 wage data, under Section H.) Occupational mix survey data received by us through March 15, 2004, were used in computing the proposed wage index in the May 18, 2004, proposed rule. Data received from intermediaries after March 15 through April 16, 2004, are included in this final rule.

The final response rate for the occupational mix survey was 93.8 percent. We received occupational mix data from 3,768 hospitals. We expected to receive completed survey data from 4,018 hospitals that submitted cost report wage data for FY 2001 and were still IPPS hospitals during calendar year 2003 or on January 1, 2004. In the proposed rule, we said that for any hospital that was expected to provide occupational mix data but did not, we would consider using proxy occupational mix data to adjust the hospital's wage data in the final wage index. One option would be to assume that the hospital only has employees in the highest level SOC for each of the general service categories included on the occupational mix survey. Another option would be to assume that such hospitals have the national SOC mix for each general service category. We invited public comment to this proposal. We noted that the wage index in the proposed rule did not include proxy data for hospitals that did not complete and submit the occupational mix survey.

Comment: Some commenters supported the intent of the occupational mix adjustment to the wage index. The commenter believed that an occupational mix adjusted wage index more accurately reflects hospitals' labor costs. Other commenters questioned whether there is a need for the occupational mix adjustment with the implementation of the provisions of Public Law 108-173 that has also increased payments to hospitals in rural areas. One commenter, an association representing hospitals in a large metropolitan area, stated that its members are concerned that any redistribution of monies from urban teaching hospitals to rural hospitals will result in further underpayment by Medicare to hospitals that utilize the most sophisticated and costly equipment, technology, and staff needed to treat the sickest patients. Further, the commenter believed that an occupational mix classification system is inherently flawed due to the diverse manner in which hospital services are rendered throughout the United States.

Several commenters expressed concern that the occupational mix adjustment is contrary to CMS' quality

initiatives that place emphasis on improvement in quality outcomes and standards of care, which may require hospitals to employ more highly skilled caregivers. In addition, some commenters believed that the occupational mix adjustment opposes the direction that State governments are undertaking in mandating registered nurse staffing ratios; the resulting adjustment may be negative for hospitals in these states. Two commenters opposed the occupational mix adjustment because the commenters believed that the adjustment is unnecessary, increases the information burden for hospitals, and adds to the data that CMS must regularly audit. A few commenters recommended that we request Congress to rescind the BIPA provision that requires the occupational mix adjustment because our proposed adjustment does not have the anticipated impact.

Response: We appreciate these and other comments and concerns we received regarding the proposed initial implementation of the occupational mix adjusted wage index. We acknowledge that a wage index adjusted for occupational mix could have a redistributive effect on Medicare payments to hospitals, and, combined with the provisions of Public Law 108-173, some hospitals may be significantly negatively impacted. However, we also agree with the theory that an occupational mix adjusted wage index should more accurately reflect relative labor costs among hospitals by removing the differences that result from hiring higher skilled or lower skilled workers. For hospitals that employ a higher skill mix because they treat more complicated cases, the DRG assignment of cases should reflect the extra cost. Therefore, we do not agree with the recommendation that we should approach Congress to rescind the law that requires the occupational mix adjustment.

While the law requires us to implement the adjustment with the FY 2005 wage index, we also intend to minimize the negative impact that this initial implementation of the occupational mix adjustment may have on some hospitals' wage index values. The final FY 2005 wage index adjustment is only partially adjusted for occupational mix. A complete discussion of the blended wage index appears in section III.G. of the preamble to this final rule. We welcome input from MedPAC, hospitals, and associations in assessing the impact of the occupational mix adjustment on hospitals' wage index values and monitoring how current hospital staffing

trends affect the expected outcome of the adjustment.

Comment: Several commenters addressed the issue of how we should handle the occupational mix adjustment for hospitals that did not complete the survey. The majority of commenters recommended that we use the unadjusted wage data or the national SOC mix so that other hospitals in the MSA are not adversely impacted by negative proxy data. One commenter requested us to adopt the first option, that, for any hospital that did not respond to the survey, CMS should assume that the hospital employs all of its workers in the highest level SOC for each category. The commenter believed that hospitals were provided enough time to ensure that their data collected for the occupational mix adjustment were accurate. One commenter suggested that we could achieve a 100 percent response rate to the survey if we make the survey mandatory. Another commenter recommended that we set the same consequences for failure to complete the occupational mix survey as those for not submitting a cost report and notify hospitals of these consequences in the survey instructions.

Response: We agree that other hospitals should not be harmed by a hospital's failure to respond to the occupational mix survey. If we were to apply the first option, the worst-case scenario, the wage index values for most of the areas that have hospitals that did not complete the survey would decrease significantly compared to leaving such hospitals' wage data unadjusted for occupational mix. Therefore, for the final FY 2005 wage index, we decided to use the unadjusted wage data for hospitals that did not submit occupational mix survey data. For calculation purposes, this equates to applying the national SOC mix to the wage data for such hospitals, because hospitals having the same mix as the nation would have an occupational mix adjustment factor equaling 1.0000. We note that we will revisit this matter with subsequent collections of the occupational mix data. We will explore the possibilities of making it mandatory for all IPPS hospitals to complete the survey, as well as establishing penalties for hospitals that fail to submit occupational mix data.

Comment: Some commenters opposed our decision to allow hospitals to provide occupational mix data prospectively for a 4-week period. The commenters believed that the 4-week reporting period occurred during hospitals' peak season and is not representative of hospitals' annual staffing (about 30 percent of hospitals

used this option). The commenter suggested that the next survey should be for a full year only.

Response: We believe that in the first year of the occupational mix adjustment, it was reasonable to use a 4-week period. A 4-week period represents a sampling of the occupational mix that occurs in a hospital during the year. We do not have available data to determine if the 4-week reporting period is a peak season for hospitals, as the commenter contends, or even whether a hospital's employment mix significantly changes during peak seasons. However based on the similarity of our results and the results found by the Bureau of Labor Statistics, we believe use of the 4-week period did not significantly affect the data we received for the adjustment. Nevertheless, in order to further assure the accuracy of the adjustment, in future years, we will require data collected from a full year.

Comment: Several commenters reported that the short timeframe for hospitals to complete, review, and correct the survey data and lack of clarity by hospitals in determining the proper category to place certain employees (for example, a registered nurse who also conducts administrative duties) led to errors and inconsistencies in reporting that may have contributed to the unexpected outcomes. One commenter noted errors in the date fields of the survey, stating that about 8 percent of hospitals appear to have incorrect dates in the date fields and large variances in hours reported between Worksheet S-3 and the occupational mix survey. The commenter recommended that CMS clarify its definitions and notify hospitals of the next survey's design at least 60 days or, ideally, 6 months prior to the period the data collection will begin. This would allow hospitals more time to prepare their payroll and other systems to collect more accurate data. Some commenters suggested that, due to possible errors and inconsistencies in the initial data collection, CMS should gather new data next year, rather than waiting 3 years for the next collection of occupational mix data.

Response: We did not believe that the survey definitions would be problematic for hospitals because of hospitals' experience with the BLS OES survey. In fact, several hospitals and associations strongly recommended that we use the BLS definitions for the occupational mix survey. In future years, if hospitals wish to receive further clarification of the definitions of the occupational categories then we welcome their assistance. We also plan in future years

to provide the next survey to hospitals prior to the period that the data collection begins. The suggested 60-day preparation period appears reasonable, and we will consider such a schedule for future occupational mix data collections. With regard to administering another survey next year, we are reluctant to do so because of the additional reporting burden for hospitals. Further, we would have to issue the survey immediately for implementation with the FY 2006 index. However, we have not ruled out the possibility of revising the survey and administering another survey before 2007. According to section 1886(d)(3)(E) of the Act, the Secretary has the authority to administer the occupational mix survey more than once during a 3-year period.

Comment: Two commenters suggested changes to the categories that are included in the occupational mix survey. One commenter recommended that CMS exclude the dietary categories and medical assistants. The commenter noted significant variations among hospitals in these categories that may have been due to lack of clarity regarding the category definitions. The commenter further cautioned that, although only a small portion of hospital workers are in these occupational categories, misreporting in these categories could significantly distort the occupational mix data because the categories have low hourly rates. MedPAC recommended that CMS assess whether including subcategories of RNs would result in a more accurate occupational mix adjustment. MedPAC believed that including all RNs in a single category may obscure significant wage differences among the subcategories of RNs, for example, the wages of surgical RNs and floor RNs may differ. To offset additional reporting burden for hospitals, MedPAC suggested that CMS could eliminate some of the general service categories that account for fewer hours, since most of the total occupational mix adjustment is correlated with the nursing general service category.

Response: We believe that it is appropriate to include the dietary and medical assistant occupations in the FY 2005 adjustment. Although these occupations represent a small portion of a hospital's total workforce, hospitals employ these occupations in different mixes, just as for the other survey categories. In the absence of data showing that there is minimum variation among hospitals in their employment of these occupations, we are not convinced, as the commenter suggests, that the variations reflected in

the survey results are due to a lack of clarity regarding the category definitions. With regards to MedPAC's recommendation to expand the RN category, we would need to investigate this matter further to assess its impact on the occupational mix adjustment, hospital's reporting burden, and intermediary's review workload. We welcome any data or studies related to both of these issues.

Comment: Several commenters noted that the occupational mix adjusted wage index in the proposed rule was based on data from the March 8, 2004 public use file. However, 263 surveys were added to the database in the May 13, 2004 public use file. The commenters urged CMS to recalculate its final analysis of the occupational mix adjustment using the data for all hospitals that submitted the survey data.

Response: As we stated in the proposed rule (69 FR 28253), and above, the occupational mix adjustment in the proposed rule was based on data we received by March 15, 2004. We further stated in the proposed rule, and above, that data received after March 15 and through April 16 would be included in the final wage index. The FY 2005 wage index in this final rule includes the most complete and updated set of occupational mix survey data that we received timely from hospitals, that is, by April 16, 2004.

Comment: Two commenters recommended that CMS collect data on hospitals' service mix to include as part of the occupational mix adjustment. The commenters believe that hospitals that provide more services requiring highly skilled workers, such as oncology services, should not be penalized in the wage index for providing those services. One of the commenters also suggested that the adjustment should account for productivity, because hospitals should not be penalized if they hire highly skilled workers who work effectively with minimum support staff.

Response: We are concerned that collecting data on service mix and productivity would substantially increase the reporting burden for hospitals and the complexity of the occupational mix adjustment. We are also uncertain as to what impact these additional factors would actually have on the occupational mix adjustment. If hospitals hire more highly skilled workers because they treat more complex cases, Medicare's DRG assignment already reflects the higher costs of providing these services. We note that the wage index under section 1886(d)(3)(E) is intended to account for geographic differences in labor costs—not skill mix. We welcome the

commenters to provide more details of the data and methodology that would be required to include these factors in the occupational mix adjustment, as well as any analysis of the impact of these factors on the occupational mix adjustment.

Comment: Several commenters expressed concern about CMS' use of unaudited occupational mix data and suggested that a review process is needed. Some commenters believed that CMS should not implement the occupational mix adjustment because the survey data were not verified by the fiscal intermediaries. One commenter added that CMS should provide the fiscal intermediaries ample time and resources to complete more thorough reviews of future occupational mix data.

Response: We plan to audit the occupational mix survey data in future years. However, given the short timeframe for collecting the occupational mix data and implementing the adjustment with the FY 2005 wage index, there was no time for fiscal intermediaries to conduct such reviews. Further, as this was the first time we collected data on hours for the 19 occupational categories, we had no baseline data to develop edit thresholds to incorporate in an intermediary review program. Thus, it would have been difficult to develop an audit program for use by fiscal intermediaries. We notified hospitals that they were responsible for submitting to us accurate data for

Medicare payment purposes. Because hospitals will be affected by their own submission of data, we believe that hospitals had ample incentive to ensure that the data they submitted were correct and, therefore, self-audited their own data. Finally, we note that our policy of applying the occupational mix adjustment to only 10 percent of the wage index takes into account that this is the first year for submitting, analyzing, and applying the occupational mix data.

Although the occupational mix data were not as extensively reviewed as may occur in future years, we are required by law to implement an occupational mix adjustment with the FY 2005 wage index. The next collection of occupational mix data will include an intermediary review period and an opportunity for hospitals to respond to any adjustments made by the intermediaries during the review.

As this was the first administration of the occupational mix survey, we did not provide fiscal intermediaries an extensive program for reviewing the hours of data collected. However, hospitals were required to be able to provide any documentation that could be used by the fiscal intermediaries to verify the survey data. In addition, after reviewing the compiled survey data, we contacted fiscal intermediaries to request corrections from a few hospitals that provided data for reporting periods that were out of range with our specified

12-month or 4-week data collection periods. As the wage index is a relative measure of labor costs across geographic areas, it is important that the data collected from hospitals reflect a common period. We also tested the validity of our occupational mix survey data by comparing our results to those of the 2001 BLS OES survey. As shown in Charts 4 and 5 below, the results of our survey are rather consistent with the findings of the BLS OES survey, especially for the nursing and physical therapy categories.

In addition, to compute the occupational mix adjustment, we collected data on the average hourly rates for the 19 SOCs so that we could derive a weighted average hourly rate for each labor market area. (More details about the occupational mix calculation are included in section III.C.2. of this preamble.) To decrease hospital's reporting burden for this initial collection of the occupational mix data, and to facilitate the timely collection of the data, we did not require hospitals to report data on their total wages or average hourly rates associated with the 19 SOCs. Instead, we used national average hourly rates from the BLS OES *2001 National Industry-Specific Occupational Employment and Wage Estimates, SIC—Hospitals* (accessible at Web site: http://www.bls.gov/oes/2001/oesi3_806.htm), as reflected in Chart 4 below.

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Chart 4.-- BLS National Occupational Employment and Wage Estimates for Hospitals

General Service Categories	Number of Hospital Employees	Percent of Service Category	Percent of Total Employees	National Average Hourly Wage
Nursing Services and Medical Assistant Services				
Registered Nurses	1,307,960	68.8%	25.88%	\$23.62
Licensed Practical Nurses	194,900	10.2%	3.86%	\$14.65
Nursing Aides, Orderlies, & Attendants	351,910	18.5%	6.96%	\$10.01
Medical Assistants	47,250	2.5%	0.93%	\$11.79
Total	1,902,020	100.0%	37.63%	
Physical Therapy Services				
Physical Therapists	46,290	61.0%	0.92%	\$27.80
Physical Therapist Assistants	17,610	23.2%	0.35%	\$17.11
Physical Therapist Aides	12,020	15.8%	0.24%	\$10.40
Total	75,920	100.0%	1.50%	
Occupational Therapy Services				
Occupation Therapists	24,110	75.3%	0.48%	\$25.62

General Service Categories	Number of Hospital Employees	Percent of Service Category	Percent of Total Employees	National Average Hourly Wage
Occupation Therapist Assistants	5,690	17.8%	0.11%	\$16.81
Occupation Therapist Aides	2,220	6.9%	0.04%	\$11.60
Total	32,020	100.0%	0.63%	
Respiratory Therapy Services				
Respiratory Therapists	68,920	72.8%	1.36%	\$19.26
Respiratory Therapy Technicians	25,710	27.2%	0.51%	\$16.96
Total	94,630	100.0%	1.87%	
Pharmacy Services				
Pharmacists	48,630	48.8%	0.96%	\$34.58
Pharmacy Technicians	44,270	44.4%	0.88%	\$12.30
Pharmacy Assistants/Aides	6,810	6.8%	0.13%	\$11.52
Total	99,710	100.0%	1.97%	
Dietary Services				
Dieticians	16,820	56.4%	0.33%	\$20.02
Dietetic Technicians	13,020	43.6%	0.26%	\$11.64
Total	29,840	100.0%	0.59%	
Medical & Clinical Lab Services				
Medical & Clinical Lab Technologists	87,380	57.8%	1.73%	\$20.74
Medical & Clinical Lab Technicians	63,900	42.2%	1.26%	\$14.90
Total	151,280	100.0%	2.99%	
Total Nursing, Therapy, Pharmacy, Dietary, and Medical & Clinical Occupations	2,385,420		47.19%	
All Other Occupations	2,669,400		52.81%	

General Service Categories	Number of Hospital Employees	Percent of Service Category	Percent of Total Employees	National Average Hourly Wage
Total Hospital Employees	5,054,820		100.0%	

Source: BLS, OES, 2001 National Industry-Specific Occupational Employment and Wage Estimates, www.bls.gov/oes/2001.

Chart 5.--Medicare Occupational Mix Survey Results

General Service Categories	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours
Nursing Services and Medical Assistant Services			
Registered Nurses	1,429,939,708.87	70.51%	26.77%
Licensed Practical Nurses	152,076,000.02	7.50%	2.85%
Nursing Aides, Orderlies, & Attendants	373,013,761.93	18.39%	6.98%
Medical Assistants	72,930,628.98	3.60%	1.37%
Total	2,027,960,099.80	100.00%	37.97%
Physical Therapy Services			
Physical Therapists	45,536,940.56	61.15%	0.85%
Physical Therapist Assistants	17,235,657.69	23.15%	0.32%
Physical Therapist Aides	11,691,298.12	15.70%	0.22%
Total	74,463,896.37	100.00%	1.39%
Occupational Therapy Services			
Occupation Therapists	19,165,885.91	79.13%	0.36%
Occupation Therapist Assistants	4,082,490.26	16.86%	0.08%
Occupation Therapist Aides	972,594.68	4.02%	0.02%
Total	24,220,970.86	100.00%	0.45%
Respiratory Therapy Services			
Respiratory Therapists	84,719,095.59	80.16%	1.59%
Respiratory Therapy Technicians	20,965,596.00	19.84%	0.39%
Total	105,684,691.58	100.00%	1.98%
Pharmacy Services			
Pharmacists	55,307,036.23	48.08%	1.04%
Pharmacy Technicians	55,248,144.37	48.03%	1.03%
Pharmacy Assistants/Aides	4,480,980.40	3.90%	0.08%
Total	115,036,161.00	100.00%	2.15%
Dietary Services			
Dieticians	19,056,751.23	42.10%	0.36%

General Service Categories	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours
Dietetic Technicians	26,209,576.38	57.90%	0.49%
Total	45,266,327.61	100.00%	0.85%
Medical & Clinical Lab Services			
Medical & Clinical Lab Technologists	116,177,701.08	58.79%	2.17%
Medical & Clinical Lab Technicians	81,437,014.90	41.21%	1.52%
Total	197,614,715.98	100.00%	3.70%
Total Nursing, Therapy, Pharmacy, Dietary, and Medical & Clinical Occupations			
	2,590,246,863.19		48.49%
All Other Occupations			
	2,751,434,492.48		51.51%
Total Hospital Employees			
	5,341,681,355.67		100.00%

Source: Medicare Wage Index Occupational Mix Survey, Form CMS-10079.

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2. Calculation of the Occupational Mix Adjustment Factor and the Occupational Mix Adjusted Wage Index

The method used to calculate the occupational mix adjusted wage index follows:

Step 1—For each hospital, the percentage of the general service category attributable to an SOC is determined by dividing the SOC hours by the general service category’s total hours. Repeat this calculation for each of the 19 SOCs.

Step 2—For each hospital, the weighted average hourly rate for an SOC is determined by multiplying the percentage of the general service category (from Step 1) by the national average hourly rate for that SOC from the 2001 BLS OES survey (see Chart 4 above). Repeat this calculation for each of the 19 SOCs.

Step 3—For each hospital, the hospital’s adjusted average hourly rate for a general service category is computed by summing the weighted hourly rate for each SOC within the general category. Repeat this calculation for each of the 7 general service categories.

Step 4—For each hospital, the occupational mix adjustment factor for a general service category is calculated by dividing the national adjusted average hourly rate for the category by the hospital’s adjusted average hourly rate for the category. (The national adjusted average hourly rate is computed in the same manner as Steps 1 through 3, using instead, the total SOC and general service category hours for all hospitals in the occupational mix survey database.) Repeat this calculation for each of the 7 general service categories. If the hospital’s adjusted rate is less than the national adjusted rate (indicating the hospital employs a less costly mix of employees within the category), the occupational mix adjustment factor will be greater than 1.0000. If the hospital’s adjusted rate is greater than the national adjusted rate, the occupational mix adjustment factor will be less than 1.0000.

Step 5—For each hospital, the occupational mix adjusted salaries and wage-related costs for a general service category is calculated by multiplying the hospital’s total salaries and wage-related costs (from Step 5 of the unadjusted wage index calculation in section F) by the percentage of the hospital’s total workers attributable to

the general service category (this is corrected from the proposed rule, in which we applied, instead, the national percentages to all hospitals) and by the general service category’s occupational mix adjustment factor (from Step 4 above). Repeat this calculation for each of the 7 general service categories. The remaining portion of the hospital’s total salaries and wage-related costs that is attributable to all other employees of the hospital is not adjusted for occupational mix.

Step 6—For each hospital, the total occupational mix adjusted salaries and wage-related costs for a hospital are calculated by summing the occupational mix adjusted salaries and wage-related costs for the 7 general service categories (from Step 5) and the unadjusted portion of the hospital’s salaries and wage-related costs for all other employees. To compute a hospital’s occupational mix adjusted average hourly wage, divide the hospital’s total occupational mix adjusted salaries and wage-related costs by the hospital’s total hours (from Step 4 of the unadjusted wage index calculation in Section F).

Step 7—To compute the occupational mix adjusted average hourly wage for an urban or rural area, sum the total occupational mix adjusted salaries and

wage-related costs for all hospitals in the area, then sum the total hours for all hospitals in the area. Next, divide the area's occupational mix adjusted salaries and wage-related costs by the area's hours.

Step 8—To compute the national occupational mix adjusted average hourly wage, sum the total occupational mix adjusted salaries and wage-related costs for all hospitals in the nation, then

sum the total hours for all hospitals in the nation. Next, divide the national occupational mix adjusted salaries and wage-related costs by the national hours. The national occupational mix adjusted average hourly wage is 26.4114.

Step 9—To compute the occupational mix adjusted wage index, divide each area's occupational mix adjusted average hourly wage (Step 7) by the

national occupational mix adjusted average hourly wage (Step 8).

Step 10—To compute the Puerto Rico specific occupational mix adjusted wage index, follow the Steps 1 through 9 above. The Puerto Rico occupational mix adjusted average hourly wage is 12.2577.

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Example of Occupational Mix Adjustment

General Service Categories/SOCs	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours	BLS National Average Hourly Wage
NATIONAL				
Nursing and Medical Assistant Services				
Registered Nurses	1,429,939,708.87	70.51%	26.77%	\$23.62
Licensed Practical Nurses	152,076,000.02	7.50%	2.85%	\$14.65
Nursing Aides, Orderlies, & Attendants	373,013,761.93	18.39%	6.98%	\$10.01
Medical Assistants	72,930,628.98	3.60%	1.37%	\$11.79
Total	2,027,960,100	100.00%	37.97%	\$20.02
HOSPITAL A				
Registered Nurses	1,642,116	79.84%		\$18.86
Licensed Practical Nurses	67,860	3.30%		\$0.48
Nursing Aides, Orderlies, & Attendants	259,177	12.60%		\$1.26
Medical Assistants	87,622	4.26%		\$0.50
Total	2,056,774	100.00%		21.11
Occupational Mix Adjustment				0.9485
HOSPITAL B				
Registered Nurses	1,510,724	64.44%		\$0.31
Licensed Practical Nurses	159,795	6.82%		\$0.09
Nursing Aides, Orderlies, & Attendants	391,201	16.69%		\$0.08

General Service Categories/SOCs	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours	BLS National Average Hourly Wage
Medical Assistants	282,728	12.06%		\$2.55
Total	2,344,449	100.00%		19.31
Occupational Mix Adjustment				1.0366
NATIONAL				
Physical Therapy Services				
Physical Therapists	45,536,940.56	61.15%	0.85%	\$27.80
Physical Therapist Assistants	17,235,657.69	23.15%	0.32%	\$17.11
Physical Therapist Aides	11,691,298.12	15.70%	0.22%	\$10.40
Total	74,463,896	100.00%	1.39%	\$22.59
HOSPITAL A				
Physical Therapists	94,987	61.40%		\$17.07
Physical Therapist Assistants	36,254	23.43%		\$4.01
Physical Therapist Aides	23,460	15.16%		\$1.58
Total	154,701	100.00%		\$22.66
Occupational Mix Adjustment				0.9971
HOSPITAL B				
Physical Therapists	60,337	57.37%		\$15.95
Physical Therapist Assistants	22,391	21.29%		\$3.64
Physical Therapist Aides	22,444	21.34%		\$2.22
Total	105,173	100.00%		\$21.81
Occupational Mix Adjustment				1.0359
NATIONAL				
Occupational Therapy Services				
Occupation Therapists	19,165,885.91	79.13%	0.36%	\$25.62
Occupation Therapist Assistants	4,082,490.26	16.86%	0.08%	\$16.81
Occupation Therapist Aides	972,594.68	4.02%	0.02%	\$11.60
Total	24,220,971	100.00%	0.45%	\$23.57
HOSPITAL A				
Occupation Therapists	40,366	90.06%		\$23.07
Occupation Therapist Assistants	0	0.00%		\$0.00
Occupation Therapist Aides	4,454	9.94%		\$1.15
Total	44,820	100.00%		\$24.23

General Service Categories/SOCs	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours	BLS National Average Hourly Wage
Occupational Mix Adjustment				0.9728
HOSPITAL B				
Occupation Therapists	26,547	79.48%		\$20.36
Occupation Therapist Assistants	1,610	4.82%		\$0.81
Occupation Therapist Aides	5,242	15.70%		\$1.82
Total	33,399	100.00%		\$22.99
Occupational Mix Adjustment				1.0253
NATIONAL				
Respiratory Therapy Services				
Respiratory Therapists	84,719,095.59	80.16%	1.59%	\$19.26
Respiratory Therapy Technicians	20,965,596.00	19.84%	0.39%	\$16.96
Total	105,684,692	100.00%	1.98%	\$18.80
HOSPITAL A				
Respiratory Therapists	75,339	97.40%		\$18.76
Respiratory Therapy Technicians	2,008	2.60%		\$0.44
Total	77,347	100.00%		\$19.20
Occupational Mix Adjustment				0.9794
HOSPITAL B				
Respiratory Therapists	73,592	65.62%		\$12.64
Respiratory Therapy Technicians	38,549	34.38%		\$5.83
Total	112,141	100.00%		\$18.47
Occupational Mix Adjustment				1.0181
NATIONAL				
Pharmacy Services				
Pharmacists	55,307,036.23	48.08%	1.04%	\$34.58
Pharmacy Technicians	55,248,144.37	48.03%	1.03%	\$12.30
Pharmacy Assistants/Aides	4,480,980.40	3.90%	0.08%	\$11.52
Total	115,036,161	100.00%	2.15%	\$22.98
HOSPITAL A				

General Service Categories/SOCs	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours	BLS National Average Hourly Wage
Pharmacists	65,863	48.65%		\$16.82
Pharmacy Technicians	69,525	51.35%		\$6.32
Pharmacy Assistants/Aides	0	0.00%		\$0.00
Total	135,388	100.00%		\$23.14
Occupational Mix Adjustment				0.9931
HOSPITAL B				
Pharmacists	45,856	39.23%		\$13.57
Pharmacy Technicians	64,986	55.60%		\$6.84
Pharmacy Assistants/Aides	6,039	5.17%		\$0.60
Total	116,881	100.00%		\$21.00
Occupational Mix Adjustment				1.0944
NATIONAL				
Dietary Services				
Dieticians	19,056,751.23	42.10%	0.36%	\$20.02
Dietetic Technicians	26,209,576.38	57.90%	0.49%	\$11.64
Total	45,266,328	100.00%	0.85%	\$15.17
HOSPITAL A				
Dieticians	13,943	100.00%		\$20.02
Dietetic Technicians	0	0.00%		\$0.00
Total	13,943	100.00%		\$20.02
Occupational Mix Adjustment				0.7576
HOSPITAL B				
Dieticians	27,458	16.29%		\$3.26
Dietetic Technicians	141,148	83.71%		\$9.74
Total	168,606	100.00%		\$13.00
Occupational Mix Adjustment				1.1668
NATIONAL				
Medical & Clinical Lab Services				
Medical & Clinical Lab Technologists	116,177,701.08	58.79%	2.17%	\$20.74
Medical & Clinical Lab Technicians	81,437,014.90	41.21%	1.52%	\$14.90

General Service Categories/SOCs	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours	BLS National Average Hourly Wage
Total	197,614,716	100.00%	3.70%	\$18.33
HOSPITAL A				
Medical & Clinical Lab Technologists	166,522	90.82%		\$18.84
Medical & Clinical Lab Technicians	16,841	9.18%		\$1.37
Total	183,363	100.00%		\$20.20
Occupational Mix Adjustment				0.9076
HOSPITAL B				
Medical & Clinical Lab Technologists	295,516	47.34%		\$9.82
Medical & Clinical Lab Technicians	328,716	52.66%		\$7.85
Total	624,232	100.00%		\$17.66
Occupational Mix Adjustment				1.0381
Total Nursing, Therapy, Pharmacy, Dietary, and Medical & Clinical Occupations	2,590,246,863.19		48.49%	
All Other Occupations	2,751,434,492.48		51.51%	
Total Hospital Employees	5,341,681,355.67		100.00%	

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In implementing an occupational mix adjusted wage index based on the above calculation, the final wage index values for 16 rural areas (36.0 percent) and 210 urban areas (4.4 percent) would decrease as a result of the adjustment. Six (6) rural areas (12.8 percent) and 111 urban areas (28.8 percent) would experience a decrease of 1 percent or greater in their wage index values. The largest negative impact for a rural area would be 2.1 percent and for an urban area, 4.0 percent. Meanwhile, 31 rural areas (66.0 percent) and 176 urban areas (45.6 percent) would experience an increase in their wage index values. Although these results show that rural hospitals would gain the most from an occupational mix adjustment to the wage index, their gains may not be as great as might have been expected. Further, it might not have been

anticipated that over one-third of rural hospitals would actually fare worse under the adjustment. Overall, a fully implemented occupational mix adjusted wage index would have a redistributive effect on Medicare payments to hospitals.

Comment: Several commenters raised concerns about the data CMS utilized to compute the occupational mix adjustment. One commenter noted that CMS computed the occupational mix adjustment using various sources of data from various time periods: (1) Average hourly wage data from the BLS 2001 OES survey; and (2) hours data collected on the Medicare occupational mix survey from calendar year 2003 or 4 weeks in 2004. The commenter added that CMS applied the adjustment to wage costs collected on the Medicare cost report during FY 2001. The

commenter believed that the data used in computing the occupational mix adjusted wage index should derive from the same time period because significant labor changes can occur in 2 to 3 years in the health care industry.

Some commenters also expressed concern about CMS' reliance on BLS data for average hourly rate information that led to CMS collecting hours data for occupations that are excluded from the wage index (certified registered nurse anesthetists (CRNAs), nurse practitioners (NPs) and clinical nurse specialists (CNSs)). The commenters recognized that CMS attempted to simplify the reporting and effort required by utilizing the BLS information. However, they recommended that future surveys collect salaries and hours from hospitals and on the same basis as Worksheet S-

3 of the cost report. The commenters believed that this would facilitate the intermediary's and CMS' review of the survey data.

Response: It is our intent to collect both salaries and hours data directly from hospitals for the computation of the occupational mix adjustment. We agree that, ideally, both the data used to compute the occupational mix adjustment and the wage data to which the adjustment is applied should derive from approximately the same time period and include the same occupational categories. However, we do not believe it was unreasonable in this instance, and in this short timeframe to use data from different time periods. We believe the consistency of our outcomes with the BLS OES data reflects this. In addition, if hospitals were concerned about collecting data from different time periods, we believe this is an issue that should have been commented upon when the actual occupational mix survey was published in 2003. We also believe that the BLS OES data are the best available for representing hospital hourly wage data. For future data collections, we will revise the occupational mix survey to allow hospitals to provide both salaries and hours data for each of the employment categories that are included on the survey. We will also assess whether future occupational mix surveys should be based on the calendar year or if the data should be collected on a fiscal year basis as part of the Medicare cost report. One logistical problem is that cost report data are collected yearly, but occupational mix survey data are collected only every 3 years.

Comment: Several comments addressed the methodology we used to calculate the occupational mix adjustment to the wage index. Most commented that the methodology appears theoretically sound, although the results appear counterintuitive. The commenters noted that one third of rural hospitals would experience a decline in their occupational mix adjusted wage index, while several large academic medical centers would experience an increase in their wage indexes. However, the commenters believed that the unexpected results are due more to errors in the data rather than our methodology for computing the occupational mix adjustment.

Four commenters cited problems with our computation of the occupational mix adjustment. The first commenter suggested that CMS should compute and apply the adjustment to the MSA average hourly wage rather than to each hospital's average hourly wage to reduce

the effect that an individual hospital's data could have on an area wage index. The second commenter suggested that CMS should calculate an occupational mix adjustment for each of the 19 SOC's rather than the 7 general service category groupings. The third commenter noted that CMS applied the occupational mix adjustment for each general service category to a percentage of total salaries that was computed based on hours represented by each general service category. This commenter believed that, instead, the adjustment should have been applied to a percentage of total salaries that was based on wage costs represented by each of the general service categories. The fourth commenter cited that, in Step 5 of the occupational mix adjustment calculation in the proposed rule, CMS applied national weights to adjust all hospitals' total salaries for occupational mix, rather than applying hospital-specific weights. This commenter suggested that, in applying the national weights to all hospitals' total wages, some area wage index values could be negatively impacted.

Response: We appreciate the input that we received from MedPAC, the Bureau of Labor Statistics, and the hospital community during our research and development of the occupational mix adjustment. We believe that our calculation of the occupational mix adjustment in this final rule is appropriate based on the purpose of the adjustment and the data we had available to calculate the adjustment.

We disagree with the comment that the occupational mix adjustment should be applied at the MSA level instead of the hospital level. By adjusting hospitals' data for occupational mix, we are treating the occupational mix adjustment consistent with the way we treat the wage index; that is, in calculating the wage index, we first compute adjusted salaries and hours for each hospital, then we sum the adjusted salaries and hours for all hospitals in an area to derive an area average hourly wage.

We also disagree with the suggestion that CMS should calculate an occupational mix adjustment for each of the 19 SOC's rather than the aggregated 7 general service category groupings. The adjustment is intended to control for hospitals' employment choices within certain service groupings, where, to an extent, the employees' skills are interchangeable. Therefore, we believe it is appropriate to apply the adjustment to the general service category grouping.

With regards to the suggestion that the adjustment should have been applied to a percentage of total salaries that was

based on salary costs represented by each of the general service categories, the initial implementation of the occupational mix adjustment did not provide for the collection of data on salaries. Therefore, we could not use the salaries for a general service category to derive the proportion of a hospital's total salaries to be adjusted for occupational mix. Based on our experience with wage and hours data, we believe that the proportions we derived from hours data would closely approximate the proportions that we would have derived if salaries data were available and used. Further, this use of hours data is consistent with a methodology we allow hospitals to use for allocating their wage-related costs on Worksheet S-3. Some hospitals base these allocations on proportions of total hours rather than salaries.

Finally, we acknowledge the error the commenter cited regarding Step 5. As shown above, we applied hospital-specific weights to adjust hospitals' total salaries in computing the occupational mix adjustment in this final rule.

Comment: Several hospitals stated that they had difficulty determining the impact of the occupational mix adjustment on their area wage index values. The commenters acknowledged that CMS provided public use files in March and May of the survey data and a public use file in June indicating hospitals' occupational mix adjustment factors. The commenters requested that CMS provide more detailed information about the findings of the occupational mix adjustment. One commenter suggested that CMS provide a table in the Addendum of the rule that shows what the area wage index values would have been without the occupational mix adjustment.

Response: In our continuing efforts to meet the information needs of the public, we will provide two additional public use files for the final occupational mix adjusted wage index: a file including each hospital's unadjusted and adjusted average hourly wage and a file including each area's unadjusted and adjusted average hourly wage and wage index value. These additional files will be posted on the Internet, at <http://cms.hhs.gov/providers/hipps/ippswage.asp>. We will also post these files with future applications of the occupational mix adjustment.

D. Worksheet S-3 Wage Data for the FY 2005 Wage Index Update

The FY 2005 wage index values (effective for hospital discharges occurring on or after October 1, 2004 and before October 1, 2005) in section

VI. of the Addendum to this final rule are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2001 (the FY 2004 wage index was based on FY 2000 wage data).

The FY 2005 wage index includes the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty).

- Home office costs and hours.

- Certain contract labor costs and hours (which includes direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services).

- Wage-related costs (The September 1, 1994, **Federal Register** included a list of core wage-related costs that are included in the wage index, and discussed criteria for including other wage-related costs (59 FR 45356)).

Consistent with the wage index methodology for FY 2004, the wage index for FY 2005 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as SNF services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The FY 2005 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours and wage-related costs of CAHs are excluded from the wage index, for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397).

Data collected for the IPPS wage index are also currently used to calculate wage indexes applicable to other providers, such as SNFs, home health agencies, and hospices. In addition, they are used for prospective payments to rehabilitation, psychiatric, and long-term care hospitals, and for hospital outpatient services.

Comment: One commenter noted that the data CMS uses to compute the wage index is 4 years old and urged CMS to use more recent data. The commenter suggested that, due to the time lapse, the wage index does not sufficiently capture trends of health care professional shortages in certain labor markets and the corresponding salary increases associated with the rise in demand for certain health care professionals.

Response: We discussed this matter in a previous notice (65 FR 47070). Due to the time period allowed for: (1)

Hospitals to complete and submit their cost reports to their intermediaries, (2) fiscal intermediaries to perform a separate, detailed review of all wage data and submit hospitals' reviewed wage data to CMS, and (3) CMS to compile a complete set of all hospitals' wage data from a common Federal fiscal year period, we do not have available more recent, complete, and reliable data to calculate the wage index. Therefore, hospitals' wage data are always 3 to 4 years old, depending on the end date of the hospital's cost reporting period, before we can use the data in calculating the wage index.

Comment: One commenter noted that, in the August 1, 2002, **Federal Register** rule (67 FR 50022), CMS stated that it would begin to collect contract labor wage costs and hours for management services and the following overhead services: administrative and general, housekeeping, and dietary. The commenter requested CMS to also add a line 25.01 to Worksheet S-3, Part II to collect wage costs and hours for contract laundry services and include the costs in the wage index calculation. Based on the commenter's analysis of the May public use file, 1,468 hospitals had no data on line 25 (direct costs for laundry services) and 1,599 hospitals had less than \$100,000 in wage costs on this line. The commenter believed that the data indicates that many hospitals contract their laundry services, and including the costs for contract laundry services would provide equity in the wage index.

Response: In the August 1, 2002, rule, we stated that, while we agree that it may be appropriate to include indirect patient care contract labor costs in the wage index, in light of concerns about hospitals' ability to accurately document and report the costs, we believe that the best approach is to assess and include these costs incrementally. We will begin collecting data on contract management, administrative and general, housekeeping, and dietary services with cost reporting periods beginning on or after October 1, 2003 (that is, the FY 2004 cost reports). Hospitals will submit their FY 2004 cost reports to their intermediaries during calendar year 2005 through early 2006. Intermediaries will complete their wage index desk reviews and submit hospitals' FY 2004 audited wage data to us by early 2007. We will use data from the FY 2004 cost reports to compute the FY 2008 wage index. Before including these additional costs in the wage index, we will analyze the impact of the costs on area wage

index values and provide a detailed analysis for public comment. Our decision on whether to include these contract costs, and other contract costs in the future, such as, contract laundry services, will depend on the outcome of our analyses and public comment.

Comment: One commenter requested CMS to designate provider-based clinics (PBCs) as an IPPS-excluded area in order to remove the costs from the wage index. The commenter stated that PBCs are like physician private offices, which are excluded from the wage index. PBCs bill the technical component under certain outpatient ambulatory payment classifications (APCs) and the professional component under the physician fee schedule. The commenter noted that PBC costs are not paid under IPPS.

Response: We appreciate the commenter's suggestion. However, as this matter was not addressed in the FY 2005 proposed rule, or any previous rulemaking, we are not prepared to provide a decision about PBC costs in this final rule. We intend to explore a comprehensive assessment of the costs in a future rule.

E. Verification of Worksheet S-3 Wage Data

The wage data for the FY 2005 wage index were obtained from Worksheet S-3, Parts II and III of the FY 2001 Medicare cost reports. Instructions for completing the Worksheet S-3, Parts II and III are in the Provider Reimbursement Manual, Part I, sections 3605.2 and 3605.3. The data file used to construct the wage index includes FY 2001 data as of June 25, 2004. As in past years, we performed an intensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our fiscal intermediaries to revise or verify data elements that resulted in specific edit failures. The unresolved data elements that were included in the calculation of the proposed FY 2005 wage index have been resolved and are reflected in the calculation of the final FY 2005 index. For the final FY 2005 wage index in this final rule, we removed the data for 237 hospitals from our database: 147 hospitals became critical access hospitals by the time we published from the FY 2005 wage index), and 76 hospitals were low Medicare utilization hospitals or failed edits that could not be corrected because the hospitals terminated the program or changed ownership. In addition, we removed the wage data for 14 hospitals with incomplete or inaccurate data resulting in zero or negative, or otherwise

aberrant, average hourly wages. As a result, the final FY 2005 wage index is calculated based on FY 2001 wage data from 3,955 hospitals.

In constructing the FY 2005 wage index, we include the wage data for facilities that were IPPS hospitals in FY 2001, even for those facilities that have terminated their participation in the program as hospitals, as long as those data do not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period. However, we exclude the wage data for CAHs (as discussed in 68 FR 45397). The wage index in this final rule excludes hospitals that are designated as CAHs by February 24, 2004, the date of the latest available Medicare CAH listing at the time we released the proposed wage index public use file on February 27, 2004.

F. Computation of the Unadjusted Wage Index

The method used to compute the FY 2005 wage index without an occupational mix adjustment follows:

Step 1—As noted above, we based the FY 2005 wage index on wage data reported on the FY 2001 Medicare cost reports. We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S-3, Parts II and III of the Medicare cost report for the hospital's cost reporting period beginning on or after October 1, 2000, and before October 1, 2001. In addition, we included data from some hospitals that had cost reporting periods beginning before October 2000 and reported a cost reporting period covering all of FY 2001. These data were included because no other data from these hospitals would be available for the cost reporting period described above, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2001 data. We note that, if a hospital had more than one cost reporting period beginning during

FY 2001 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2000, and before October 1, 2001), we included wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2—Salaries—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. In calculating a hospital's average salaries plus wage-related costs, we subtracted from Line 1 (total salaries) the GME and CRNA costs reported on lines 2, 4.01, 6, and 6.01, the Part B salaries reported on Lines 3, 5 and 5.01, home office salaries reported on Line 7, and excluded salaries reported on Lines 8 and 8.01 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtracted from Line 1 the salaries for which no hours were reported. To determine total salaries plus wage-related costs, we added to the net hospital salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 9 and 10), home office salaries and wage-related costs reported by the hospital on Lines 11 and 12, and nonexcluded area wage-related costs (Lines 13, 14, and 18).

We note that contract labor and home office salaries for which no corresponding hours are reported were not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 18) are excluded if no corresponding salaries are reported for those employees on Line 4.

Step 3—Hours—With the exception of wage-related costs, for which there are no associated hours, we computed total hours using the same methods as described for salaries in Step 2.

Step 4—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocated overhead costs to areas of the hospital excluded from the wage

index calculation. First, we determined the ratio of excluded area hours (sum of Lines 8 and 8.01 of Worksheet S-3, Part II) to revised total hours (Line 1 minus the sum of Part II, Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, and Part III, Line 13 of Worksheet S-3). We then computed the amounts of overhead salaries and hours to be allocated to excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Line 13 of Worksheet S-3, Part III. Next, we computed the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determined the ratio of overhead hours (Part III, Line 13) to revised hours (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, and 7); (2) we computed overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 13, 14, and 18; and (3) we multiplied the computed overhead wage-related costs by the above excluded area hours ratio. Finally, we subtracted the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5—For each hospital, we adjusted the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimated the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2000 through April 15, 2002 for private industry hospital workers from the Bureau of Labor Statistics' *Compensation and Working Conditions*. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated below.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2000	11/15/2000	1.07771
11/14/2000	12/15/2000	1.07273
12/14/2000	1/15/2001	1.06767
01/14/2001	02/15/2001	1.06245
02/14/2001	03/15/2001	1.05706
03/14/2001	04/15/2001	1.05168
04/14/2001	05/15/2001	1.04645
05/14/2001	06/15/2001	1.04139
06/14/2001	07/15/2001	1.03638
07/14/2001	08/15/2001	1.03134
08/14/2001	09/15/2001	1.02627
09/14/2001	10/15/2001	1.02133
10/14/2001	11/15/2001	1.01665
11/14/2001	12/15/2001	1.01224
12/14/2001	01/15/2002	1.00803
01/14/2002	02/15/2002	1.00395
02/14/2002	03/15/2002	1.00000
03/14/2002	04/15/2002	0.99610

For example, the midpoint of a cost reporting period beginning January 1, 2001, and ending December 31, 2001, is June 30, 2001. An adjustment factor of 1.03638 would be applied to the wages of a hospital with such a cost reporting period. In addition, for the data for any cost reporting period that began in FY 2001 and covered a period of less than 360 days or more than 370 days, we annualized the data to reflect a 1-year cost report. Dividing the data by the number of days in the cost report and then multiplying the results by 365 accomplish annualization.

Step 6—Each hospital was assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B) or section 1886(d)(10) of the Act. Within each urban or rural labor market area, we added the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine

the total adjusted salaries plus wage-related costs for the labor market area.

Step 7—We divided the total adjusted salaries plus wage-related costs obtained under both methods in Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8—We added the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the nation and then divided the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage. Using the data as described above, the national average hourly wage is \$26.3570.

Step 9—For each urban or rural labor market area, we calculated the hospital wage index value by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10—Following the process set forth above, we developed a separate Puerto Rico-specific wage index for purposes of adjusting the Puerto Rico standardized amounts. (The national Puerto Rico standardized amount is adjusted by a wage index calculated for all Puerto Rico labor market areas based on the national average hourly wage as described above.) We added the total adjusted salaries plus wage-related costs (as calculated in Step 5) for all hospitals in Puerto Rico and divided the sum by the total hours for Puerto Rico (as calculated in Step 4) to arrive at an overall average hourly wage of \$12.2568 for Puerto Rico. For each labor market area in Puerto Rico, we calculated the Puerto Rico-specific wage index value by dividing the area average hourly wage (as calculated in Step 7) by the overall Puerto Rico average hourly wage.

Step 11—Section 4410 of Public Law 105-33 provides that, for discharges on

or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. Furthermore, this wage index floor is to be implemented in such a manner as to ensure that aggregate IPPS payments are not greater or less than those that would have been made in the year if this section did not apply. For FY 2005, this change affects 208 hospitals in 57 urban areas. The areas affected by this provision are identified by a footnote in Table 4A in the Addendum of this final rule.

G. Computation of the FY 2005 Blended Wage Index

As we proposed in the May 18, 2004, proposed rule, for the final FY 2005 wage index, we are using a blend of the occupational mix adjusted wage index and the unadjusted wage index, in order to minimize the redistributive impact of the occupational mix adjustment (as discussed in section III.C.2. of this preamble) for the first year of its implementation. Specifically, we are basing the FY 2005 wage index on a blend of 10 percent of an average hourly wage, adjusted for occupational mix, and 90 percent of an average hourly wage, unadjusted for occupational mix. Using this blend, the national average hourly wage is \$26.3624 and the Puerto Rico specific average hourly wage is \$12.2569. We chose this blend for FY 2005 in recognition that this was the first time, for the administration of the occupational mix survey, hospitals had a short timeframe for collecting their occupational mix survey data and documentation, we could not collect optimum data (that is, wages and hours data from a 1-year period for all hospitals) within the mandatory timeframe for implementing the adjustment, and we had no baseline data to use in developing a desk review program that could ensure the accuracy of the occupational mix survey data.

In addition, we are moving cautiously with implementing the occupational mix adjustment in recognition of changing trends in the hiring of nurses, the largest group in our survey. Since the enactment of section 304(c) of Public Law 106–554, the law requiring the occupational mix adjustment to the wage index, some States have implemented laws that establish floors on the minimum level of registered nurse staffing that hospitals must maintain in order to continue to be licensed and certified by the State. In addition, some rural areas that are facing a shortage of physicians may be hiring more registered nurses as

extenders or substitutes for physicians. Such trends may explain why the occupational mix impacts in section III.C.2. of this preamble are not as expected for rural areas in particular.

Further, we are using this blend because, although we want to minimize the immediate impact of the occupational mix adjustment on hospitals' wage index values, we do not want to nullify the value and intent of the occupational mix adjustment. We believe that the blended wage index we are proposing satisfies both of these goals. With only 10 percent of the wage index adjusted for occupational mix, the wage index values for 14 rural areas (21.3 percent) and 205 urban areas (53.1 percent) would decrease as a result of the adjustment. However, the decreases would be minimum; the largest negative impact for a rural area would be only 0.21 percent and for an urban area, 0.40 percent. Conversely, 31 rural areas (66 percent) and 172 urban areas (44.6 percent) would benefit from this adjustment, with 1 urban area increasing 2.2 percent and all other areas gaining 0.7 percent or less. Overall, a wage index that has only 10 percent of the salaries adjusted for occupational mix would have a minimal redistributive effect on Medicare payments to hospitals. (See Appendix A to this final rule for further analyses of the impact of the occupational mix adjustment on the FY 2005 wage index.)

The wage index values in Tables 4A, 4B, 4C, 4F, 4G, and 4H and the average hourly wages in Tables 2, 3A, and 3B in the Addendum to this final rule include the occupational mix adjustment. We note that, although we are using a blended wage index for FY 2005, at this time we are not applying an incremental phase-in of the occupational mix adjustment beyond FY 2005. The application of the occupational mix adjustment beyond FY 2005 will be determined and discussed in subsequent IPPS updates.

Comment: Commenters generally agreed with CMS' decision to only partially implement the occupational mix adjustment with the FY 2005 wage index. A majority of commenters supported the proposed blended wage index in which the occupational mix adjusted portion is 10 percent. A few commenters suggested other applications of the adjustment as follows:

- Lower the percent adjusted for occupational mix to 5 percent or less. In addition, CMS should not raise the percent until the occupational mix survey process is improved.

- Apply an occupational mix adjustment to only 1 percent of the wage index.

- Apply a higher percentage of the occupational mix adjustment if the results for the hospital are positive and a lower percentage if the results are negative.

- Fully apply the adjustment to hospitals that are positively impacted and use a blend of 10 percent for hospitals that are negatively impacted.

- Phase in the adjustment, for example, over a period of 10 years (apply 10 percent per year). After the adjustment is fully implemented, cap the adjustment at 2 percent. That is, an occupational mix adjusted wage index value should be no greater or less than 2 percent of what the wage index value would have been in the absence of the occupational mix adjustment.

- Hold hospitals harmless on the use of occupational mix adjustment for 3 years.

One commenter stated that CMS should impose a temporary moratorium on the use of the occupational mix data until more accurate and reliable data can be gathered and studied.

Response: Due to the general support we received for our proposal to base the FY 2005 wage index on a blend of 10 percent of an average hourly wage adjusted for occupational mix and 90 percent of an average hourly wage unadjusted for occupational mix, we are proceeding as proposed. As we stated above, we will determine and discuss the application of future adjustments in subsequent IPPS updates.

H. Revisions to the Wage Index Based on Hospital Redesignation

1. General

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify by September 1 of the year preceding the year during which reclassification is sought. Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassification to become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in §§ 412.230 through 412.280.

Section 1886(d)(10)(D)(v) of the Act provides that, beginning with FY 2001,

a MGCRB decision on a hospital reclassification for purposes of the wage index is effective for 3 fiscal years, unless the hospital elects to terminate the reclassification. Section 1886(d)(10)(D)(vi) of the Act provides that the MGCRB must use the 3 most recent years' average hourly wage data in evaluating a hospital's reclassification application for FY 2003 and any succeeding fiscal year.

Section 304(b) of Public Law 106-554 provides that the Secretary must establish a mechanism under which a statewide entity may apply to have all of the geographic areas in the State treated as a single geographic area for purposes of computing and applying a single wage index, for reclassifications beginning in FY 2003. The implementing regulations for this provision are located at § 412.235.

Section 1886(d)(8)(B) of the Act requires the Secretary to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the MSA to which the greatest number of workers in the county commute if: the rural county would otherwise be considered part of an urban area under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of *all* contiguous MSAs. In light of the new CBSA definitions and the Census 2000 data, we undertook to identify those counties meeting these criteria. The eligible counties are identified below, as well as a discussion of counties that no longer meet the criteria under this provision.

2. Effects of Reclassification

Section 1886(d)(8)(C) of the Act provides that the application of the wage index to redesignated hospitals is dependent on the hypothetical impact that the wage data from these hospitals would have on the wage index value for the area to which they have been redesignated. These requirements for determining the wage index values for redesignated hospitals is applicable both to the hospitals located in rural counties deemed urban under section 1886(d)(8)(B) of the Act and hospitals that were reclassified as a result of the MGCRB decisions under section 1886(d)(10) of the Act. Therefore, as provided in section 1886(d)(8)(C) of the Act,⁵ the wage index values were

determined by considering the following:

- If including the wage data for the redesignated hospitals would reduce the wage index value for the area to which the hospitals are redesignated by 1 percentage point or less, the area wage index value determined exclusive of the wage data for the redesignated hospitals applies to the redesignated hospitals.

- If including the wage data for the redesignated hospitals reduces the wage index value for the area to which the hospitals are redesignated by more than 1 percentage point, the area wage index determined inclusive of the wage data for the redesignated hospitals (the combined wage index value) applies to the redesignated hospitals.

- If including the wage data for the redesignated hospitals increases the wage index value for the urban area to which the hospitals are redesignated, both the area and the redesignated hospitals receive the combined wage index value. Otherwise, the hospitals located in the urban area receive a wage index excluding the wage data of hospitals redesignated into the area.

- The wage data for a reclassified urban hospital is included in both the wage index calculation of the area to which the hospital is reclassified (subject to the rules described above) and the wage index calculation of the urban area where the hospital is physically located.

- Rural areas whose wage index values would be reduced by excluding the wage data for hospitals that have been redesignated to another area continue to have their wage index values calculated as if no redesignation had occurred (otherwise, redesignated rural hospitals are excluded from the calculation of the rural wage index).

- The wage index value for a redesignated rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located.

3. FY 2005 Issues

Recent policies and decisions that will affect hospitals' geographic classifications for FY 2005 are discussed below. First, we describe decisions by

hospitals if the urban area wage index is below the wage index for rural areas in the State in which the urban area is located, this was effectively made moot by section 4410 of Pub. L. 105-33, which provides that the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State.

Also, section 1886(d)(8)(C)(iv)(II) of the Act provides that an urban area's wage index may not decrease as a result of redesignated hospitals if the urban area is located in a State that is composed of a single urban area.

the MGCRB on applications received in accordance with the ongoing reclassification process described in the regulations at §§ 412.230 through 412.280. Second, we describe the implications for reclassification decisions by the MGCRB to be effective during FY 2005 of our adoption of new MSA definitions for the FY 2005 wage index. Third, we discuss the new counties identified under the standards at section 1886(d)(8)(B) of the Act, based on the new CBSA and the Census 2000 data. Fourth, we discuss the interactions of these changes with reclassifications approved under the one-time appeal process for hospital wage index reclassifications at section 508 of Public Law 108-173. Fifth, we discuss our implementation of section 505 of Public Law 108-173. Under this provision, the Secretary must establish a new process, similar to the current wage index reclassification process, to make adjustments to the hospital wage index, based on commuting patterns of hospital employees.

a. FY 2005 MGCRB Reclassifications

In the August 1, 2003 IPPS final rule, we indicated that hospitals submitting applications for reclassification by the MGCRB for FY 2005 should base those applications on the current (for Medicare payment purposes) MSAs (68 FR 45401). At the time this final rule was constructed, the MGCRB had completed its review of FY 2005 reclassification requests. There were 339 hospitals approved for wage index reclassifications by the MGCRB for FY 2005. Because MGCRB wage index reclassifications are effective for 3 years, hospitals reclassified during FY 2003 or FY 2004 are eligible to continue to be reclassified based on prior reclassifications to current MSAs during FY 2005. There were 55 hospitals reclassified for wage index in FY 2003 and 102 hospitals reclassified for wage index in FY 2004.

In the past, hospitals have been able to apply to be reclassified for purposes of either the wage index or the standardized amount. Existing regulations at § 412.230(a)(5)(ii) state that, after 2002, a hospital may not be reclassified for purposes of the standardized amount if the area to which the hospital seeks reclassification does not have a higher standardized amount than the standardized amount the hospital currently receives. Standardized amount reclassifications are only effective for 1 year, so hospitals must reapply every year. At the time the FY 2005 reclassification applications were due, hospitals applied on the basis that the law still provided for a higher

⁵ Although section 1886(d)(8)(C)(iv)(II) of the Act also provides that the wage index for an urban area may not decrease as a result of redesignated

standardized amount for hospitals in large urban areas. However, section 401 of Public Law 108–173 established that all hospitals will be paid on the basis of the large urban standardized amount beginning with FY 2004. Consequently, all hospitals will be paid on the basis of the same standardized amount, which effectively makes standardized amount reclassifications moot, at least for purposes of the standardized amount. As a result, the MGCRB denied all applications for standardized amount reclassifications for FY 2005. In light of the fact that all hospitals are now paid on the basis of the same standardized amount, in the proposed rule, we explained our proposed method for eliminating standardized amount reclassifications. Although there could still be some benefit in terms of payments for some hospitals under the DSH adjustment for operating IPPS, section 402 of Public Law 108–173 equalized DSH payments for rural and urban hospitals, with the exception that the rural DSH adjustment is capped at 12 percent (except that rural referral centers have no cap) (a detailed discussion appears in section IV.H. of this preamble).

No commenters objected to our proposal to eliminate standardized amount reclassifications.

b. Implementation of New MSAs

As discussed above, we are implementing the new CBSAs for FY 2005. Under these new CBSAs definitions, many existing MSAs are reconfigured. Therefore, because hospitals applied for reclassification during FY 2005 on the basis of the MSAs currently used to define labor market areas for FY 2004, the definition of the MSA to which they have been reclassified, or the area where they are located, may have changed under our implementation. Hospitals that were reclassified for FY 2005 were asked to verify that the reclassified wage index for the labor market area into which they had been reclassified (in Table 4C in the Addendum to the May 18, 2004 proposed rule) exceeded the wage index of the labor market area where they are located (in Table 4A or 4B in the Addendum of the May 18, 2004 proposed rule) after our proposed implementation of the new MSAs. Hospitals could have withdrawn their FY 2005 reclassifications within 45 days of the publication of the proposed rule.

In some cases, the new CBSA definitions result in previously existing MSAs being divided into two or more separate MSAs. Given that the areas to which the hospitals reclassified no longer exist in FY 2005, we needed to

propose rules we could use to determine such hospitals' reclassification areas. We proposed assigning the hospital to the nearest county in the current MSA, and the hospital's FY 2005 reclassification is to the new MSA (under the CBSA definitions) that includes that county to which it has been assigned.

For example, the Ann Arbor, MI MSA currently includes the counties of Lenawee, MI; Livingston, MI; and Washtenaw, MI. Under the new CBSA definitions, the Ann Arbor, MI MSA is comprised solely of the county of Washtenaw, MI. Lenawee, MI now comprises the Adrian, MI Micropolitan Area, and Livingston, MI is now in the Warren-Farmington Hills-Troy, MI Metropolitan Division of Detroit. Therefore, a hospital that was reclassified by the MGCRB into Ann Arbor for either FY 2003, FY 2004, or FY 2005 would be assigned to either the Ann Arbor, MI MSA or the Warren-Farmington Hills-Troy, MI Metropolitan Division, depending on whether the hospital was closer to Washtenaw or Livingston (A reclassified hospital located closest to Lenawee County would be assigned to an MSA based on whether it is closer to Washtenaw or Livingston, which are still in MSAs. We would not consider Lenawee because it is now considered part of the statewide rural area.)

Reclassified hospitals that have been assigned to a new MSA are identified in Table 9A in the Addendum of this final rule by the identification of the county used to designate them. We determined that the hospital is in closest proximity to the county listed based on mapping data available to us at the time of the preparation of this final rule. Hospitals that disagreed with our determination of the closest proximate county on which to assign them to a new MSA were given the opportunity to submit a comment indicating the basis for their disagreement.

Comment: Many hospitals approved for reclassification under the traditional reclassification process objected to our proposal to assign hospitals to the nearest county in the MSA to which it was reclassified. Several hospitals recommended allowing hospitals to amend their FY 2005 reclassification applications or implementing the policy adopted in 1994. Others recommended that CMS consider retracting the proposal, in its entirety and, in doing so, allow hospitals to be reclassified to the area approved by the MGCRB for the full 3 years. In the September 1, 1993 final rule (58 FR 46292), the adopted methodology for effectuating FY 1994 MGCRB decisions resulted in the

assignment of hospitals to the revised labor market area that included "most or all of the counties that comprised the labor market area to which the hospital was reclassified by the MGCRB based on the current labor market area definitions." Others recommended that CMS consider retracting the proposal in its entirety and in doing so allow hospitals to be reclassified to the area approved by the MGCRB for the full 3 years.

Finally, two sets of hospitals commented on special circumstances that would arise under the rule as proposed. One group of hospitals from Rhode Island commented that the nearest county proposal does not take into consideration instances where a hospital or group of hospitals reclassified to an area defined under the old MSA definitions is assigned to the nearest county which, under the new definitions, is in its own home MSA. In another situation, a group of hospitals in the Midwest described a situation where, under the new definitions, the MSA the hospitals reclassified to splits and the hospitals are assigned to the MSA that contains the nearest county from the old MSA. In some cases, a hospital may also satisfy the normal distance requirement for reclassification into one or more of the new MSAs that were once part of the old MSA. In these cases, the commenter believed that a hospital should be permitted to reclassify to any MSA that was once part of the old MSA for which it meets the normal proximity requirement.

Response: We acknowledge that the new MSA designations have considerable effect on hospital geographic reclassifications under both section 1886(d)(8)(B) and 1886(d)(10) of the Act. Because the MGCRB reclassifications approved for FY 2005 and prior years are based on the old MSA designations, it was necessary to reconcile (as we did with the FY 1994 reclassification decisions) the processes of implementing the new MSA designations with the MGCRB decisions for FY 2003, FY 2004, and FY 2005. As was the case with the implementation of new MSA definitions in FY 1994, we have sought to implement the MGCRB decisions in the manner that is most consistent with implementing the new labor market areas. As we stated in the May 25, 1993 proposed rule (58 FR 30234), " * * * we believe that in reconciling the two processes, we must balance our obligation to implement the reclassifications prescribed by the MGCRB's decisions with our duty to implement the new labor market areas in as uniform a manner as possible. Thus, we believe that when a hospital

has been reclassified based on the old MSA definitions, payment to the hospital should be based on the new MSA definition most compatible with the reclassification decision." On the basis of our evaluations, we decided not to employ the FY 1994 reclassification assignment rule. This is because doing so would have led in many cases to anomalous results in the context of the current MSA changes. For example, we needed to take in account instances where MSAs split, creating smaller MSAs on the boundaries of what was the old MSA. If we were to apply the FY 1994 rule to the new MSA designations, many hospitals would have been reclassified into MSAs farther away than a new bordering MSA. We believe this would have been inconsistent with the proximity rules that govern reclassifications.

However, the commenters on the two situations described above persuade us that two refinements to the basic rule are appropriate.

- We will assign the hospital or group of hospitals previously reclassified in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act to an MSA that is splitting, to the MSA outside the hospital's own MSA that contains the nearest county from the old MSA. For example, under the new MSA designations, the Boston-Worcester-Lancaster-Lowell-Brockton, MA-NH NECMA was split into several new MSAs. The reclassification of Rhode Island hospitals to the old Boston NECMA resulted, under our proposal, in an assignment to the Providence-New Bedford-River Falls, RI-MA MSA, their home MSA. This is because the nearest proximate county of the old Boston NECMA, Bristol County, is now part of the Providence-New Bedford-River Falls, RI-MA MSA. Under this revision, the Rhode Island hospitals approved for reclassification for FY 2005 will be assigned to the Boston-Cambridge-Quincy, MA-NH MSA, the nearest outside MSA that contains a county from the old Boston-Worcester-Lancaster-Lowell-Brockton, MA-NH NECMA.

- In cases where a hospital (or group of hospitals) was reclassified under section 1886(d)(8)(B) or section 1886(d)(10) of the Act to an MSA that has been split, the hospital may be reclassified to any MSA containing counties from the old MSA reclassification provided that the hospital demonstrates that it meets the applicable proximity requirements in 42 CFR 412.230(b) and (c) (for individual hospitals), § 412.232(a)(1) (for a rural group), and § 412.234(a)(2) and (a)(3)

(for an urban group) or in relation to the MSA.

We have changed the reclassification assignments for hospitals that brought this situation to our attention. Hospitals in this situation that wish to be reassigned to the nearest alternate county, for which they meet the applicable proximity criteria, may notify us in writing within 30 days of the date of publication of this final rule. The notification should contain:

- The hospital's name and street address.
- The hospital's provider number.
- The name, title, and telephone number of a contact person.
- The area (name and MSA number) identified in the FY 2005 reclassification application and the name and MSA number of the "assigned" area.
- Documentation certifying that they meet the requisite proximity requirement for assignment to the nearest alternate county.

We also note that the 1-year transition blend that we have adopted for FY 2005 will have the effect of giving hospitals that would experience a decrease in wage index due to the new MSA designations, 50 percent of the wage index determined using the old area definitions for MSAs to which the hospital reclassified, and 50 percent of the wage index determined using the new area definition for the MSA to which the hospital is assigned in this final rule. This provision will mitigate any negative effects of the new labor market areas on reclassifying hospitals and all other hospitals.

Comment: One commenter suggested that CMS provide that a hospital will not lose SCH status, or other special designations that are dependent upon being located in a rural area, by being redesignated into an MSA. The commenter further elaborated that the loss of SCH status can have profound implications for a hospital, including loss of special payment under the hospital inpatient and outpatient payment systems and loss of favorable treatment for purposes of geographic reclassification. The commenter recommended that CMS provide that hospitals with SCH status that are redesignated into an urban area will maintain SCH status. The commenter also recommended that, likewise, CMS provide that these hospitals will continue to be eligible for hold-harmless payments under the outpatient PPS, even though these hospitals will no longer be physically located in an urban area.

Response: The regulations at § 412.103(a)(3) provide for a hospital

located in an urban area to be reclassified as a rural hospital if it would qualify as an SCH if it were located in a rural area, or if it meets any of the other conditions specified. Because any reclassification under this provision is effective as of the filing date of the application, existing SCHs that have been redesignated to urban areas and otherwise meet all of the requirements for SCH status could retain their SCH designation by filing an application for reclassification as rural with their CMS Regional Office before October 1, 2004.

In order to retain its SCH status when the area in which it is located is redesignated from rural to urban, a hospital must apply for reclassification as rural under the regulations at § 412.103(a). Section 412.103(a) specifies that a prospective payment hospital that is located in an urban area may be reclassified as a rural hospital if it submits a complete application and meets any of the specified conditions, including § 412.103(a)(3), which states, "The hospital would qualify as a rural referral center as set forth in § 412.96, or as a sole community hospital as set forth in § 412.92, if the hospital were located in a rural area." A hospital seeking reclassification under this section must submit a complete application in writing to its CMS Regional Office. Because any reclassification under this provision is effective as of the filing date of the application, existing SCHs that have been redesignated to urban areas effective October 1, 2004, and otherwise meet all of the requirements for SCH status, could retain their SCH designation, without a break in status, by filing an application for reclassification as rural with their CMS Regional Office before October 1, 2004.

We note that a hospital located in an urban area and more than 35 miles from other like hospitals would qualify as an SCH under § 412.92(a). In order to retain its SCH status by qualifying as an urban SCH under this provision, a hospital must submit an application to its fiscal intermediary, in accordance with the classification procedure at § 412.92(b). According to that procedure, the fiscal intermediary would review the request and send the request, with its recommendation, to the CMS Regional Office responsible for the hospital. The CMS Regional Office would review the request and the fiscal intermediary's recommendation and notify the fiscal intermediary of its approval or disapproval. SCH status is effective 30 days after the date of CMS' written notification to the fiscal intermediary. Therefore, written notification dated by

September 1, 2004, would be effective by October 1, 2004.

We note that comments regarding the hospital outpatient PPS will need to be addressed as part of the outpatient prospective payment system rule that is under development.

Comment: One commenter requested CMS to clarify that rural RRCs will not lose that status when they become urban.

Response: Section 4202(b) of Public Law 105–33 states, in part, “Any hospital classified as a rural referral center by the Secretary * * * for fiscal year 1991 shall be classified as such a rural referral center for fiscal year 1998 and each subsequent year.” In the August 29, 1997 final rule with comment period, we reinstated RRC status for all hospitals that lost the status due to triennial review or MGCRB reclassification, but not to hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban (62 FR 45999).

However, subsequently, in the August 1, 2000 final rule, we indicated we were revisiting that decision (65 FR 47089). Specifically, we stated we would permit hospitals that previously qualified as an RRC and that lost their status due to OMB redesignation of the county in which they are located from rural to urban to be reinstated as an RRC. This policy extends to RRCs located in counties that become urban as a result of the new MSAs implemented in this final rule.

Comment: One commenter suggested that CMS utilize its broad discretion under the Act to designate urban hospitals as RRCs for purposes of geographic reclassification if such hospitals reflect the same characteristics of those facilities currently designated urban RRCs. The commenter stated that, otherwise, CMS will fail in its desire to treat all RRCs equally and will continue to significantly disadvantage other urban hospitals that play the same

critical role in treating Medicare rural beneficiary populations. The commenter suggested designating any hospital meeting the criterion of § 412.103(a)(3) as it relates to RRCs as an urban RRC for geographic reclassification purposes.

Response: While CMS has broad discretion regarding establishing criteria for geographic reclassification purposes under section 1886(d)(10) of the Act, we are limited in designating a hospital as an RRC. Section 1886(d)(5)(C)(I) of the Act limits the Secretary to giving RRC status to a hospital that is classified as a rural hospital (with certain exceptions for previously designated RRCs, as noted above). In other words, CMS is, in fact, limited from granting first-time RRC status to a hospital that is not classified as a rural hospital.

Comment: Another commenter stated that some hospitals, due to geography and market size, are located in an urban area but serve a high number of rural patients. The commenter further stated that CMS noted RRCs play a significant role in treating Medicare beneficiaries from rural areas, whether or not a particular hospital is physically located in a rural or urban area. The commenter asked that CMS review the RRC criteria and revise it so that urban hospitals can qualify for RRC status and be on the same level as their urban RRC counterparts.

Response: There is already a regulatory provision for these urban hospitals that are like RRCs to obtain that status by first being reclassified as rural. Section 412.103(a)(3) provides for hospitals that would otherwise qualify as an RRC if they were rural to be reclassified as rural.

c. Redesignations Under Section 1886(d)(8)(B) of the Act

Beginning October 1, 1988, section 1886(d)(8)(B) of the Act required us to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the MSA to which the greatest number of workers in the

county commute, if the rural county would otherwise be considered part of an urban area under the standards published in the **Federal Register** on January 3, 1980 (45 FR 956) for designating MSAs (and for designating NECMAs), and if the commuting rates used in determining outlying counties (or, for New England, similar recognized areas) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous MSAs (or NECMAs). Hospitals that met the criteria using the January 3, 1980 version of these OMB standards were deemed urban for purposes of the standardized amounts and for purposes of assigning the wage data index.

Section 402 of Public Law 106–113 provides that, with respect to FYs 2001 and 2002, a hospital may elect to have the 1990 standards applied to it for purposes of section 1886(d)(8)(B) of the Act and that, beginning with FY 2003, hospitals will be required to use the standards published in the **Federal Register** by the Director of OMB based on the most recent decennial census. We implemented section 402 in the August 1, 2001, **Federal Register** (66 FR 39868). However, at that time, updated standards based on the Census 2000 data were not available.

For FY 2005, we are using OMB’s 2000 CBSA standards and the Census 2000 data to identify counties qualifying under section 1886(d)(8)(B) of the Act for FY 2005. The number of qualifying counties, shown in the following chart, increases from 28 to 98. As we proposed, we are providing that, effective for discharges on or after October 1, 2004, hospitals located in the rural counties listed in the first column of the following table will be redesignated for purposes of assigning the wage index to the urban area listed in the second column.

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**Chart 6.--Counties Redesignated as Urban under
Section 1886(d)(8)(B) of the Act
(Based on CBSAs and Census 2000 Data)**

Rural County	MSA
Cherokee, AL	Rome, GA
Macon, AL	Auburn, AL
Talladega, AL	Anniston, AL
Hot Spring, AR	Hot Spring, AR
Litchfield, CT	Hartford, CT
Windham, CT	Hartford, CT
Bradford, FL	Gainesville, GA
Flagler, FL	Deltona-Daytona Beach-Ormond Beach, FL
Hendry, FL	Miami, FL
Levy, FL	Gainesville, FL
Walton, FL	Ft. Walton, Beach, FL
Banks, GA	Gainesville, FL
Chattooga, GA	Chattanooga, TN-GA
Jackson, GA	Atlanta, GA
Lumpkin, GA	Atlanta, GA
Morgan, GA	Atlanta, GA
Peach, GA	Macon, GA
Polk, GA	Atlanta, GA
Talbot, GA	Columbus, GA-AL
Bingham, ID	Idaho Falls, ID
Christian, IL	Springfield, IL
DeWitt, IL	Bloomington-Normal, IL
Iroquois, IL	Kankakee, IL
Logan, IL	Springfield, IL
Mason, IL	Peoria, IL
Ogle, IL	Rockford, IL
Clinton, IN	Lafayette, IN
Henry, IN	Indianapolis, IN
Spencer, IN	Evansville, IN-KY
Starke, IN	Chicago, IL-IN
Warren, IN	Lafayette, IN
Boone, IA	Ames, IA
Buchanan, IA	Waterloo, IA
Cedar, IA	Iowa City, IA
Allen, KY	Bowling Green, KY
Assumption Parish, LA	Baton Rouge, LA
St. James Parish, LA	Baton Rouge, LA
Allegan, MI	Holland, MI
Montcalm, MI	Grand Rapids, MI
Oceana, MI	Muskegon, MI
Shiawassee, MI	Lansing, MI
Tuscola, MI	Saginaw, MI
Fillmore, MN	Rochester, MN

Rural County	MSA
Dade, MO	Springfield, MO
Pearl River, MS	Biloxi-Gulfport, MS
Caswell, NC	Burlington, NC
Granville, NC	Durham, NC
Harnett, NC	Raleigh, NC
Lincoln, NC	Charlotte NC-SC
Polk, NC	Spartanburg, NC
Los Alamos, NM	Sante Fe, NM
Lyon, NV	Carson City, NV
Cayuga, NY	Syracuse, NY
Columbia, NY	Albany, NY
Genesee, NY	Rochester, NY
Greene, NY	Albany, NY
Schuyler, NY	Ithaca, NY
Sullivan, NY	Poughkeepsie-Newburgh, NY
Wyoming, NY	Buffalo, NY
Ashtabula, OH	Cleveland, OH
Champaign, OH	Springfield, OH
Columbiana, OH	Youngstown, OH-PA
Cotton, OK	Lawton, OK
Linn, OR	Corvallis, OR
Adams, PA	York, PA
Clinton, PA	Williamsport, PA
Greene, PA	Pittsburgh, PA
Monroe, PA	New York-Newark, NY-NJ-CT
Schuylkill, PA	Reading, PA
Susquehanna, PA	Binghamton, NY-PA
Clarendon, SC	Sumter, SC
Lee, SC	Sumter, SC
Oconee, SC	Greenville, SC
Union, SC	Spartanburg, SC
Meigs, TN	Cleveland, TN
Bosque, TX	Waco, TX
Falls, TX	Waco, TX
Fannin, TX	Dallas-Fort Worth-Arlington, TX
Grimes, TX	College Station-Bryan, TX
Harrison, TX	Longview, TX
Henderson, TX	Dallas-Fort Worth-Arlington, TX
Milam, TX	Austin, TX
Van Zandt, TX	Dallas-Fort Worth-Arlington, TX
Willacy, TX	Brownsville, TX

Rural County	MSA
Buckingham, VA	Charlottesville, VA
Floyd, VA	Blacksburg, VA
Middlesex, VA	Virginia Beach, VA
Page, VA	Harrisonburg, VA
Shenandoah, VA	Winchester, VA
Island, WA	Seattle, WA
Mason, WA	Olympia-Lacey, WA
Wahkiakum, WA	Longview, WA-OR
Jackson, WV	Charleston, WV
Roane, WV	Charleston, WV
Green, WI	Madison, WI
Green Lake, WI	Fond du Lac, WI
Jefferson, WI	Milwaukee, WI
Walworth, WI	Chicago, IL-IN

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As in the past, hospitals redesignated under section 1886(d)(8)(B) of the Act are also eligible to be reclassified to a different area by the MGCRB. Affected hospitals were requested to compare the reclassified wage index for the labor market area in Table 4C in the Addendum of the proposed rule into which they have been reclassified by the MGCRB to the wage index for the area to which they are redesignated under section 1886(d)(8)(B) of the Act. Hospitals were given the opportunity to withdraw from an MGCRB reclassification within 45 days of the publication of the proposed rule.

When we apply the OMB 2000 CBSA standards, 16 rural counties no longer meet the qualifying criteria to be redesignated, either because they are now included in a metropolitan area (with the exception of Barry, MI and Cass, MI, most of the counties are now in the metropolitan area in which they were grouped in accordance with section 402) or they fail to meet the 25-percent cumulative out-migration threshold when we apply the new OMB standards. Counties that are now identified as metropolitan are: Chilton, AL; Macoupin, IL; Piatt, IL; Brown, IN; Carroll, IN; Jefferson, KS; Barry, MI; Cass, MI; Ionia, MI; Greene, NC; Preble, OH.

Counties that failed to meet the 25-percent threshold are: Marshall, AL; Putnam, FL; Wilson, NC; Van Wert, OH; and Lawrence, PA.

Comment: Several commenters expressed concern with our proposed adoption of the OMB area designations and the impact on county designations governed by section 1886(d)(8)(B). Specifically, these commenters objected to the proposed adoption because use of

the 2000 Census data to develop the revised designations resulted in five counties no longer meeting the qualifying criteria for section 1886(d)(8)(B) county designation. The commenters argue that because they were not given adequate notice that these counties were in danger of losing their section 1886(d)(8)(B) county designation, the abrupt decrease will have a significant impact on operations. The commenters are requesting that CMS extend the three-year hold harmless transition to hospitals located in those counties losing their section 1886(d)(8)(B) county designation.

Response: In the proposed rule, to help alleviate dramatic negative impacts in payment for hospitals designated as urban under the old MSA standards, but slated to be classified as rural, we proposed to implement a 3-year hold harmless transition period that would allow these hospitals to maintain their assignment to the MSA where they are currently located for FY 2005, FY 2006, and FY 2007. Specifically, we will assign these hospitals, as we did in the proposed rule, the prereclassified wage index of the urban area to which they currently belong. (For purposes of wage index computation, the wage data of these hospitals will remain assigned to the statewide rural area in which they are located.) We are finalizing this policy in the final rule. We did not propose that the transition period apply to hospitals located in those counties losing their designation under section 1886(d)(8)(B). Consistent with our longstanding policy that counties redesignated under section 1886(d)(8)(B) of the Act, are considered urban for purposes of the standardized amount, we are extending the 3-year transition to the hospitals located in

counties formerly designated as urban under 1886(d)(8)(B), because the hospitals are, in fact, losing their designated urban status. We are using the wage data from these hospitals as part of setting the rural wage index. The higher wage indexes these hospitals are receiving are being taken into consideration in determining whether they qualify for the out-commuting adjustment and the amount of any adjustment. During this 3-year transition period, these hospitals are eligible to apply for reclassification by the MGCRB. In FY 2008, these hospitals will receive their statewide rural wage index. Thus, the hospital would not be eligible, for example, for a large urban add-on under capital PPS. Thus, it is the wage index, but not the urban or rural status of the hospitals, that is being affected by this transition.

Comment: Commenters indicated that CMS utilized an older 2000 Census Crosswalk that has since been updated in December of 2003. Commenters wanted to know whether or not CMS intends to use this updated crosswalk for the final regulation.

Response: Our initial investigation and analysis of the impact of the new metropolitan areas began in the early fall of 2003. In the process of this analysis, the update of the crosswalk was overlooked and was not incorporated into the proposed rule. We have updated the crosswalk for this final regulation and, therefore, the updates are incorporated in the calculations and the subsequent output in the tables.

Comment: Commenters noted that CMS improperly classified Merrimack, NH and Litchfield, CT. These counties are "deemed urban" and, therefore, must be included in an urban area.

Response: We recognize this oversight. Based on the strongest commuting ties, we have incorporated Merrimack, NH into the Manchester-Nashua, MA MSA (31700), and Litchfield, CT has been placed into the Hartford-West Hartford-East Hartford, CT MSA (25540).

Comment: Commenters expressed opposition to and support of the decision to not adopt micropolitan areas. They indicated that the financial and reimbursement impact of using these areas is unknown at this time, and it appears that further consideration of the effects of these changes by CMS is necessary. Some commenters argued that those micropolitan areas that were previously included in a metropolitan area are now unjustly dubbed "rural."

Response: We have provided hospitals in urban counties now designated as micropolitan and therefore rural as "hold harmless," assigning them the urban wage index for the MSA from which they came. We will continue to review the role of micropolitan areas in the development of labor market areas for the purposes of the wage index.

d. Reclassifications Under Section 508 of Public Law 108–173

Under section 508 of Public Law 108–173, a qualifying hospital may appeal the wage index classification otherwise applicable to the hospital and apply for reclassification to another area of the State in which the hospital is located (or, at the discretion of the Secretary, to an area within a contiguous State). Hospitals were required to submit their applications by February 15, 2004. We implemented this process through notices published in the **Federal Register** on January 6, 2004 (69 FR 661) and February 13, 2004 (69 FR 7340). Such reclassifications are applicable to discharges occurring during the 3-year period beginning April 1, 2004 and ending March 31, 2007. Under section 508(b), reclassifications under this process do not affect the wage index computation for any area or for any other hospital and cannot be effected in a budget neutral manner.

The applications submitted under this process were reviewed and decided upon by the MGCRB. The MGCRB issued notifications of its decisions on April 16, 2004. Reclassifications under this one-time appeal process interact with: FY 2005 MGCRB reclassification decisions under the ongoing reclassification process described in the regulations at §§ 412.230 through 412.280; the implementation of the new MSA definitions; and the new

redesignations under section 1886(d)(8)(B) of the Act.

In the notices implementing this process, we indicated that, with limited exceptions, hospitals eligible for reclassification under section 508 of Public Law 108–173 are not otherwise reclassified, effective for discharges on or after October 1, 2004. Therefore, aside from the exceptions specified in the notices, hospitals reclassified under this one-time appeal process were not otherwise reclassified by the MGCRB for FY 2005. For the hospitals exempted from the "not otherwise classified" requirement and that received a section 508 reclassification under the one-time appeal process, the section 508 takes precedence over any other MGCRB reclassification. We show the reclassifications effective under the one-time appeal process in Table 9B, in the Addendum to this final rule.

Comment: One hospital commented that the proposed adoption of the new MSA designations will result in the hospital being located in a county that has been incorporated, under the new designations, into the MSA to which they were approved for reclassification. Because they will now be located in the area to which they were granted reclassification, the hospital argued that its FY 2005 reclassification is, in effect, moot.

Response: We acknowledge that there are situations where hospitals that have been reclassified by the MGCRB are located in counties that have been incorporated, under the new designations, into the area to which the hospitals were approved for reclassification. As a result, hospitals in this situation are already located in the area to which they requested to be reclassified. In this case, under the new designations, these hospitals will be paid by virtue of this change based on the payment rates applicable to the requested area and their wage data will be reflected in the wage index for that area. Although we have acknowledged above that hospitals reclassified to MSAs that split need not be reclassified back into their home area, that rule would not apply in the situation raised by the commenter. In the commenter's case, the area to which it reclassified has now been expanded to absorb the hospital's home county. Thus, we need not identify an area that can serve as a substitute for the reclassification area. Rather, there is no need for the hospital to reclassify when it now is originally classified into its desired area.

Comment: Several hospitals approved for reclassification under section 508 objected to our proposal regarding the treatment of hospitals that were

reclassified under section 508 to areas that have since divided because of implementation of the new labor market definitions. As we discuss in further detail in section III.H.3.b. above, in some cases, the new CBSA definitions result in previously existing MSAs being divided into two or more separate MSAs. Given that the areas to which the hospitals reclassified no longer exist in FY 2005, we proposed assigning the hospital to the nearest county in the current MSA, and the hospital's FY 2005 reclassification is to the new MSA (under the CBSA definitions) that includes that county to which it has been assigned. The hospitals argue that consistent with section 508, when a previous labor market area has split into several different areas, they should be permitted to select the area to which to reclassify.

Response: We appreciate the commenters' suggestions and their interest in this matter. Based on those comments, and on a careful review of the provisions of section 508, we have decided to change our proposed policy in the limited case of hospitals that reclassified in accordance with section 508 to areas that, because of the new labor market definitions, have now been divided into several areas. Because section 508(a)(1) of Public Law 108–173 allows a hospital to appeal its wage area classification to the Board and "select another area within the state (or, at the discretion of the Secretary, to a contiguous State) to which to be reclassified," we believe, in these limited circumstances, a hospital should be permitted to select the area into which it should be reclassified. Specifically, a hospital reclassified under the section 508 process to an MSA that, under the new labor market definitions, divided into several areas, will be given the opportunity to select which of those areas it wishes to reclassify to. We believe this is in keeping with the statutory intent of section 508. To effect the selection, we will automatically assign these hospitals to the divisor MSA with the highest wage index. Hospitals reclassified under the one-time appeals process that have been assigned to a new MSA are identified in Table 9B, column 7, in the Addendum of this final rule. If these hospitals disagree with our selection, they must submit to us, in writing, a request to select a different divisor area. Requests must be received by us within 30 days of publication of this final rule. Requests should be sent to the following address: Centers for Medicare and Medicaid Services, Center for Medicare Management, Hospital and Ambulatory

Policy Group, Division of Acute Care, Mailstop C4-08-06, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Attn: Section 508 Appeals.

In the proposed rule, we also stated that hospitals reclassified under the section 508 one-time appeal process that are also in counties identified under the redesignation process in accordance with section 1886(d)(8)(B) of the Act were asked to compare the wage index applicable to the area to which they were reclassified under section 508 with the wage index applicable to the area to which they were redesignated under section 1886(d)(8)(B) of the Act, if those areas are different. Again, affected hospitals were allowed to withdraw their one-time appeal process reclassifications within 45 days of the publication of the proposed rule.

Comment: A hospital association expressed concern that, due to our proposal to implement the new CBSAs, hospitals granted a reclassification under section 508 of Public Law 108-173 or the traditional MGCRB reclassification process may realize little or no benefit from the reclassification. The association stated that the requirement that a hospital base its decision to withdraw an existing reclassification is “unnecessary” and “unfair” because it requires the hospital to “give up” the reclassification when there exists the possibility that changes effected in the final rule could result in the reclassification being beneficial. The association believed that, for hospitals reclassified under section 508 or the traditional MGCRB process, we should automatically apply the higher wage index for each hospital, with no action required by the hospital. Many other commenters recommended that CMS allow reclassifying hospitals 30 days after publication of the final rule to withdraw their reclassification requests.

Response: In the August 1, 2001 final rule, we included a detailed discussion of the withdrawal, termination, and cancellation procedures for reclassified hospitals (66 FR 39887). In that rule, we stated that a hospital may cancel a previous withdrawal or termination of a 3-year wage index reclassification by submitting written notice of intent to the MGCRB no later than the deadline for submitting reclassification applications effective at the start of the following fiscal year. This provision allows the hospital to reinstate the original reclassification for the wage index. As we stated in the August 1, 2001 final rule, we provided this option so that “a hospital that later discovers that the withdrawal of its approved wage index reclassification was disadvantageous would have the ability

to reinstate its MGCRB approval for the wage index for the remaining years in the 3-year term.” Even in light of the existing provision, we are persuaded by the comments received in response to the proposed rule, in this limited circumstance, to allow hospitals a 30-day period where they can make final, informed determinations regarding whether to maintain or withdraw their existing reclassification on the basis of the information published in the final rule. This 30-day period is also applicable to those hospitals that adhered to the established process and notified the MGCRB of their decision to withdraw or terminate their section 1886(d)(10) or section 508 reclassification. Hospitals will have 30 days after the publication date of this rule to submit, in writing, to the MGCRB a request to withdraw their reclassification request or to rescind their previous withdrawal or termination request.

e. Wage Index Adjustment Based on Commuting Patterns of Hospital Employees (Section 505 of Pub. L. 108-173)

Section 505 of Public Law 108-173 established new section 1886(d)(13) of the Act. The new section 1886(d)(13) requires that the Secretary establish a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees. The process provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county with a higher wage index. Such adjustments to the wage index are effective for 3 years beginning with discharges occurring on or after October 1, 2004. Adjustments under this provision are not subject to the inpatient PPS budget neutrality requirements at section 1886(d)(3)(E) or section 1886(d)(8)(D) of the Act.

The Secretary is required to establish criteria to identify “qualifying counties,” and hospitals located in such qualifying counties are to receive an adjustment to their wage index. Section 1886(d)(13)(B)(i) of the Act directs the Secretary to establish a threshold percentage difference between the county’s wage index and the weighted average of the wage indexes of the surrounding higher wage index area(s) to which hospital employees commute that must be met in order for the county to qualify. Section 1886(d)(13)(B)(ii) of the Act specifies that the Secretary is also to establish the minimum out-migration threshold in order to qualify, which may not be less than 10 percent.

Section 1886(d)(13)(iii) of the Act requires that the average hourly wage for all hospitals in the county must be equal to or exceed the average hourly wage for all hospitals in the labor market area. Section 1886(d)(13)(E) of the Act indicates this process may be based on the process used by the MGCRB. This section also gives the Secretary the authority to require hospitals to submit data necessary to implement this provision, or to use other data sources as available.

Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the differences between the wage indexes of the MSA(s) with higher wage indexes and the wage index of the resident county, weighted by the overall percentage of hospital workers residing in the qualifying county who are employed in any MSA with a higher wage index. We have employed the prereclassified wage indexes in making these calculations. We also are not taking into account any of the transition payments that are being used to account for the change in labor market definitions announced by CMS. We believe it is reasonable to interpret the term “wage index” in section 1886(d)(13)(D) to mean the prereclassified, preadjusted wage index. In response to comment, we discuss below our reasons for using the prereclassified wage indexes in both identifying higher wage index areas and in calculating the out-migration adjustment. We believe that it is also reasonable to interpret “wage index” under section 1886(d)(13) as applying solely to the wage index that exists using the most recent CMS definitions for labor market areas. Section 505 is a new provision, first being implemented for FY 2005, and we do not believe it is necessary to incorporate transitional wage index payments, when there is no transition necessary. Hospitals were fully able to assess the implications of the new labor market areas on implementation of section 505 through review of the proposed rule. Thus, the higher wage index areas will be identified, and the out-migration adjustment will be calculated without taking into account the effect on wage index caused by either of our transitional rules. We include a detailed discussion of these transitional rules in section III.B.3. of this preamble. The wage index increase is effective for 3 years, unless a hospital requests to waive the application of the payment adjustment. Hospitals that receive this payment adjustment are not eligible for

reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

(1) Data

To implement this provision, we analyzed commuting data compiled by the U.S. Census Bureau. The data derive from a special tabulation of Census 2000 journey-to-work data, compiled from responses to the long-form (sample) census survey questions on where people worked. When the Census conducts its decennial survey, each household receives either a short form or a long form. On average, about 1 in every 6 households receive the long form. The results from the long form are used to formulate descriptive population estimates. Thus, the data set is based on the Census 2000 sample and represents estimates of the actual figures that would be obtained from a complete count.

The data provide information about commuting patterns of workers at the county level for residents of the 50 States and the District of Columbia. Each record within the data set represents a combination of a particular resident county, a workplace county, and a particular industry category. Thus, the record shows the county-of-residence by county-of-work commuter flows. The resident county represents the county where the worker resides, while the workplace county represents the county where the worker works. The industry category associated with workers is based on the 108 Industrial Structure codes developed by the Bureau of Economic Analysis. These Industrial Structure codes break down economic activities by defining industries (such as "fabricated metal product manufacturing," "legal services," and "gasoline stations"). We limited the data set to those employees working in the category designated "hospitals" (BEA code 622000).

Using these data, we are able to identify the total number of hospital workers who live in each county and the number of workers within that county who commute to hospitals in other counties. For example, the data can be used to determine that, from a sample of 100 hospital employees who live in County A, 50 commute to work at hospitals within County A, 20 commute to work at hospitals within County B, and 30 commute to work at hospitals within County C.

There are some intrinsic limitations to the data. The file shows the weighted worker estimate for flows using a threshold or minimum size of 50 unweighted worker (from all industry codes) records. This means that only county-to-county flows that are

comprised of at least 50 unweighted worker records are shown in this file. The Census Bureau omitted all other county-to-county flows from the file for confidentiality reasons. While this could eliminate the workflows of some hospital residents, we believe the eliminations would not have a major impact on the policy.

When Census calculated this special tabulation, the estimates of workers numbering from 1 through 7 have been rounded to 4. Values of 8 or greater have been rounded to the nearest multiple of 5, unless the estimate already ended in 5 or 0, in which case it was not changed. In addition, in this special tabulation, workers are defined as people 16 years and older who were employed and at work during the Census long form reference week. This is the week prior to when the questionnaire was filled out, which was the last week of March 2000 for most people.

In addition, because these data derive from the decennial census, the data file will not change until the census is taken again in 2010. This does not mean that the list of qualifying counties will not change from year to year. The out-migration percentage for each county is a function both of the commuting data and changes in the wage index values. Because the wage indexes associated with each work and resident county change each year, a county's out-migration percentages can still vary each year because a higher wage index area in one year, might not be a higher wage index area in the next year. For example, if 100 hospital employees living in County A (wage index 1.00 in FY 2004) commute to County B (wage index 1.10 in FY 2004), then County B would be a higher wage index area for 2004. If in FY 2005, County A's wage index increases to 1.02 and County B's wage index decreases to 1.01, those 100 workers commuting from County A to County B will not be commuting to a higher wage index area for 2005. Consequentially, County A's out-migration percentage would decrease from 100 percent in 2004 to 0 percent in 2005. These normal changes in wage index values could also result in a county not deemed a qualifying county for FY 2005, becoming a qualifying county in FY 2006 or later.

We believe these data provide a useable data source to implement this provision. However, in the May 18, 2004 proposed rule, we solicited comments on the availability and value of alternative data sources. Although the statute authorizes the Secretary to require all hospitals to submit data on the commuting patterns of their employees, such a requirement would

be a major undertaking for the hospital industry and CMS. It was not possible to pursue this approach in time to implement the provision by FY 2005. However, in addition to soliciting comments on the merits of relying on the Census data, we welcomed comments on the feasibility of surveying hospitals on the residence and commuting patterns of all their hospital employees for purposes of developing future year adjustments.

Comment: One commenter questioned whether it would be possible in future years to update commuting data using data from U.S. Census Bureau's American Community Survey (ACS) rather than using data from the 2000 census.

Response: The ACS is part of the U.S. Census Bureau's effort to streamline and improve the census, and is intended to replace the long form and provide some demographic information every year instead of once every 10 years. Starting in July 2004, 1 in every 480 households throughout America will receive and be asked to participate in the survey each month. Since this is a new initiative, we are unable to determine whether the data that will be collected is appropriate for use in calculating the out-migration adjustment. However, as the U.S. Census Bureau moves forward with this initiative, we will continue to monitor the initiative's progress and evaluate the feasibility of using data from the ACS to calculate the out-migration adjustment.

Comment: Several comments stated that the commuting data does not reflect the "new potential for increased commuting," in a specific instance where a county used to be part of an MSA, but no longer is due to the new MSA definitions. The commenters stated that the reduced reimbursement resulting from the new MSA definitions will create the potential for increased commuting in future years, even though the county qualified for an out-migration adjustment. The commenters recommended we "adjust the commuting index to a more appropriate value based on opportunity and not based solely on historical data."

Response: The commenters did not provide suggestions on how we would consistently measure the "opportunity" for increased commuting. Therefore, we are unable to address the commenters' concerns at this time. As we stated in the proposed rule, we will use the decennial census in order to determine commuting rates. We note that as part of its new definitions of statistical areas, OMB takes into account the level of commuting. Thus, the new areas should reflect any increased commuting that

has already occurred from one county to another.

Comment: One commenter stated that it is unclear as to how we will measure commuting patterns and determine the applicability of the wage index adjustment. The commenter requested that we describe the proposed data resources and methodology that will be used for applying the wage index adjustment.

Response: We note that in the May 18, 2004 proposed rule and in this final rule, we discussed the data set used for measuring out-migration patterns and the process for determining the out-migration adjustments. (See sections III.H.3.e.(1) and 3.e.(3) of this preamble, respectively.)

Comment: A commenter asked if the data used by CMS to compute the out-migration adjustment will be made available via a public use file.

Response: We plan to make the data used for determining the qualifying counties and the out-migration adjustment available after the publication of this final rule on the CMS Web site at <http://www.cms.gov>.

Comment: One commenter requested that CMS allow hospitals to submit their own commuting data to apply for the out-migration adjustment.

Response: Because the adjustment is based on the number of hospital workers in a county who commute to other higher wage index areas, we believe it would be extremely problematic for individual hospitals to track and submit the data necessary for the out-migration adjustment. The hospital could not simply survey their own employees to obtain this necessary data, but would have to survey all hospital workers who live in the county where the hospital is located and commute to hospitals in other higher wage index areas.

In addition, we did not receive any specific comments on the availability of an alternative data source or on the feasibility of surveying hospitals on the residence and commuting patterns of their employees for purposes of developing future year adjustments. We also received comments supportive of our general implementation process and its administrative simplicity. The commenters noted the merits of using this data set and not placing an additional burden on hospitals through a survey of employees. Therefore, we will use our proposed data set for purposes of computing the qualifying counties and the out-migration adjustment. However, we will continue to explore the possibility that hospitals could submit their own data in future refinements of our policy.

(2) Qualifying Counties

As noted previously, section 1886(d)(13)(B)(iii) of the Act requires that, to qualify for this commuting wage index adjustment, the average hourly wage for all hospitals in the county must be equal to or exceed the average hourly wage for all hospitals in the labor market area in which the county is located. To determine which counties meet this requirement, we calculated the average of hospitals' 3-year average hourly wages for all hospitals in a given county. We compared this county average 3-year average hourly wage to the 3-year average hourly wage for the labor market area where the county is located. We chose to use the 3-year average hourly wage because we believe it provides a more accurate and stable estimate for the wages paid by a given hospital over a period of time. This statutory requirement limits the number of eligible counties, as counties with an average 3-year average hourly wage less than the 3-year average hourly wage of the MSA where the county is located were not considered to meet this requirement.

Some resident counties do not have average hourly wages because either there is no hospital located in the county, or the only hospital in the county is new and has not yet submitted wage data. We did not consider these counties to have met the average hourly wage criteria and thus hospitals in these counties are not yet eligible to receive an increase in wage index. This is consistent with our regulations at § 412.230(e)(2)(iii), which require a new hospital to accumulate at least 1 year of wage data, before it is eligible to apply for reclassification.

As noted previously, section 1886(d)(13)(B)(ii) of the Act specifies that the Secretary is to establish the minimum out-migration threshold in order to qualify, which may not be less than 10 percent. To determine the out-migration percentage for each county, we identified higher wage index areas, by comparing 2005 prereclassified wage index of a resident county with the 2005 prereclassified wage index of the MSA or rural statewide area where the work county is located. We use the prereclassified wage index so that hospitals in the county are not disadvantaged by reclassification of other hospitals into the county.

Comment: One commenter recommended that the wage index amounts utilized in the calculation for the higher wage county be based on the wage index utilized for Medicare payment including those increases in wage index due to a group

reclassification appeal. The commenter stated that not utilizing this higher wage index amount would put the hospitals addressed by the commuting adjustment provision at a serious disadvantage.

Response: We considered using the post-reclassified wage index as the basis for computing the higher wage index counties. In situations like the group reclassification where all hospitals in a given county are receiving the same wage index, it could be possible to use the post-reclassified wage index for determining higher wage index counties and for calculating the out-migration adjustment. However, it is not as straightforward for counties where not all hospitals are receiving the same wage index due to individual hospital reclassifications. For example, in one county there may be two hospitals that receive different wage indexes because one hospital has been reclassified. Given the differing wage indexes in this situation, it is unclear which wage index would be most appropriate to use as the basis for comparison for this county or if some form of a blended wage index should be calculated. This issue is further complicated by the use of a blended wage index this year to mitigate the effects of the new MSA definitions. Due to these complicating factors, and the fact that the prereclassified wage index most accurately reflects the wages being paid to hospital employees in a given geographic area, we believe that the most equitable method is to use the prereclassified wage index when calculating the qualifying counties and the out-migration adjustment. However, we will continue to examine the possibility of employing post-reclassification wage indexes as we refine our policy for future adjustments.

Comment: One commenter asked how the out-migration adjustment will be made in subsequent years, specifically if CMS increases the wage index of qualifying counties by the out-migration adjustment when calculating higher wage index counties in subsequent years. The commenter identified a potential ripple effect if the data we use in year two incorporates the new higher wage index value (resulting from the additional out-migration adjustment) when identifying the county-to-county flows where hospital employees were commuting to a higher wage index area.

Response: We appreciate the opportunity to clarify this important point. We recognize that if we used the new wage index (wage index plus commuting adjustment) when computing the higher wage index counties, the effect of the out-migration adjustment could ripple out each year to

more counties. Consequently, in future years, we plan to identify the higher wage index counties and compute the adjustment using the prereclassified wage index without the additional out-migration adjustment. We believe that this will more appropriately reflect the intent of the statute without creating unanticipated effects.

Once we limited the dataset to those county-to-county flows where hospital employees were commuting to a higher wage index area, we calculated the out-migration percentage for resident counties. To calculate the out-migration percentage, we calculated the total number of hospital employees in a resident county who were commuting to a higher wage area as a percentage of the total number of hospital employees residing in the resident county. For example, there are 100 hospital employees who live in County A (wage index 1.0). Of those 100 employees, 50 commute to County B (wage index 1.10), 20 commute to County C (wage index 1.05), and 30 work within County A. Because 70 out of 100 people commute to higher wage areas, County A's out-migration percentage is equal to 70 percent.

To implement section 1886(d)(13)(B)(ii) of the Act, in the May 18, 2004 proposed rule (69 FR 28267), we proposed that the out-migration threshold to qualify for this adjustment would be the statutory minimum of 10 percent. We believe that this threshold provides an opportunity for a reasonable number of hospitals that would not have recourse to the normal reclassification process to receive an appropriate adjustment to their wage index. We welcomed public comment on this proposed threshold.

Comment: Many commenters supported our decision to set the out-migration threshold at the statutory minimum of 10 percent.

Response: We note that we did not receive any comments recommending that we increase the threshold and we do not plan to change the threshold in this final rule. Therefore, we are finalizing the out-migration threshold at the statutory minimum of 10 percent.

As noted previously, section 1886(d)(13)(B)(i) of the Act directs the Secretary to establish a threshold percentage difference between the county's wage index and the weighted average wage indexes of the higher wage index areas to which hospital employees commute. However, unlike the threshold for the level of out-migration, the statute does not designate a minimum level for this threshold. Because of the nature of the adjustment provided under this provision, in the

May 18, 2004 proposed rule (69 FR 28268), we proposed to establish that the minimum difference in the wage indexes between the resident county and the work county can be any percentage greater than zero. We proposed this threshold because the wage index increment for hospitals in qualifying counties under the statutory formula is a function of the differences between that county's wage index and the wage indexes of the areas into which resident hospital workers of that county are commuting. In those cases where that difference is very small, the adjustment to the wage index will also be very small. (See the discussion of the statutory formula in section III.H.3.e.(3) of this preamble.) Therefore, we believe that a threshold of anything greater than zero is justifiable and consistent with the purposes of this provision.

Comment: Many commenters supported our decision not to set a minimum difference between the wage index that applies to the county and the higher wage index areas.

Response: We do not plan to change the minimum difference requirement in this final rule; and therefore, establish the minimum difference in the wage indexes between the resident county and the work county to be any percentage greater than zero.

Our analysis for the proposed rule indicated that 224 counties qualify under the proposed criteria. There were 411 hospitals located in these qualifying counties. For the final rule, we have identified 230 counties that qualify under the proposed criteria. There were 415 hospitals located in these qualifying counties. Hospitals located in qualifying counties are identified in Table 4J in the Addendum to this final rule. Of the 415 hospitals, 181 are reclassified under section 1886(d)(8) of the Act, redesignated under section 1886(d)(10) of the Act or received a section 508 reclassification and are signified in Table 4J in the Addendum to this final rule with asterisks. Given the statutory limitation on hospitals receiving the out-migration adjustment and reclassification under section 1886(d)(8) of the Act, redesignation under section 1886(d)(10) of the Act, or reclassification under section 508, we assume that hospitals represented by asterisks that have already been reclassified or redesignated, wish to retain their reclassification or redesignation and not receive the out-migration adjustment. Only one of the redesignated hospitals informed us that they would like to waive the application of their redesignation for the purposes of receiving the out-migration adjustment. As described in section

III.H.3.e.(4) of this preamble, hospitals have an additional 30 days from the date of publication of this final rule to notify CMS if they would like to waive their reclassification or redesignation in order to receive the out-migration adjustment.

(3) The Adjustment

Hospitals located in the qualifying counties identified in Table 4J in the Addendum to this final rule that have not already reclassified through section 1886(d)(10) of the Act, redesignated through section 1886(d)(8) of the Act, received a section 508 reclassification, or requested to waive the application of the out-migration adjustment will receive the wage index adjustment listed in the table. This adjustment increase is equal to the percentage of the hospital employees residing in the qualifying county who are employed in any higher wage area, multiplied by the sum of: the products, for each higher wage index area, of the difference between the wage index for such higher wage index area and the wage index of the qualifying county, and the percentage of hospital employees residing in the qualifying county who are employed in any higher wage index area who are employed in such higher wage index area. This increase in wage index is depicted using the following equation:

$$\text{Adjustment} = A * \Sigma[(B-C) * (D/E)]$$

A is the percentage of hospital employees residing in a qualifying county who are employed in any higher wage index area. B represents the wage index of the higher wage index area. C represents the wage index of the qualifying resident county. D represents the number of hospital employees residing in the qualifying county involved who are employed in such higher wage index area. E represents the total number of hospital employees residing in qualifying county who are employed in any higher wage index area.

For example, County A is identified as a qualifying county. As illustrated before, if 100 hospital employees live in County A (wage index = 1.00), 50 commute to County B (wage index = 1.10), 20 commute to County C (wage index = 1.05); and 30 commute within County A, the out-migration percentage is equal to 70 percent.

$$\begin{aligned} & \text{The adjustment for hospitals in} \\ & \text{County A would be:} \\ & = .70 * (((1.10 - 1.00)*(50/70)) + ((1.05 \\ & \quad - 1.00)*(20/70))) \\ & = .70 * ((.10 * .714) + (.05 * .285)) \\ & = .70 * (0.0714 + 0.01428) \\ & = .70 * (0.0856) \end{aligned}$$

= 0.05998

So, hospitals in County A could receive a new wage index of 1.05998, instead of 1.000 for the following 3 years.

The adjustments calculated for qualifying hospitals are listed in Table 4J in the Addendum to this final rule. These adjustments are effective for each county for a period of 3 fiscal years beginning with discharges occurring on or after October 1, 2004. The commuting adjustments for each county will remain static for the 3-year period, after which the county's status as a qualifying county and the adjustment will be recalculated.

Comment: Several commenters questioned the temporary nature of the out-migration adjustment. They suggested that CMS modify the rule to extend the out-migration adjustment beyond the 3-year period in order to reflect ongoing wage competition.

Response: Section 1886(d)(13)(F) of the Act specifies that the wage index increase shall be applied for a period of 3 fiscal years. Therefore, we do not have the discretion to extend the time period. However, we will evaluate and designate qualifying counties each year. Therefore, it is possible that after a qualifying county's 3-year period ends, the county again will become a qualifying county and receive a new out-migration adjustment for another 3-year time period.

Comment: Several commenters noted that the commuting adjustment is based on the commuting flows of hospital employees alone, while clinicians can work in many nonhospital environments. Thus, the commenter stated that the data used for the commuting adjustment does not address the economic reality facing certain areas because it does not incorporate data from clinicians working in nonhospital environments.

Response: Section 1886(d)(13) of the Act specifies that the adjustment be based on the out-migration patterns of hospital employees. Thus, we do not have flexibility to incorporate data based on the commuting patterns of clinicians working in nonhospital environments in the out-migration adjustment.

Comment: One commenter requested that the out-migration adjustment be given to all counties within an MSA, to avoid competitive disadvantages within an MSA.

Response: Section 1886(d)(13) of the Act specifies that the adjustment is applied to qualifying counties, not to MSAs. In keeping with this provision, we are adopting the provision that was

in the proposed rule that we will apply the out-migration adjustment at a county level and not to all counties within an MSA.

Comment: Several commenters stated that the out-migration adjustment only captures the success of other hospitals recruiting labor from areas, but fails to recognize the cost of recruiting and retaining hospital employees. One commenter noted that the formula does not take into account the in-migration of hospital employees who live in other MSAs and recommends that CMS address this issue to include a more comprehensive measure of the interchange between adjacent MSAs.

Response: Section 1886(d)(13) of the Act specifies that the adjustment be made based on the out-migration of hospital employees. Therefore, we do not have the discretion to make additional adjustments based on the in-migration of hospital employees.

Comment: One commenter stated that the out-migration adjustment demonstrates that "CMS is aware that many hospital's wage index would be significantly affected by the OMB's revised definitions of geographic statistical areas." The commenter also stated that the provision does not go far enough to stabilize the severe impact of changes in the MSAs.

Response: Section 505 of Public Law 108-173 established a provision to recognize the out-migration of hospital employees. This statutory provision is separate and distinct from OMB's release of updated MSA definitions. We believe the commenter is incorrect in linking the two provisions, because the out-migration adjustment was not explicitly established to mitigate the effects of the new MSA definitions. We also note that the blended wage index described in section III.G. of the preamble of this final rule is specifically intended to help mitigate the impacts of the adoption of the new MSA definitions.

(4) Automatic Adjustments

Section 1886(d)(13)(A) of the Act allows the Secretary to establish the process for receiving this increase in wage index through application or otherwise. Listed in Table 4J in the Addendum to this final rule are the counties and corresponding hospitals that qualify for an increase in wage index through our implementation of the section. This list includes the universe of hospitals that could receive the adjustment, including those who are redesignated under section 1886(d)(8) of the Act or reclassified under section 1886(d)(10) of the Act. Hospitals located in qualifying counties that have not

already been reclassified or redesignated to another geographic area for purposes of the wage index amount (including reclassifications under section 508 of Pub. L. 108-173) will automatically receive the increase in wage index. This commuting wage index adjustment will be effective for the county for a period of 3 fiscal years, FY 2005 through FY 2007. As discussed previously, yearly changes in the wage indexes associated with areas could result in changes in the out-migration percentage for a given county. Irrespective of these changes, a county will not lose its status as a qualifying county due to wage index changes during the 3-year period, and counties will receive the same wage index increase for those 3 years. However, a county that qualifies in FY 2005 may no longer qualify in FY 2008, or it may qualify but receive a different adjustment level.

In the May 18, 2004 proposed rule, we invited public comment on the automatic application of such a wage index adjustment, and whether an application process should be developed under which individual hospitals would have to apply in order to receive the adjustment. We noted that, given the short timeframe before implementation of this provision on October 1, 2004, we believe that there is no practical alternative to providing for an automatic adjustment for FY 2005. However, one possibility was to employ an automatic adjustment process this year, and to replace the automatic process with an application process for future years. We invited comments on whether to establish the automatic process permanently, or to devise an application process for future years. We also invited public comment on whether any application process should be the responsibility of the MGCRB or some other entity.

Comment: One commenter expressed support for the automatic nature of the out-migration adjustment.

Response: We appreciate the commenter's support. In addition, we did not receive specific comments on whether we should devise an application process for the out-migration adjustment in future years. However, we believe that numerous comments in support of our general implementation process and its administrative simplicity suggest that hospitals also appreciate the merits of an automatic application of the out-migration adjustment. Thus, we are adopting our proposal of applying the adjustment on an automatic basis to all hospitals in qualifying counties except those that have already been reclassified under section 1886(d)(10) of the Act, or

under section 508 of Public Law 108–173 redesignated under section 1886(d)(8) of the Act, or requested waiver of the application of the out-migration adjustment.

Hospitals receiving this wage index increase under section 1886(d)(13)(F) of the Act are not eligible for reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act, including reclassifications under section 508 of Public Law 108–173. As previously noted, the wage index increase is effective for 3 years, unless a hospital elects to waive the application of the wage index adjustment. Hospitals that wished to waive the application of this wage index adjustment were asked to notify CMS within 45 days of the publication of the proposed rule. However, consistent with § 412.273, hospitals that have been reclassified by the MGCRB were permitted to withdraw their applications within 45 days of the publication of the proposed rule in the **Federal Register**. Hospitals that have been reclassified by the MGCRB (including reclassifications under section 508 of Public Law 108–173) were permitted to terminate an existing 3-year reclassification within 45 days of the publication of the proposed rule in order to receive the wage index adjustment under this provision. Hospitals that are eligible for this adjustment and that have not been reclassified through section 1886(d)(10) of the Act or under section 508 of Public Law 108–173, redesignated through section 1886(d)(8) of the Act, or requested waiver of the application of the out-migration adjustment will automatically receive the wage index adjustment listed in Table 4J in the Addendum to this final rule. In our proposed rule, we stated that the request for withdrawal of an application for reclassification or termination of an existing 3-year reclassification had to be received by the MGCRB within 45 days of publication of the proposed rule. We asked hospitals to carefully review the wage index adjustment that they would receive under this provision (as listed in Table 2 in the Addendum to the proposed rule) in comparison with the wage index that they would receive under MGCRB reclassification (Table 9 in the Addendum to the proposed rule).

Comment: Many commenters questioned the timing of hospitals reclassification decisions for FY 2005 because of the changes to the wage index reclassification in this year's proposed rule (including the new MSA definitions, section 1886(d)(8)(B) redesignations, and the out-migration adjustment). The commenters noted that

since the 45-day timeframe for hospitals to waive their reclassification request ends before publication of the final rule, hospitals are unable to appropriately evaluate the impacts of their reclassification decisions before the deadline for withdrawing an approved reclassification. Commenters suggested that CMS allow hospitals 30 days after publication of the final rule to withdraw a reclassification request in order to receive the out-migration adjustment instead. Commenters also requested that CMS clarify that hospitals eligible for the out-migration adjustment, but were already reclassified for FY 2005, were not required to submit a formal waiver request to retain their existing reclassification.

In addition, several commenters questioned how the out-migration adjustment affects counties that are redesignated under section 1886(d)(8)(B) of the Act (Lugar counties). Specifically, one commenter requested clarification on how hospitals that are eligible for redesignation under section 1886(d)(8)(B) of the Act and the out-migration adjustment are to notify CMS as to which provision they wish to take advantage of because hospitals are automatically redesignated under section 1886(d)(8)(B) of the Act, and do not have a reclassification request to withdraw. The commenter also requested that hospitals be given the opportunity to determine whether they want to accept the section 1886(d)(8)(B) of the Act redesignation or the out-migration adjustment when the final rule is published.

Response: Section 1886(d)(13)(G) of the Act specifies that the out-migration adjustment is not eligible for a hospital that has received redesignation under section 1886(d)(8) of the Act or reclassification under section 1886(d)(10) of the Act during that period (unless they waive their reclassification/redesignation). In the vast majority of cases, we believe that it is most advantageous for hospitals that have been granted redesignation under section 1886(d)(8) of the Act, reclassification under section 1886(d)(10) of the Act or section 508 of Public Law 108–173 to retain the redesignation or reclassification instead of the out-migration adjustment. However, there may be a circumstance in which it is in the hospital's best interest to terminate its redesignation or reclassification because the out-migration adjustment results in a higher wage index. Given the number of changes in the proposed rule and the apparent confusion regarding the automatic application of the out-migration adjustment, we are allowing

hospitals a 30-day period from the date of this final rule during which they can decide if they would rather take advantage of their redesignation or reclassification or the out-migration adjustment. Therefore, hospitals will have 30 days from the date of publication of this final rule to submit to CMS a request to withdraw their reclassification requests under section 1886(d)(10) of the Act, section 508 of Public Law 108–173, or their redesignated status under section 1886(d)(8) of the Act and receive the out-migration adjustment instead. Hospitals must submit their request to the following address: Centers for Medicare & Medicaid Services, Center for Medicare Management, Attention: Wage Index Adjustment Waivers, Division of Acute Care, C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850.

As previously noted, we will assume that hospitals that have been redesignated under section 1886(d)(8) of the Act, reclassified under section 1886(d)(10) of the Act or under section 508 of Public Law 108–173 would prefer to keep their redesignation/reclassification unless they explicitly notify CMS that they would like to receive the out-migration adjustment instead. Additionally, we are clarifying that hospitals that wish to retain their redesignation/reclassification (instead of getting the out-migration adjustment) for FY 2005 did not and do not have to submit a formal request to CMS, and will automatically retain their reclassification/redesignation status for FY 2005.

The hospitals listed in Table 4J include all the hospitals that could possibly take advantage of the out-migration adjustment. Hospitals marked with an asterisk represent those hospitals that could have received the out-migration adjustment, but are assumed to be taking advantage of their reclassification or redesignation status (and consequently not the out-migration adjustment) for FY 2005. These hospitals do not have to do anything if they would like to remain reclassified/redesignated and not receive the out-migration adjustment.

Comment: Several commenters requested that we clarify if hospitals will have the same option to withdraw their reclassification or redesignation if they would rather receive the out-migration adjustment in subsequent years.

Response: In subsequent fiscal years, we will use the same process we proposed for FY 2005 to allow hospitals to withdraw their reclassification or redesignation requests and receive the

out-migration adjustment as long as their county remains a qualifying county. That is, hospitals will be able to terminate their reclassification or redesignation and take advantage of the out-migration adjustment if they notify CMS within 45 days of the notice of proposed rulemaking. We note that in upcoming years, we do not expect to allow any withdrawals after that date, as we have done in this final rule (allowing 30 days after publication of the final rule to withdraw a reclassification or redesignation). We note that by the time the proposed rule is published in 2005, hospitals will be familiar with the new labor market areas and the policies for adopting such areas will have been finalized.

Comment: Several commenters requested clarification on the ability of hospitals to apply for reclassification in future year if they receive the out-migration adjustment in FY 2005. Specifically, the commenter asked whether a hospital that qualifies for the out-migration adjustment effective for October 1, 2004, through September 30, 2005, will be able to request geographic reclassification effective for October 1, 2005, under the normal reclassification process. Similarly, another commenter asked if a hospital would be able to receive the out-migration adjustment at the time their MGCRB reclassification expires.

Response: It is our intent that hospitals should be able to evaluate the merits of reclassification and the out-migration adjustment on an annual basis. Given the statutory prohibition on hospitals being redesignated or reclassified (under section 1886(d)(8) or section 1886(d)(10) of the Act) and receiving the commuting adjustment, hospitals cannot receive both the out-migration adjustment and reclassification in the same year. We agree with the commenter that a hospital should not have to forgo the out-migration adjustment in FY 2005 in order to be able to apply for reclassification in FY 2006. Hospitals that qualify for the out-migration adjustment in a given year can take advantage of that adjustment in that year, and can still apply to be reclassified in the subsequent year. Hospitals that apply for reclassification for FY 2005 will be viewed as implicitly waiving the out-migration adjustment for that fiscal year, assuming they receive the reclassification requested. Conversely, if a hospital's reclassification request is not approved in a given year and the hospital remains eligible for the out-migration adjustment, the hospital will

automatically receive the out-migration adjustment.

4. FY 2005 Reclassifications

The wage index values for FY 2005 (except those for hospitals receiving wage index adjustments under section 505 of Pub. L. 108-173) are shown in Tables 4A, 4B, 4C, and 4F in the Addendum to this final rule. Hospitals that are redesignated will be required to use the wage index values shown in Table 4C. Areas in Table 4C may have more than one wage index value because the wage index value for a redesignated urban or rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located. Therefore, those areas with more than one wage index shown have hospitals from more than one State reclassified into them, and the rural wage index for a State in which at least one hospital is physically located is higher than the wage index for the area to which the hospital is reclassified.

Tables 3A and 3B in the Addendum to this final rule list the 3-year average hourly wage for each labor market area before the redesignation of hospitals, based on FYs 1999, 2000, and 2001 cost reporting periods. Table 3A lists these data for urban areas and Table 3B lists these data for rural areas. In addition, Table 2 in the Addendum to this final rule includes the adjusted average hourly wage for each hospital from the FY 1999 and FY 2000 cost reporting periods, as well as the FY 2001 period used to calculate the FY 2005 wage index. The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its average hourly wage for the 3-year period is calculated based on the data available during that period.

We are including in the Addendum of this final rule Table 9A, which shows hospitals that have been reclassified under either section 1886(d)(8) or section 1886(d)(10)(D) of the Act. This table includes 400 hospitals reclassified for FY 2005 by the MGCRB (for wage index purposes), as well as hospitals that were reclassified for the wage index in either FY 2003 (53 hospitals) or FY 2004 (102 hospitals) and are, therefore, in either the second or third year of their 3-year reclassification. This table also includes hospitals located in urban areas that have been redesignated rural in accordance with section 1886(d)(8)(E) of the Act (17). In addition, it includes rural hospitals redesignated to urban

areas under section 1886(d)(8)(B) of the Act for purposes of the wage index (98).

Under § 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of a proposed rule. The request for withdrawal of an application for reclassification or termination of an existing 3-year reclassification that would be effective in FY 2004 must be received by the MGCRB within 45 days of the publication of the proposed rule. If a hospital elects to withdraw its wage index application after the MGCRB has issued its decision but prior to the above date, it may later cancel its withdrawal in a subsequent year and request the MGCRB to reinstate its wage index reclassification for the remaining fiscal year(s) of the 3-year period (§ 412.273 (b) (2) (i)). The request to cancel a prior withdrawal must be made in writing to the MGCRB no later than the deadline for submitting reclassification applications for the following fiscal year (§ 412.273 (d)). For further information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer the reader to § 412.273, as well as the August 1, 2002, IPPS final rule (67 FR 50065) and the August 1, 2001 IPPS final rule (66 FR 39887).

Changes to the wage index that result from withdrawals of requests for reclassification, wage index corrections, appeals, and the Administrator's review process have been incorporated into the wage index values published in this final rule. These changes may affect not only the wage index value for specific geographic areas, but also the wage index value redesignated hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated hospitals. Further, the wage index value for the area from which the hospitals are redesignated may be affected.

Applications for FY 2006 reclassifications are due to the MGCRB by September 1, 2004. We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under § 412.273(d). Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2004, via the CMS Internet Web site at: <http://cms.hhs.gov/providers/prrb/mginfo.asp>, or by calling the MGCRB at (410) 786-1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244-2670.

I. Requests for Wage Index Data Corrections

1. Worksheet S-3 Wage Data

In the August 1, 2003, final rule (68 FR 27194), we revised the process and timetable for application for development of the wage index, beginning with the FY 2005 wage index. The preliminary and unaudited Worksheet S-3 wage data file was made available on October 8, 2003 through the Internet on CMS's Web site at: <http://cms.hhs.gov/providers/hipps/ippswage.asp>. In a memorandum dated October 10, 2003, we instructed all Medicare fiscal intermediaries to inform the IPPS hospitals they service of the availability of the wage data file and the process and timeframe for requesting revisions (including the specific deadlines listed below). We also instructed the fiscal intermediaries to advise hospitals that these data are also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in that wage data file, the hospital was to submit corrections along with complete, detailed supporting documentation to its intermediary by November 24, 2003. Hospitals were notified of this deadline and of all other possible deadlines and requirements, including the requirement to review and verify their data as posted on the preliminary wage data file on the Internet, through the October 10, 2003 memorandum referenced above.

The fiscal intermediaries notified the hospitals in early February of any changes to the wage data as a result of the desk reviews and the resolution of the hospitals' early November change requests. The fiscal intermediaries also submitted the revised data to CMS in early February. CMS published the proposed wage index public use file that included hospitals' revised wage data on February 27, 2004. In a memorandum also dated March 1, 2004, we instructed fiscal intermediaries to notify all hospitals regarding the availability of the proposed wage index public use file and the criteria and process for requesting corrections and revisions to the wage data. Hospitals had until March 12, 2004, to submit requests to the fiscal intermediaries for reconsideration of adjustments made by the fiscal intermediaries as a result of the desk review, and to correct errors due to CMS's or the intermediary's mishandling of the wage data. Hospitals were also required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, fiscal

intermediaries transmitted any additional revisions resulting from the hospitals' reconsideration requests by April 16, 2004. The deadline for hospitals to request CMS intervention in cases where the hospital disagreed with the fiscal intermediary's policy interpretations was April 23, 2004.

Hospitals were also instructed to examine Table 2 in the Addendum to the proposed rule. Table 2 of the proposed rule contained each hospital's adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2001 data used to construct the FY 2005 wage index. We noted that the hospital average hourly wages shown in Table 2 of the proposed rule only reflected changes made to a hospital's data and transmitted to CMS by March 15, 2004.

The final wage data public use file was released in May 2004 to hospital associations and the public on the Internet at <http://www.cms.hhs.gov/providers/hipps/ippswage.asp>. The May 2004 public use file was made available solely for the limited purpose of identifying any potential errors made by CMS or the fiscal intermediary in the entry of the final wage data that result from the correction process described above (revisions submitted to CMS by the fiscal intermediaries by April 16, 2004). If, after reviewing the May 2004 final file, a hospital believed that its wage data were incorrect due to a fiscal intermediary or CMS error in the entry or tabulation of the final wage data, it was provided the opportunity to send a letter to both its fiscal intermediary and CMS that outlined why the hospital believed an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). These requests had to be received by CMS and the fiscal intermediaries no later than June 11, 2004. The intermediary reviewed requests upon receipt and contacted CMS immediately to discuss its findings.

After the release of the May 2004 wage index file, changes to the hospital wage data were only made in those very limited situations involving an error by the intermediary or CMS that the hospital could not have known about before its review of the final wage data file. Specifically, neither the intermediary nor CMS accepted the following types of requests:

- Requests for wage data corrections that were submitted too late to be included in the data transmitted to CMS by fiscal intermediaries on or before April 16, 2004.
- Requests for correction of errors that were not, but could have been,

identified during the hospital's review of the March 1, 2004, wage data file (or the March 8 occupational mix data; see section III.H.2. of this preamble).

- Requests to revisit factual determinations or policy interpretations made by the intermediary or CMS during the wage index data correction process.

2. Occupational Mix Data

The process and criteria for requesting corrections to the occupational mix survey data are described in section III.C.1 of this preamble. As stated in that section, from April 16, 2004 forward, the process for correcting the final occupational mix survey data is the same, and on the same schedule, as described above for correcting the final Worksheet S-3 wage data.

3. All FY 2005 Wage Index Data

Verified corrections to the wage index received timely (that is, by June 11, 2004) have been incorporated into the final wage index in this final rule, and are effective October 1, 2004.

We created the processes described above to resolve all substantive wage index data index correction disputes before we finalize the wage and occupational mix data for the FY 2005 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage data corrections or to dispute the intermediary's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to challenge later, before the Provider Reimbursement Review Board, the failure of CMS to make a requested data revision (*See W. A. Foote Memorial Hospital v. Shalala*, No. 99-CV-75202-DT (E.D. Mich. 2001), also *Palisades General Hospital v. Thompson*, No. 99-1230 (D.D.C. 2003)).

Again, we believe the wage index data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage data to the fiscal intermediaries' attention. Moreover, because hospitals had access to the final wage index data by early May 2004, they had the opportunity to detect any data entry or tabulation errors made by the fiscal intermediary or CMS before the development and publication of the final FY 2005 wage index in this final rule, and the implementation of the FY 2005 wage index on October 1, 2004. If hospitals availed themselves of this opportunity, the wage index implemented on October 1 should be

accurate. Nevertheless, in the event that errors are identified after publication of the final rule, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with § 412.63(x)(2) of our existing regulations, we make midyear corrections to the wage index for an area only if a hospital can show: (1) That the intermediary or CMS made an error in tabulating its data; and (2) that the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of FY 2005 (that is, by the June 11, 2004 deadline). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index. As described earlier, since a hospital had to show that it could not have known about the error, or that it did not have the opportunity to correct the error, before the publication of the FY 2005 wage index. As indicated earlier, since a hospital had the opportunity to verify its data, and the fiscal intermediary notified the hospital of any changes, we do not expect that midyear corrections will be necessary. However, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is approved.

Comment: One national hospital association commended CMS for the revised wage index development process and timeframe that CMS implemented with the FY 2005 wage index. The commenter believed that releasing the wage data file before intermediaries begin their desk reviews of the wage data makes the process more efficient than in prior years and recommended that CMS follow a similar process for 2006. The commenter suggested that notifying hospitals of the schedule as soon as possible and extending the hospital review timeframe would enhance the process.

Another commented that nearly 13 percent of hospitals made changes to their wage data after the release of the February public use file. The commenter believed that this percentage of changes is too high and creates budgeting challenges for hospitals, as well as, contributes to difficulties in determining reclassification decisions.

Response: We will continue to explore ways to improve the process for developing the wage index. With the new process in place, the rate of revisions between the proposed (February) and final (May) public use files has decreased dramatically, from

approximately 30 percent in prior years to less than 15 percent for the FY 2005 wage index. However, we agree with the commenter that the volume of changes after the proposed rule is still too high. We encourage hospitals to work with their intermediaries as early as possible to ensure that their wage data are correct early in the process. For the FY 2006 wage index, we will apply the same process that we used for the FY 2005 wage index.

Comment: One commenter requested that CMS provide more specific guidance to fiscal intermediaries for handling the June appeals, that is, hospitals' requests to correct errors in the May public use files, just as CMS provides for the earlier stages of the correction process.

Response: We plan to provide more specific instructions regarding the intermediaries' handling of the June appeals in forthcoming instructions for the wage index development process, beginning with the FY 2006 wage index.

Comment: One commenter suggested that CMS should put a process in place that allows other hospitals negatively impacted by another hospital's incorrect data to make a request to obtain a correction. The commenter is concerned that sometimes the hospital with the incorrect data has no incentive to request a correction, for example, the hospital has closed or changed enrollment status to a CAH other non-IPPS hospital.

Response: The opportunity that the commenter requested is already available. If a hospital believes that another hospital's wage data may be erroneous in the public use files, the hospital may notify CMS that there is a potential problem with the other hospital's data. CMS and the other hospital's intermediary will review the data and attempt to contact the other hospital to determine the appropriate action. Any correction to a hospital's wage data can only be based on data that derives directly from the hospital.

J. Revision of the Labor-Related Share of the Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related: "The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to

wages and wage-related costs of the DRG prospective payment rates. * * *

The portion of hospital costs attributable to wages and wage-related costs is referred to as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index. In the past, we have defined the labor-related share for prospective payment acute care hospitals as the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share for the acute care hospital inpatient prospective payment system has been calculated as the sum of the weights for wages and salaries, fringe benefits, nonmedical professional fees, contract labor, postage, and labor-intensive services.

In its June 2001 Report to Congress, MedPAC recommended that the Secretary "should reevaluate current assumptions about the proportion of providers' costs that reflect resources purchased in local and national markets." (Report to the Congress: Medicare in Rural America, Recommendation 4D, page 80.) MedPAC recommended that the labor-related share include the weights for wages and salaries, fringe benefits, contract labor, and other labor-related costs for locally purchased inputs only. MedPAC noted that this would likely result in a lower labor share, which would decrease the amount of the national base payment amount adjusted by the wage index. As a result, hospitals located in low-wage markets (those with a wages index less than 1.0) would receive higher payments, while those located in high-wage labor markets would receive lower payments.

In our proposed and final regulations updating the IPPS for FY 2003 (67 FR 31404, May 9, 2002 and 67 FR 49982, August 1, 2002), we discussed the methodology that we have used to determine the labor-related share. We noted that, at that time, the results of employing that methodology suggested that an increase in the labor-related share (from 71.066 percent to 72.495 percent) was warranted. However, we decided not to propose such an increase in the labor-related share until we conducted further research to determine whether a different methodology for determining the labor-related share should be adopted. The labor-related share has thus remained 71.066 percent.

Section 403 of Public Law 108-173 amended sections 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this "would result in lower

payments than would otherwise be made.” However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate “from time to time” the proportion of hospitals’ costs that are “attributable to wages and wage-related costs.” In fact, section 404 of Public Law 108–173 requires the Secretary to develop a frequency for revising the weights used in the hospital market basket, including the labor share, to reflect the most current data more frequently than once every 5 years. This reflects Congressional intent that hospitals will receive payment based on a 62-percent labor share, or the labor share estimated from time to time by the Secretary, whichever results in higher payments.

Section 404 further requires us to include in the final IPPS rule for FY 2006 an explanation of the reasons for, and options considered, in determining the frequency for revising the weights used in the hospital market basket, including the labor share. In the meantime, we are also continuing our research into the assumptions employed in calculating the labor-related share. Our research involves analyzing the compensation share separately for urban and rural hospitals, using regression analysis to determine the proportion of costs influenced by the area wage index, and exploring alternative methodologies to determine whether all or only a portion of professional fees and nonlabor intensive services should be considered labor-related. We will present our analysis and conclusions regarding the frequency and methodology for updating the labor share in the proposed and final rules for FY 2006.

In section IV.F. of this preamble, we discuss our incorporation of the requirements of section 403 of Public Law 108–173 in a new § 412.64(h) of the regulations.

As discussed above, the Secretary had determined, prior to the enactment of Public Law 108–173, that the labor-related share would be 71.066 percent. As a result, application of a 62-percent labor share would result in lower payments for any hospital with a wage index greater than 1.0. Therefore, we are modifying our payment system software for FY 2005 to apply wage indexes greater than 1.0 to 71.066 percent of the standardized amount, and to apply wage indexes less than or equal to 1.0 to 62 percent of the standardized amount.

We did not receive any specific comments on the proposed implementation of section 403 of Public Law 108–173. Therefore, we are

adopting as final the proposed policy change without modification.

IV. Other Decisions and Changes to the IPPS for Operating Costs and GME Costs

A. Postacute Care Transfer Payment Policy (§ 412.4)

1. Background

Existing regulations at § 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines transfers from one acute care hospital to another, and § 412.4(c) defines transfers to certain postacute care providers. Our policy provides that, in transfer situations, full payment is made to the final discharging hospital and each transferring hospital is paid a per diem rate for each day of the stay, not to exceed the full DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full DRG payment by the geometric mean length of stay for the DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy provides for payment that is double the per diem amount for the first day (§ 412.4(f)(1)). Transfer cases are also eligible for outlier payments. The outlier threshold for transfer cases is equal to the fixed-loss outlier threshold for nontransfer cases, divided by the geometric mean length of stay for the DRG, multiplied by the length of stay for the case, plus one day.

Medicare adopted its IPPS transfer policy because, if the program were to pay the full DRG payment regardless of whether a patient is transferred or discharged, there would be a strong incentive for hospitals to transfer patients to another IPPS hospital early in the patients’ stay in order to minimize costs while still receiving the full DRG payment. The transfer policy adjusts the payments to approximate the reduced costs of transfer cases.

Previously, when a patient chose to depart from a hospital against the medical opinion of treating physicians, the case was treated as a left against medical advice (LAMA) discharge and coded as discharge status “07-Left Against Medical Advice (LAMA)” on the inpatient billing claim form. Because, by definition, LAMA discharges were assumed not to involve the active participation of the hospital administration, our policy had been to treat LAMA cases as discharges. This

policy applied even if the patient was admitted to another hospital on the date of the LAMA discharge. Consequently, until FY 2004, we made a full DRG payment for any discharge coded as a LAMA case.

Last year, in response to an Office of Inspector General (OIG) report issued in March 2002 (A–06–99–00045), we became concerned that some hospitals were incorrectly coding transfers as LAMA cases. Therefore, in the August 1, 2003 final IPPS rule (68 FR 45405), we expanded our definition of a transfer under § 412.4(b) to include all patients who are admitted to another IPPS hospital on the same day that the patient is discharged from an IPPS hospital, unless the first (transferring) hospital can demonstrate that the patient’s treatment was completed at the time of discharge from that hospital. In other words, unless the same-day readmission is to treat a condition that is unrelated to the condition treated during the original admission (for example, the beneficiary is in a car accident later that day), any situation where the beneficiary is admitted to another IPPS hospital on the same date that he or she is discharged from an IPPS hospital would be considered a transfer, even if the patient left against medical advice from the first hospital.

This policy prohibits payment of two claims for the same patient on the same day. Therefore, if a hospital believes a claim has been wrongly denied, the original discharging hospital must resubmit the claim with documentation that the discharge was appropriate and unrelated to the subsequent same-day admission.

Comment: One commenter requested that we clarify our policy regarding LAMAs. The commenter noted that in the FY 2004 proposed rule, we “considered and appropriately rejected * * * a knowledge standard” when we amended the transfer policy to include LAMAs. Under the standard that was rejected, a hospital would have been required to code LAMAs as transfers based on knowledge of a same-day admission to another hospital. However, the commenter notes that in the May 18, 2004 proposed rule, we stated that hospitals “are now allowed to report a patient as left against medical advice only if they have no knowledge that the patient has been admitted to another hospital on the same day.” The commenter notes that this could be interpreted as reflecting a change in policy, returning to the knowledge standard that we rejected in the August 1, 2003 final rule.

Response: We did not intend to change our policy in the preamble of the

May 18, 2004 proposed rule. A discharging hospital is not required to identify cases in which a patient is admitted to another hospital on the same day. Our claims processing software has been revised to identify cases in which a patient is admitted to a hospital after being discharged from another hospital on the same day.

Comment: Some commenters noted that the edits to the CWF will cause claims to be rejected and that providers will have to recode the claims and resubmit them. Others expressed concerns that hospitals appropriately discharge their patients to home "only to have other providers outside of the hospital admit patients to other entities and healthcare settings," imposing on hospitals an unfair burden that is caused by patient choice and is not of their own doing. As a result, claims are frequently denied for these providers as a result of the lack of a method to ensure consistent inpatient processing of claims. The commenter cites "unplanned situations (for example, LAMA, readmissions post-discharge to home, patients seeking additional care at other facilities)" that result in "unnecessary payment delays and rework of claims" by the facilities that originally treated the patients. The commenter further argues, "these unnecessary process issues result in additional overhead costs that will never be recovered by the already reduced transfer per diem payments that the original treating facility ultimately receives."

Response: As we discussed above, we adopted this policy in the August 1, 2003 final rule (68 FR 45404 through 45406) in response to an OIG report indicating that transfers were frequently miscoded as LAMAs. Since we have implemented the systems edits to identify these cases, the number of cases identified by these edits has provided further evidence that this policy is appropriate.

2. Changes to DRGs Subject to the Postacute Care Transfer Policy (§ 412.4(c) and (d))

Under section 1886(d)(5)(j) of the Act, a "qualified discharge" from one of 10 DRGs selected by the Secretary to a postacute care provider is treated as a transfer case beginning with discharges on or after October 1, 1998. This section required the Secretary to define and pay as transfers all cases assigned to one of 10 DRGs selected by the Secretary, if the individuals are discharged to one of the following postacute care settings:

- A hospital or hospital unit that is not a subsection 1886(d) hospital. (Section 1886(d)(1)(B) of the Act

identifies the hospitals and hospital units that are excluded from the term "subsection (d) hospital" as psychiatric hospitals and units, rehabilitation hospitals and units, children's hospitals, long-term care hospitals, and cancer hospitals.)

- A SNF (as defined at section 1819(a) of the Act).

- Home health services provided by a home health agency, if the services relate to the condition or diagnosis for which the individual received inpatient hospital services, and if the home health services are provided within an appropriate period (as determined by the Secretary).

In the July 31, 1998 IPPS final rule (63 FR 40975 through 40976), we specified the appropriate time period during which we would consider a discharge to postacute home health services to constitute a transfer as within 3 days after the date of discharge. In addition, in the July 31, 1998 final rule, we did not include in the definition of postacute care transfer cases patients transferred to a swing-bed for skilled nursing care (63 FR 40977).

Section 1886(d)(5)(j) of the Act directed the Secretary to select 10 DRGs based upon a high volume of discharges to postacute care and a disproportionate use of postacute care services. As discussed in the July 31, 1998 final rule, these 10 DRGs were selected in 1998 based on the MedPAR data from FY 1996. Using that information, we identified and selected the first 20 DRGs that had the largest proportion of discharges to postacute care (and at least 14,000 such transfer cases). In order to select 10 DRGs from the 20 DRGs on our list, we considered the volume and percentage of discharges to postacute care that occurred before the mean length of stay and whether the discharges occurring early in the stay were more likely to receive postacute care. We identified 10 DRGs to be subject to the postacute care transfer rule starting in FY 1999.

Section 1886(d)(5)(j)(iv) of the Act authorizes the Secretary to expand the postacute care transfer policy beyond 10 DRGs for FY 2001 or subsequent fiscal years. In the FY 2004 IPPS final rule (68 FR 45412), we expanded the postacute care transfer policy to include additional DRGs. We established the following criteria that a DRG must meet, for both of the 2 most recent years for which data are available, in order to be added to the postacute care transfer policy:

- At least 14,000 postacute care transfer cases;

- At least 10 percent of its postacute care transfers occurring before the geometric mean length of stay;

- A geometric mean length of stay of at least 3 days; and

- If a DRG is not already included in the policy, a decline in its geometric mean length of stay during the most recent 5 year period of at least 7 percent.

We identified 21 new DRGs that met these criteria. We also determined that one DRG from the original group of 10 DRGs (DRG 263) no longer met the volume criterion of 14,000 transfer cases. Therefore, we removed DRGs 263 and 264 (DRG 264 is paired with DRG 263) from the policy and expanded the postacute care transfer policy to include payments for transfer cases in the new 21 DRGs, effective October 1, 2003. As a result, a total of 29 DRGs were subject to the postacute care transfer policy in FY 2004.

In the FY 2004 IPPS final rule, we indicated that we would review and update this list periodically to assess whether additional DRGs should be added or existing DRGs should be removed (68 FR 45413). We have analyzed the available data from the FY 2003 MedPAR file. For the 2 most recent years of available data (FY 2002 and FY 2003), we have found that no additional DRGs qualify under the four criteria set forth in the IPPS final rule for FY 2004. We have also analyzed the DRGs included under the policy for FY 2004 to determine if they still meet the criteria to remain under the policy. In addition, we have analyzed the special circumstances arising from a change to one of the DRGs included under the policy in FY 2004.

As discussed in the May 18, 2004 IPPS proposed rule (69 FR 28212) and in section II.B.9. of this final rule, we proposed to eliminate DRG 483. Under our proposal, the cases that would have been placed into DRG 483 would be split into two proposed new DRGs, 541 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses With Major O.R. Procedure) and 542 (Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses Without Major O.R. Procedure). This would be done by subdividing the cases in the existing DRG 483 based on the presence of a major O.R. procedure, in addition to the tracheostomy code that is currently required to be assigned to this DRG. Therefore, if the patient's case involves a major O.R. procedure (a procedure whose code is included on the list that is assigned to DRG 468 (Extensive O.R. Procedure Unrelated to Principal

Diagnosis), except for tracheostomy codes 31.21 and 31.29), the case would be assigned to the proposed new DRG 541. We indicated that if the patient does not have an additional major O.R. procedure (that is, there is only a tracheostomy code assigned to the case), the case would be assigned to proposed new DRG 542. In section II.B.9. of this preamble, we are finalizing our proposal to eliminate DRG 483 and create new DRGs 541 and 542.

As discussed in the May 18, 2004 proposed rule, neither of the new DRGs 541 and 542 would have enough cases to meet the first criterion for inclusion in the postacute care transfer policy. DRG 483 had 44,788 total cases with 15,520 transfer cases in FY 2002, and 44,618 total cases with 20,034 transfer cases in FY 2003. These cases will now split between new DRG 541 (20,812 total cases) and new DRG 542 (23,387 total cases). As a result, neither of these new DRGs would meet the existing threshold of 14,000 transfer cases (6,779 projected transfer cases for new DRG 541, and 8,570 projected transfer cases for new DRG 542). Nevertheless, we indicated that we believe the cases that will now be incorporated into these two new DRGs remain appropriate candidates for application of the postacute care transfer policy. The new DRGs 541 and 542 will contain the same cases that were included in existing DRG 483, which qualified for inclusion in the postacute care transfer policy. Furthermore, many of the cases in the new DRGs 541 and 542 will continue to require postacute care.

For the proposed rule, when we analyzed the cases that we projected would fall into the two new DRGs in the FY 2005 GROUPE Version 22.0, we found that a high proportion of cases in both the new DRGs were projected to be transfer cases: 33 percent of all cases in DRG 541, and 37 percent in DRG 542. In addition, based on the data from cases in DRG 483 in the FY 2003 MedPAR file, a high proportion of the transfer cases in these proposed new DRGs were projected to fall into the short-stay transfer category: 41 percent of transfer cases in new DRG 541 and 42 percent of transfer cases in new DRG 542 were projected to occur before the geometric mean length of stay for these new DRGs. By contrast, among all DRGs, approximately 15 percent of transfer cases are short-stay transfer cases. The percentage of transfer cases that were short-stay cases that would be in both new DRGs 541 and 542 would be more than 2 standard deviations above the mean percentage of short-stay cases across all DRGs. (Two standard deviations above the mean across all

DRGs is 37 percent for FY 2005.) Therefore, we proposed that the subdivision of DRG 483 should not change the original application of the postacute care transfer policy to the cases once included in that DRG. We did not believe that it was appropriate for these cases to fall outside the scope of this policy solely because of a revision to the DRG structure that was driven by policy reasons unrelated to the postacute care transfer provision. We proposed that the high proportion of transfer cases among all cases that would be assigned to these new DRGs, along with the unusually high proportion of short-stay cases among those transfer cases, provided solid reasons for considering whether alternate criteria might better address the special circumstances that can arise from changes in DRGs unrelated to the postacute care transfer policy.

Therefore, in the May 18, 2004 proposed rule, we proposed alternate criteria to be applied in cases where DRGs do not satisfy the existing criteria, for discharges occurring on or after October 1, 2004 (69 FR 28273–28374). The proposed new criteria were designed to address situations such as those posed by the split of DRG 483, where there remain substantial grounds for inclusion of cases within the postacute care transfer policy, although one or more of the original criteria may no longer apply. Therefore, we proposed to examine DRGs for inclusion within the policy against two sets of criteria, first, the original four criteria, and then, the proposed alternate set of criteria. Under our proposal, DRGs that did not satisfy the first set of criteria would still be included if they satisfied the second set. Specifically, a DRG would still be subject to the postacute care transfer policy under the alternative set of criteria if, for the 2 most recent years for which data are available, there were at least 5,000 total transfers to postacute care among the cases included in the DRG, and if, among the cases included in the DRG, the percentage of transfer cases that were short-stay transfer cases was at least 2 standard deviations above the geometric mean length of stay across all DRGs (which is 37 percent for FY 2005). We indicated that we would also continue to require a geometric mean length of stay of at least 3 days among the cases included in the DRG. Finally, we proposed to require that, if a DRG was not already included in the policy, it either experienced a decline in its geometric mean length of stay during the most recent 5-year period of at least 7 percent or contained only cases that would have been included in a DRG to

which the policy applied in the prior year.

Under the proposed alternate criteria, DRGs 430, 541, and 542 would have qualified for inclusion in the postacute care transfer policy. DRG 430 met the proposed threshold of 5,000 transfer cases in both of the 2 most recent years, with 11,973 transfer cases and 46 percent short-stay transfer cases in FY 2002, and 12,202 transfer cases and 38 percent short-stay transfers in FY 2003. In addition, DRG 430 experienced a 7-percent decline in length of stay from FY 2000 to FY 2004. DRG 430 also had a 5.8 day average length of stay during those years. As discussed in the proposed rule, the cases to be included in new DRGs 541 and 542 contain a sufficient number of transfers to meet the first alternate criterion, and among the cases to be included in these DRGs, the percentages of transfer cases occurring before the geometric mean length of stay new DRGs exceed 2 standard deviations above the geometric mean length of stay for all DRGs. The average lengths of stay for the cases to be included in new DRGs 541 and 542 are 37.7 days and 28.9 days, respectively.

We proposed to revise the regulations governing the postacute transfer policy to include the alternative criteria described above (§ 412.4(d)). We also proposed that DRG 430 and new DRGs 541 and 542 would be included in the postacute care transfer policy.

In the May 18, 2004 proposed rule, we also called attention to the data concerning DRG 263, which was subject to the postacute care transfer policy until FY 2004. We removed DRG 263 from the postacute care transfer policy for FY 2004 because it did not have the minimum number of cases (14,000) transferred to postacute care (13,588 transfer cases in FY 2002, with more than 50 percent of transfer cases being short-stay transfers). The FY 2003 MedPAR data show that there were 15,602 transfer cases in the DRG in FY 2003, of which 46 percent were short-stay transfers. Because we removed the DRG from the postacute care transfer policy in FY 2004, it must meet all criteria to be included under the policy in subsequent fiscal years. Because the geometric mean length of stay for DRG 263 shows only a 6-percent decrease since 1999, DRG 263 does not qualify to be added to the policy for FY 2005 under the existing criteria that were included in last year's rule. DRG 263 would have qualified under the volume threshold and percent of short-stay transfer cases under the proposed new alternate criteria contained in the proposed rule. However, it still did not

meet the proposed required decline in length of stay to qualify to be added to the policy in FY 2005.

Comment: Several commenters objected to the proposed alternate criteria for DRGs to be included in the postacute care transfer policy. Some commenters believed that the proposed criteria were inappropriate because they appeared contrived to ensure that cases in the former DRG 483, which had a very high DRG weight and resulted in significant Medicare payments, would not be paid at the higher rate associated with those cases. One commenter stated that if CMS' creation of the two new DRGs for tracheostomies with and without surgical procedures does not create less variation in length of stay and cost per case, there is no need to split DRG 483 and no need to expand the transfer policy criteria. The commenters argued that if the split of DRG 483 into more specific DRGs will better account for variations in the original DRG, then the historical logic behind the transfer policy in these cases is no longer valid. Some commenters also believed that the alternate criteria did not meet the objective of the provision, which is to ensure that the postacute care transfer policy only subjects high volume DRGs to this payment method.

Response: We disagree with some of the points raised by these commenters. In the proposed rule (69 FR 28273) we clearly indicated that the alternate criteria to be included in the postacute care transfer policy still required relatively high volumes of postacute care transfer cases, as well as very high proportions of short stay transfer cases. We specifically chose a very high threshold for the percent of these postacute care transfer cases that are short-stay cases in order to avoid including inappropriate DRGs within the postacute care transfer policy. In many areas of Medicare program policy we employ a threshold of one standard deviation or less in order to qualify for inclusion to or exclusion from certain provisions. In this instance, we deliberately chose a much higher threshold in order to ensure that only those DRGs with the highest rate of short-stay postacute care transfers would be included in the policy.

However, in the light of these and other comments, we are not adopting the proposed alternate criteria in this final rule. We note that the postacute care transfer policy was not considered at the time the decision was made to split DRG 483. We do not intend to change our rationale for reorganizing DRGs into more coherent groups or to compromise the clinical cohesiveness of

the DRG system in order ensure cases are included in or excluded from the postacute care transfer policy or other CMS policies. We have discussed the reasons for splitting DRG 483 in section II.B.9. of the proposed rule and in this final rule. However, we do note that, while these cases will continue to be included in the postacute care transfer policy and subject to per diem payments, we anticipate that fewer cases will actually receive these reduced payments as the new DRGs better reflect the resources required to treat these patients. As a result, hospitals will have less incentive to discharge these patients to postacute care.

Comment: Some commenters suggested that in place of the proposed alternate criteria, we should adopt a policy of keeping cases within the scope of the postacute care transfer policy permanently once they initially qualify for inclusion in the policy. These commenters noted that removing DRGs from the postacute care transfer policy makes the payment system less stable and results in inconsistent incentives over time. They also argued that "a drop in the number of transfers to postacute settings is to be expected after the transfer policy is applied to a DRG, but the frequency of transfers may well rise again if the DRG is removed from the policy." Other commenters expressed concern about our changing of the policy criteria in 2 consecutive years. These commenters argued that such frequent changes in policy give the appearance that the policy has been contrived to achieve certain desired results and make the regulatory process unpredictable and unfair. They further imply that these "band-aid fixes" to the 20-year old Medicare system do not bode well for the confidence of outside organizations in regards to the program.

Response: We did consider grandfathering cases already included in the policy because this approach is, on the surface, the simplest method of ensuring these cases continue to be paid appropriately. However, we determined that in order to adopt this approach, we would also need to determine an appropriate timeframe for the grandfathering period. We did not believe that we could adequately predict or project what timeframe would be appropriate, not only in the case of the splitting of DRG 483 into DRGs 541 and 542, but also for future situations where this kind of split may occur. Therefore, we tried to develop appropriate, alternative criteria based on actual case data that could be monitored and applied from year to year.

However, due to the large number of comments received and the strong

arguments they have raised in favor of a more straightforward approach, we have decided not to adopt the alternate criteria proposed in the May 18, 2004 proposed rule. Instead, in this final rule we are adopting the policy of simply grandfathering, for a period of 2 years, any cases that were previously included within a DRG that has split, when the split DRG qualified for inclusion in the postacute care transfer policy for both of the previous 2 years. Under this policy, the cases that were previously assigned to DRG 483, and that will now fall into DRGs 541 and 542, will continue to be subject to the postacute care transfer policy for the next 2 years. We will monitor the frequency with which these cases are transferred to postacute settings and the percentage of these cases that are short-stay transfer cases. Because we are not adopting the proposed alternate criteria for DRG inclusion the postacute care transfer policy at this time, DRG 430 (Psychoses) does not meet the criteria for inclusion and will not be subject to the postacute care transfer policy for FY 2005.

We appreciate the recommendation to address situations such as the splitting of DRGs by simply including all cases within the postacute care transfer policy permanently once they have initially qualified. While we are not adopting this policy at this time, we will actively consider it for adoption at a later date. Meanwhile, we believe that grandfathering the cases formerly included in DRG 483 for 2 years is an appropriate interim measure that ensures a consistent payment approach to these cases while affording us sufficient time to undertake a thorough review of this issue. In the meantime, we welcome comments on how to treat the cases formerly included in a split DRG after the grandfathering period. We note that, if we were to adopt the policy recommended by the commenter, cases in DRGs 263 and 264 would again become subject to the policy. As noted above, these DRGs are already very close to meeting the criteria required to be re-included in the policy. However, we will monitor cases until next year or until such time that another change to this policy is warranted.

The table below displays the 30 DRGs that we are including in the postacute care transfer policy, effective for discharges occurring on or after October 1, 2004. This table includes the effects of dropping DRG 483, which we are deleting from the DRG list, and adding the two new DRGs 541 and 542 that will now incorporate the cases formerly assigned to DRG 483. As discussed above, these cases are being grandfathered into the policy for 2

years. The other DRGs meet the criteria specified above during both of the 2 most recent years for which data were

available prior to the publication of this final rule (FYs 2002 and 2003), as well as their paired-DRG if one of the DRGs

meeting the criteria includes a CC/no-CC split.
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DRG	DRG Title
12	Degenerative Nervous System Disorders
14	Intracranial Hemorrhage and Stroke with Infarction
24	Seizure and Headache Age >17 With CC
25	Seizure and Headache Age >17 Without CC
88	Chronic Obstructive Pulmonary Disease
89	Simple Pneumonia and Pleurisy Age > 17 With CC
90	Simple Pneumonia and Pleurisy Age >17 Without CC
113	Amputation for Circulatory System Disorders Except Upper Limb and Toe
121	Circulatory Disorders With AMI and Major Complication, Discharged Alive
122	Circulatory Disorders With AMI Without Major Complications Discharged Alive
127	Heart Failure & Shock
130	Peripheral Vascular Disorders With CC
131	Peripheral Vascular Disorders Without CC
209	Major Joint and Limb Reattachment Procedures of Lower Extremity
210	Hip and Femur Procedures Except Major Joint Age >17 With CC
211	Hip and Femur Procedures Except Major Joint Age >17 Without CC
236	Fractures of Hip and Pelvis
239	Pathological Fractures and Musculoskeletal and Connective Tissue Malignancy
277	Cellulitis Age >17 With CC
278	Cellulitis Age >17 Without CC
294	Diabetes Age>35
296	Nutritional and Miscellaneous Metabolic Disorders Age >17 With CC
297	Nutritional and Miscellaneous Metabolic Disorders Age >17 Without CC
320	Kidney and Urinary Tract Infections Age >17 With CC
321	Kidney and Urinary Tract Infections Age >17 Without CC
395	Red Blood Cell Disorders Age >17
429	Organic Disturbances and Mental Retardation
468	Extensive O.R. Procedure Unrelated to Principal Diagnosis
541 (formerly 483)	Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses With Major O.R. Procedure
542 (formerly 483)	Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses Without Major O.R. Procedure

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Section 1886(d)(5)(J)(i) of the Act recognizes that, in some cases, a substantial portion of the costs of care is incurred in the early days of the inpatient stay. Similar to the policy for transfers between two acute care hospitals, the transferring hospital in a

postacute care transfer receives twice the per diem rate for the first day of treatment and the per diem rate for each following day of the stay before the transfer, up to the full DRG payment. However, three of the DRGs subject to the postacute care transfer policy

exhibit a disproportionate share of costs very early in the hospital stay in postacute care transfer situations. For these DRGs, hospitals receive 50 percent of the full DRG payment plus the single per diem (rather than double the per diem) for the first day of the stay and

50 percent of the per diem for the remaining days of the stay, up to the full DRG payment.

In previous years, we determined that DRGs 209 and 211 met this cost threshold and qualified to receive this special payment methodology. Because DRG 210 is paired with DRG 211, we include payment for cases in that DRG for the same reason we include paired DRGs in the postacute care transfer policy (to eliminate any incentive to code incorrectly in order to receive higher payment for those cases). The FY 2003 MedPAR data show that DRGs 209 and 211 continue to have charges on the first day of the stay that are higher than 50 percent of the average charges in the DRGs. Therefore, we proposed to continue the special payment methodology for DRGs 209, 210, and 211 for FY 2005 (69 FR 28274).

We received no comments on this proposal. Therefore, we will continue the special payment methodology for these DRGs in FY 2005.

Comment: One commenter requested that we require physicians and postacute care facilities to notify the original treating hospital that a patient has been treated within 3 days at another facility. The commenter indicated that this step would reduce the burden on hospitals in relation to the postacute transfer policy.

Response: While we appreciate the commenter's concern to reduce the burdens on hospitals, we are reluctant to impose this burden on other entities, especially since these other entities are not affected by the payment decisions that are involved.

B. Payments for Inpatient Care in Providers That Change Classification Status During a Patient Stay (§§ 412.2(b)(3) and 412.521(e))

Situations may occur in hospital inpatient care settings where a Medicare provider changes its Medicare payment classification status during a patient's stay, for example, an acute care hospital is reclassified as a LTCH. (We refer to the patients in these situations as "crossover patients.") Different Medicare payment systems apply to care furnished to Medicare beneficiaries during inpatient stays, depending on the classification status of the provider. For example, payments to an acute care hospital for inpatient services are made under the IPPS on a per discharge basis, using a DRG classification system. Payments to LTCHs that are classified under section 1886(d)(1)(B)(iv)(I) of the Act are made under the LTCH PPS on a per discharge basis using a LTC-DRG classification system. The main difference between a LTCH that is

classified under section 1886(d)(1)(B)(iv)(I) of the Act and an acute care hospital is the average length of stay at the hospital. Specifically, section 1886(d)(1)(B)(iv)(I) of the Act defines a LTCH as "a hospital which as an average inpatient length of stay (as determined by the Secretary) of greater than 25 days."

Questions have arisen as to how Medicare should pay for an inpatient stay in a hospital when the hospital changes its classification status during the course of the beneficiary's single hospital stay. Specifically, how should Medicare pay for a patient's stay when the first part of that stay is in the acute care hospital (before the hospital was reclassified as a LTCH and the second part of that stay is in the same hospital after it is reclassified as a LTCH. Although the situation may occur in other settings, this payment issue is most prevalent for services furnished to crossover patients in a newly established LTCH. The fact is that all new LTCHs that seek LTCH classification under section 1886(d)(1)(B)(iv)(I) of the Act begin as other provider types, generally as acute care hospitals, and then these providers under the regulations at § 412.23(e)(3) are required to meet the average length of stay criterion by showing that for the period of at least 5 months of a preceding 6-month period, the hospital's average Medicare inpatient length of stay is greater than 25 days. Once the entity meets the criteria under § 412.23(e)(3), they are reclassified as LTCHs and are then paid under the LTCH PPS. It is for those patients who were admitted to the acute care hospital before the acute care hospital was reclassified as a LTCH and are discharged after the hospital is classified as a LTCH that we proposed to codify a revised crossover policy in the May 18, 2004 IPPS proposed rule.

To address payment for inpatient care for such crossover patients, we had issued instructions for hospital billing purposes (paper-based manual, Hospital Manual, HCFA Pub. 10, section 404, which has been replaced by the Medicare Claims Processing Manual, Pub. 100-4, Chapter 3, section 100.4.1) that were in effect prior to the implementation of the PPS for LTCHs (that is, prior to October 1, 2002). The manual instructed hospitals as follows: "The hospital must submit a discharge bill with the old provider number and an admission notice with the new provider number. The date of discharge and the date of admission are the same date, which is the first day of the new fiscal period. All subsequent billings are

submitted under the new provider number."

It is important to note that at the time this manual provision was written, IPPS-excluded hospitals were reimbursed under the reasonable cost-based (TEFRA) payment system, not other prospective payment systems. Thus, under the manual instructions, if a patient was in an acute care hospital and the hospital reclassified to a LTCH during the patient's stay, Medicare would then make payment for what was, in reality, only one episode of care as if it were two episodes. Specifically, the days of the stay while the facility was certified as an acute care hospital generated a full DRG payment under the IPPS; and the services provided from the time the facility was reclassified as a LTCH were paid under the TEFRA payment system. The patients were treated as if they were "admitted" to the "new" facility until the patient was actually discharged. We had proposed to revisit the issue of Medicare payment for crossover patients now that there has been a fundamental change in the Medicare payment system for LTCHs. That is, LTCHs are now being paid under a LTCH PPS which was effective for LTCHs for cost reporting periods beginning on or after October 1, 2002.

Under the LTCH PPS for crossover patients, under the existing Manual instructions, Medicare makes a full DRG payment under the IPPS to the acute care hospital for the "first portion" of the patient stay, and when the acute care hospital is reclassified as a LTCH, Medicare makes a second PPS payment under the LTCH PPS for the "second portion" of the stay. We believe that this results in excessive Medicare payments and results in the inappropriate use of the Medicare Trust Fund. We believe the result described above is contrary to a basic premise of a PPS, which is that a single PPS payment is adequate and appropriate reimbursement for the entire bundle of services that a hospital provides during the course of a patient's stay. We believe the care provided prior to and after the reclassification of a LTCH is really one bundle of services associated with a single hospitalization. The "discharge" from the acute care hospital and "admission" to the LTCH has only been a "paper discharge" that was triggered solely by a change in the classification status of the hospital treating the patient. In the instant case, the beneficiary by mere coincidence, was an inpatient of the acute care hospital when it reclassified—the acute care hospital did not materially change the medical care it provided to the beneficiary during his/her single hospitalization because its classification

as an acute care hospital ended on one day and changed to LTCH classification on the next day. Under the existing manual instructions, the hospital is receiving not one payment, but two PPS payments, for a bundle of services that should have been adequately and properly reimbursed by a single PPS payment.

As explained in the May 18, 2004 proposed rule (69 FR 28275), presently, if the DRG assigned to the "discharge" from the acute care hospital for a crossover patient falls within one of the DRGs covered by the postacute care transfer policy at § 412.4(c) of the regulations, the provider will receive a payment under the postacute care transfer policy as if the patient, who in fact has not moved, was transferred to a postacute care provider. Payment under the postacute care transfer policy is triggered when a discharge bill with the old provider number and an admission notice with the new provider number is submitted and processed by the Medicare standard bill processing systems as a transfer. Because the patient is, in reality, at the "same" facility (an acute care hospital that has been reclassified as a LTCH) and is in one episode of care, we do not believe the application of the existing transfer policy is the appropriate methodology for dealing with the crossover patient situation described above. Under the postacute care transfer policy, the affect on payment is limited to a specific scenario; the payment to the transferring hospital is only affected if the patient is discharged prior to the day before the geometric mean length of stay for the DRG. When the patient is discharged by the day before the geometric mean length of stay, the "discharging" acute care hospital will receive the equivalent of the full IPPS DRG payment and the LTCH hospital will also receive a full LTCH PPS payment. Therefore, although the transfer policy addresses discharges from an acute care hospital that occur prior to the geometric mean length of stay for each DRG, it does not address crossover patients where the hospital is reclassified after the patient has a length of stay of at least the geometric mean length of stay.

As we have stated previously in this discussion, we believe that it is inappropriate to continue to allow the current payment policy for crossover patients. An acute care hospital before reclassification as a LTCH may admit and treat patients with multicomorbidities that result in longer hospital stays than are characteristic of the patient census at a LTCH. Invariably, at the time the acute care hospital becomes a LTCH, there will be

patients who were admitted to the acute care hospital and who remain in the facility when it is reclassified as a LTCH and are ultimately discharged from the LTCH. An acute care hospital's change in classification status to a LTCH should have no impact on the course of treatment that is already underway for the patient in what would now be a LTCH. Thus, since we believe the proposed patient is receiving one consistent course of treatment throughout this stay, in the May 18, 2004 proposed rule, we proposed to revise the present policy and allow for only one Medicare payment for the patient's entire stay. In proposing this change in policy, we proposed to provide for one Medicare payment where previously there would have been two payments made for one stay; instead payment would be based on the PPS of the facility that is actually discharging the patient.

Under the proposed approach, we would include those days of care and costs incurred by the hospital for the crossover patient before the facility met the LTCH classification criteria, in determining payments to the LTCH for that patient under the LTCH PPS. Under this policy, for example, if an acute care hospital admits a patient on December 28 and the hospital reclassifies to a LTCH on January 1 when its cost reporting period begins, and the patient is physically discharged from the LTCH on February 5, one payment would be made for this entire stay (December 28–February 5), and payment would be based on the LTCH-DRGs under the LTCH PPS. We are counting the patient's entire hospitalization (that is, all days and costs of the patient stay in the facility that occurred prior to and after reclassification) in determining the applicable payment under the LTCH PPS. This provision would also count all the days of the patient stay, that is prior to and after reclassification, as LTCH days for purposes of determining whether the facility continues to meet the average length of stay requirement for LTCHs. We believe this is consistent with the discretionary authority granted to the Secretary at section 1886(d)(1)(B)(iv)(I) of the Act for determining lengths of stay for LTCHs. Specifically, section 1886(d)(1)(B)(iv)(I) of the Act provides that a LTCH is a hospital that has an average length of stay (as determined by the Secretary) of greater than 25 days. Thus, the Secretary determines how a LTCH's average length of stay is to be determined. (We are also using the broad discretionary authority provided in section 1871 of the Act to not count the days of the

patient's stay in the acute care hospital prior to reclassification as acute care days.)

In addition, we are using the broad authority in section 1871 of the Act to not pay for the days of the patient's stay in the acute care hospital as acute care days. Section 1871 authorizes the Secretary to promulgate regulations that are necessary to carry on the administration of the Medicare program. In addition, as stated in the proposed rule, we believe counting all days for the patient's stay and applying them in determining the PPS at the hospital that actually discharges the patients even though part of the stay was in a prior cost reporting period is consistent with the policy as recently revised at § 412.23(e)(3) of the regulations, which provides that if a LTCH patient is admitted in one cost reporting period and discharged in a second cost reporting period, all of the days of the patient's stay even those from prior fiscal years are counted in the cost reporting period in which the patient is discharged. In this example of the crossover patient, including the days in December may result in a full LTC-DRG payment rather than a lower payment possible under the short-stay outlier policy (§ 412.529) based solely on the length of the stay of the patient at the LTCH once it was reclassified. (Under the short-stay policy, we would adjust (lower) the Federal prospective payment if the payment is for a length of stay that is up to and including five-sixths of the geometric average length of stay for the LTC-DRG assigned to the case.)

While this final rule specifically addresses the situation of a crossover patient that is in an acute hospital that reclassifies as a LTCH during the course of the patient's stay, we believe the policy may be equally applicable to other crossover situations. For example, an acute care hospital may meet the requirements to be paid as a rehabilitation hospital (under IRF PPS) and there could be rehabilitation patients who were admitted to the acute care hospital who were not discharged from the hospital until after the facility was designated as an IRF. However, at this time, we are not making a change to the existing payment policy in situations other than the LTCH crossover patient. We have only addressed the LTCH crossover patient since, based on the statutory and regulatory qualifying criteria, every LTCH must first be certified as a hospital before it can meet the LTCH criteria. Therefore, it is inevitable that there will be crossover patients in the newly classified LTCH. However, the same is not true for other hospital

certifications. For example, a rehabilitation hospital can be certified as an IRF, without first being certified and paid as an acute care hospital for inpatient services. However, we intend to revisit the existing crossover patient policy as it affects other crossover situations in the future and would welcome receiving the industry's views on how Medicare payment policy should address those situations.

Accordingly, we are finalizing our proposed revisions to § 412.2(b) of the regulations to add a new paragraph (3) which would be applicable to acute care hospitals, and to add a new paragraph (e) to § 412.521 which would be applicable to LTCHs. The additions will specify that Medicare would make only one payment for a crossover patient to the LTCH that is discharging the patient based on the entire stay, both prior to the change to LTCH status and after the change. In order to implement the final policy, we will create systems adjustments that will enable the single claim generated by the discharging provider to include patient days under the initial provider number. We note that our final provisions to define and pay for crossover patient stays as one episode of care based on the PPS of the discharging provider are consistent with existing regulations. (Existing regulations have established that payment under the per discharge PPS constitutes "payment-in-full" for acute care hospitals and for LTCHs.

Comment: The commenters agreed that hospitals should not be receiving two payments for crossover patients, and stated that our proposed change in policy to pay for only one stay appears reasonable. Moreover, they suggested that we consider applying this policy to all conversions, including acute care to rehabilitation, rehabilitation to LTCH, and LTCH to rehabilitation so that payment rules could be consistent with those presented in this final rule.

Response: We appreciate the commenters' support of our policy change to allow only one payment in crossover situations. As we stated above, we believe this policy could be equally applicable in other crossover situations, and will be revisiting the crossover policy as it affects other similar situations in the future.

Therefore, we are proposing to finalize our proposal without modification.

C. Geographic Reclassifications—Definitions of Urban and Rural Areas (§ 412.63(b), § 412.64(b), and 412.102)

1. Revised MSAs

As we discussed in section III.B. and III.G. of the May 18, 2004 proposed rule and of this final rule, we proposed how we would implement OMB's revised standards for defining MSAs and our plan to use the New England MSAs established by OMB. These proposals relate to our policies in established regulations under § 412.63(b) governing geographic classification of hospitals for purposes of the wage index and the standardized amounts in determining the Federal rates for inpatient operating costs. In this section, we define the geographic areas for purposes of reclassification of hospitals. Therefore, consistent with our proposed changes to reflect the new definitions of CBSAs based on the Census 2000 data, effective for discharges occurring on or after October 1, 2004, in the May 18, 2004 proposed rule (69 FR 28277), we proposed to revise § 412.63(b) and add a new § 412.64(b) to reflect the existing geographic classification definitions.

We note that commenters did not express objections to this specific proposal. However, commenters expressed concern regarding various aspects of our proposal to adopt the new definition of CBSAs. We address these comments throughout this final rule.

2. Transition Period for DSH Payments to Redesignated Hospitals

Section 412.102 of the regulations provides for a 3-year transition to the standardized amount and DSH adjustment payments to a hospital redesignation from urban to rural.

Comment: One commenter asked CMS to clarify whether the transition period that allows urban hospitals reclassified as rural to maintain their assignment to the MSA where they are currently located for 3 years applies to both the wage index and the DSH payment adjustment.

Response: As described in § 412.102, in the first year after a hospital loses urban status, the hospital will receive an additional payment that equals two-thirds of the difference between the urban DSH payments applicable to the hospital before its designation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an additional payment that equals one-third of the difference between the urban DSH payment applicable to the hospital

before its redesignation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural.

D. Equalization of Urban and Rural Standardized Amounts (§ 412.63(c) and § 412.64)

Sections 1886(d)(2)(D) and (d)(3) of the Act previously required the Secretary to compute two average standardized amounts for discharges occurring in a fiscal year: one for hospitals located in large urban areas and one for hospitals located in other areas. In addition, under sections 1886(d)(9)(B)(iii) and (d)(9)(C)(i) of the Act, the average standardized amount per discharge was determined for hospitals located in large urban and other areas in Puerto Rico. In accordance with section 1886(b)(3)(B)(i) of the Act, prior to April 1, 2003, the large urban average standardized amount was 1.6 percent higher than the other area average standardized amount. The two standardized amounts are currently equal, as discussed in the following paragraphs.

Section 402(b) of Public Law 108–7 required that, effective for discharges occurring on or after April 1, 2003, and before October 1, 2003, the Federal rate for all IPPS hospitals would be based on the large urban standardized amount. Subsequently, Public Law 108–89 extended section 402(b) of Public Law 108–7 to discharges occurring on or after October 1, 2003, and before April 1, 2004. Finally, section 401(a) of Public Law 108–173 required that, beginning with FY 2004 and thereafter, an equal standardized amount is to be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. This provision in effect makes permanent the equalization of the standardized amounts at the level of the previous standardized amount for large urban hospitals. Section 401(c) also equalizes the Puerto Rico-specific urban and other area rates.

Accordingly, in the May 18, 2004 proposed rule (69 FR 28277) and in this final rule, we are providing for a single national standardized amount and a single Puerto Rico standardized amount for FY 2005 and thereafter, as discussed in detail in the Addendum to this final rule. We are revising existing § 412.63 that includes the provisions related to computation of the standardized amount to make it applicable to fiscal years through FY 2004 and establishing a new § 412.64 that will include the provisions applicable to the single national standardized amount applicable for FY 2005 and subsequent

years. Similarly, we are revising existing § 412.210 for Puerto Rico to make it applicable to fiscal years through FY 2004 and adding a new § 412.211 for FY 2005 and subsequent years for the Puerto Rico standardized amount. We are also making conforming changes to various other sections of the regulations to reflect the single standardized amount for the States and for Puerto Rico.

The comments received in response to this specific proposal concurred with the proposal on the basis that it is consistent with the implementation of recent legislative changes.

E. Reporting of Hospital Quality Data for Annual Hospital Payment Update (§ 412.64(d))

1. Background

Section 501(b) of Public Law 108–173 amended section 1886(b)(3)(B) of the Act to add a new subclause (vii) to revise the mechanism used to update the standardized amount for payment for inpatient hospital operating costs. Specifically, the amendment provides that the update percentage increase (also known as the market basket update) for each of FYs 2005 through 2007 will be reduced by 0.4 percentage points for any “subsection (d) hospital” that does not submit data on a set of 10 quality indicators established by the Secretary as of November 1, 2003. (The statutory reference to a “subsection (d) hospital” restricts the application of this provision to hospitals paid under the IPPS. Therefore, the provision does not apply to hospitals and hospital units excluded from the IPPS, nor to payments to hospitals under other systems such as the outpatient hospital PPS.) The statute also provides that any reduction will apply only to the fiscal year involved, and will not be taken into account in computing the applicable percentage increase for a subsequent fiscal year. This measure establishes an incentive for IPPS hospitals to submit data on the quality measures established by the Secretary.

In the May 18, 2004 proposed rule (69 FR 28277), we proposed to implement the provisions of section 501(b) as described at the CMS Web site: <http://www.cms.hhs.gov/quality/hospital>.

At a press conference on December 12, 2002, the Secretary of HHS announced a series of steps that HHS and its collaborators are taking for public reporting of hospital quality information. These collaborators include the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, the Joint Commission

on Accreditation of Healthcare Organizations (JCAHO), the National Quality Forum, the American Medical Association, the Consumer-Purchaser Disclosure Project, the American Association of Retired Persons, the American Federation of Labor-Congress of Industrial Organizations and the Agency for Healthcare Research and Quality, as well as CMS, QIOs, and others.

CMS began the public reporting initiative in July 2003 with a professional Web site that provides data intended for health care professionals. The professional Web site will be followed by a consumer Web site. The information on the consumer Web site will include the data from the professional Web site but in an easy-to-use format for consumers. It is intended to be an important tool for individuals to use in making decisions about their health care coverage. This information will assist beneficiaries by providing comparison information for consumers who need to select a hospital. It will also serve as a way of encouraging hospitals to adopt quality improvement strategies.

The 10 measures that were employed in this voluntary initiative as of November 1, 2003, are:

- Heart Attack (Acute Myocardial Infarction)
 - Was aspirin given to the patient upon arrival to the hospital?
 - Was aspirin prescribed when the patient was discharged?
 - Was a beta-blocker given to the patient upon arrival to the hospital?
 - Was a beta-blocker prescribed when the patient was discharged?
 - Was an ACE inhibitor given for the patient with heart failure?
 - Heart Failure
 - Did the patient get an assessment of his or her heart function?
 - Was an ACE inhibitor given to the patient?
 - Pneumonia
 - Was an antibiotic given to the patient in a timely way?
 - Had a patient received a pneumococcal vaccination?
 - Was the patient's oxygen level assessed?

These measures have been endorsed by the National Quality Forum (NQF) and are a subset of the same measures currently collected for the JCAHO by its accredited hospitals. Many hospitals are currently participating in the Department's National Voluntary Hospital Reporting Initiative (NVHRI) and are already submitting data to the QIO Clinical Warehouse. The Secretary adopted collection of data on these 10 quality measures in order to: (1) Provide

useful and valid information about hospital quality to the public; (2) provide hospitals a sense of predictability about public reporting expectations; (3) begin to standardize data and data collection mechanisms; and (4) foster hospital quality improvement.

2. Requirements for Hospital Reporting of Quality Data

For the hospital reporting initiative for the Medicare annual payment update provided for under section 501(b) of Public Law 108–173, we will be collecting data on the 10 clinical measures for all patients. We refer to this program as the Reporting Hospital Quality Data for the Annual Payment Update (RHQDAPU) program to distinguish it from the continuing NVHRI.

The procedures for participating in the RHQDAPU can be found on the QualityNet Exchange at the Web site: <http://www.qnetexchange.org> in the “Reporting Hospital Quality Data for Annual Payment Update Reference Checklist.” This checklist also contains all of the forms to be completed by hospitals participating in the program. In order to participate in the RHQDAPU, hospitals must follow the following steps:

- The hospital must identify a QualityNet Exchange administrator who follows the registration process and submits the information through the QIO. This must be done, regardless of whether the hospital uses a vendor for transmission of data.
- All participants must first register with the QualityNet Exchange, regardless of the method used for data submission. If a hospital is currently participating in the voluntary reporting initiative, re-registration on the QualityNet Exchange is unnecessary. However, registration includes completion of the RHQDAPU Notice of Participation form. All hospitals must send the RHQDAPU form to their QIOs no later than August 1, 2004, for the FY 2005 update.
- The hospital must collect data for all 10 measures and submit the data to the QIO Clinical Warehouse either using the CMS Abstraction & Reporting Tool (CART), the JCAHO Oryx Core Measures Performance Measurement System (PMS), or another third-party vendor who has met the measurement specification requirements for data transmission to the QualityNet Exchange. The QIO Clinical Warehouse will submit the data to CMS on behalf of the hospitals. The submission will be done through QualityNet Exchange, which is a secure site that voluntarily

meets or exceeds all current Health Insurance Portability and Accountability Act (HIPAA) requirements, while maintaining QIO confidentiality as required by law. The information in the Clinical Warehouse is considered QIO data, and therefore, is subject to the stringent confidentiality regulations in 42 CFR Part 480.

Hospitals must begin the submission of data under the provisions of section 1886(b)(3)(B)(vii)(II) of the Act, as added by section 501(b) of Public Law 108-173, by July 1, 2004. Because section 501(b) of Public Law 108-173 grants a 30-day grace period for submission of data with respect to FY 2005, in the May 18, 2004 proposed rule, we proposed to allow hospitals until August 1, 2004, for completed submissions to be successfully accepted into the QIO Clinical Warehouse. Hospitals would be required to submit data for the first calendar quarter of 2004 discharges in order to meet the requirements for the FY 2005 payment update. Hospitals participating in the NVHRI that submitted the required 10 measures for the fourth calendar quarter of 2003 by the CMS-established deadline of May 15, 2004, and that met the registration requirements for the market basket update, would be given until August 15, 2004, to submit data for the first calendar quarter of 2004. There will be no chart-audit validation criteria in place for the FY 2005 payment update beyond the CART edits, currently in force, applied to data entering the QIO Clinical Warehouse. In addition, we proposed that we would estimate the minimum number of discharges anticipated to be submitted by a hospital using Medicare administrative data. We proposed to use this anticipated minimum number to establish our expectations of the number of cases for each hospital. Hospitals that do not treat a condition or have very few discharges would not be penalized and would receive the full annual payment update if they submit all the data they do possess. New hospitals should begin collecting and reporting data immediately and complete the registration requirements for the market basket update. The same standards that are applied to established hospitals would be applied to new hospitals when determining the expected number of discharges for the calendar quarters covered for each fiscal year.

In the May 18, 2004 proposed rule, we stated that the annual payment updates would be based on the successful submission of data to CMS via the QIO Clinical Warehouse by the established deadlines. Hospitals may withdraw from RHQDAPU at any time up to

August 1, 2004. Hospitals withdrawing from the program would not receive the full market basket update. Instead, they would receive a 0.4 percentage points reduction in the update. By law, a hospital's actions each fiscal year will not affect its update in a subsequent fiscal year. Therefore, a hospital must meet the requirements for RHQDAPU each fiscal year the program is in effect, and failure to receive the full update in one fiscal year will not affect its update in a succeeding fiscal year.

Comment: All of the commenters who addressed our proposed plans to implement section 501(b) of Public Law 108-173 supported hospitals providing quality performance data. Most of the commenters also mentioned that it was important for CMS and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to align their respective quality measures and procedures to make collection and submission of this data as easy as possible.

Response: We are working with the JCAHO to accomplish this alignment on the current quality measures. We are also setting up a process to align any and all future measures that may be required by either organization. In addition, we have taken the necessary steps to ensure that this alignment is reflected in our chart audit validation process. We are committed to making the submission of the quality measures as seamless as possible for submitting either the core measures defined by JCAHO or the quality measures contained in the CMS Abstraction and Reporting Tool (CART).

Comment: Many of the comments expressed concerns about the proposed chart audit validation procedures.

Response: We believe that all of the data to be collected by CMS in its Clinical Warehouse must be timely, complete, and accurate. To accomplish this, we proposed reabstraction of data submitted to the Warehouse using the Clinical Data Abstraction Contractors (CDAC). The CDAC will request paper charts from each hospital that has submitted data to the warehouse and reabstract the quality measures using the CMS CART. Based upon the percent agreement rate at the element level (that is, the variables abstracted from the chart and used to construct each measure), hospitals achieving an 80-percent agreement with the CDAC abstraction will be considered as providing valid data. We will randomly sample charts for each hospital each quarter and aggregate across all charts to calculate the percent agreement. Several comments were concerned about our process for requesting copies of the

charts. Under the proposed rules, hospitals are allowed 30 days to provide the charts. A followup request is sent, if necessary, 15 days following the initial request. Charts not received by the 31st day are considered missing and a zero-percent agreement is assigned to that missing chart.

Comment: One commenter asked that we notify the hospital through our QNet Exchange Web site to alert the hospitals that a request for charts has been sent.

Response: We agree that this alert would be helpful and have included this in future enhancements to our processes.

Comment: Several commenters asked that we allow hospitals to submit additional information should the initial results be unfavorable.

Response: At this time, we believe allowing hospitals to submit additional information would create an untenable workload for our contractors. We have approximately 4,000 hospitals submitting data in response to section 501(b) of Public Law 108-173. In addition, we are collecting data from other hospitals that are participating in the NVHRI. We estimate that we will be receiving data from as many as 4,500 hospitals. We also believe it is important to keep the turnaround time for processing the validation records as short as possible. It is important both for our reporting requirements and for the hospitals to receive the validation results as soon as possible. To allow extensions for providing data on a piecemeal basis would extend the process beyond reasonable time limits. The CDAC process for requesting charts has been in place for over 6 years. We have been collecting both quality data and administrative data from all hospitals in the country during that time. We believe our process is functioning well, and we take steps to ensure that the chart requests are properly addressed and sent in a timely manner. We believe that hospitals understand the importance of these requests and will provide the charts in a timely manner.

Comment: Many of the commenters expressed concern about reconciling differences between the hospital abstracted and CDAC abstracted data. Several commenters asked that we allow hospitals to supplement the submitted medical charts during an appeal process.

Response: We have devised an appeal process that allows a hospital to review the validation results with their local QIO. If, after this review, the QIO agrees with the hospital's interpretation, the appeal is forwarded to the CDAC for review and correction, if necessary. We

do not believe we can allow hospitals to supplement the submitted medical charts during this appeal process. The original request asks for the complete chart, and we expect to receive all the information and documentation necessary to support the abstraction of the quality measures. Additional documentation puts the CDAC abstractors at a disadvantage and extends the time to complete the validation process. We understand that human error is possible and this is why we have set the required percent agreement at less than 100 percent.

Comment: Other commenters recommended that the adjudication of any differences noted between the hospital abstraction and the CDAC abstraction should be subject to third party review and verification.

Response: We believe that adopting this recommendation would create a lengthy and complicated process. We also believe that abstraction of the clinical data to calculate the quality measures is a straight-forward process. The information requested by each question in the abstraction tool is either there, as stated, or it is not. These data are not qualitative in their derivation and not subject to human opinion. Also, our stated policy for ensuring that the data in the warehouse meet our requirements for consistency and accuracy is that the CDAC abstraction using the CART tool constitutes the correct data, or gold standard. We have devoted a great deal of resources to ensuring that the CDAC abstraction process is consistent and accurate through our training and internal quality assurance. We consistently achieve inter rater reliability rates approaching 100 percent in the CDAC.

Comment: All of the commenters who addressed the sampling process asked that we reduce the percent agreement from our current 80 percent to at least 60 percent initially and gradually raise the rate to 80 percent.

Response: We do not believe that this is necessary or desirable for two reasons. First, we believe that the 80 percent level is a minimum level of agreement that we can accept at any time. This means that four out of five comparisons are the same. A 60 percent agreement would mean that only three out of five comparisons are the same. We do not believe this level of agreement is acceptable to meet our goal of ensuring submission of timely, complete, and accurate data.

Second, for the FY 2005 annual payment update, we do not have a chart audit validation requirement. We realize that hospitals need time to understand the chart audit validation process and

learn how to provide accurate and reliable data. We also need time to implement and test our procedures to ensure that we meet our goals of timely and accurate submission of data and provide a fair opportunity to hospitals to become familiar with the process. In support of the NVHRI program, we have started the validation process on data submitted to the warehouse beginning with calendar year 2003. We are providing feedback to the participating NVHRI hospitals that have deposited data in the warehouse and have instructed the QIOs to assist hospitals in correcting any issues or problems that are identified. The first data submission requirement for section 501(b) is the first calendar quarter of 2004. We will conduct chart audit validation on these data and provide feedback to all of the hospitals. The results of this first quarter will not affect annual payment update determinations for FY 2005 or subsequent fiscal years. We believe that this test period will provide hospitals the necessary lead time to improve their data abstraction processes and provide them with the opportunity to achieve the necessary 80 percent level of agreement prior to institution of the validation requirement for the annual payment update for FY 2006. By allowing the hospitals a penalty free period to meet the 80 percent level we maintain consistent expectations regarding the submission of accurate data and reduce any confusion that a constantly changing goal might introduce.

Comment: One commenter suggested we modify our assessment of percent agreement to differentiate between transcription errors and errors of omission. This commenter contended that the goal of the validation process is to determine if the standard of care has been met.

Response: We disagree. The goal of the chart audit validation process is to ensure that the hospital is submitting accurate data. In order to calculate quality measures, which are used to determine the standard of care, we need to have complete and accurate data. Errors of omission and transcription errors both contribute to errors in calculation of quality measures. Therefore, we believe it is important to include both errors in calculating the percent agreement. We agree that it is important to differentiate between these errors in order to provide feedback to the hospitals. The process we have in place to provide this feedback gives each hospital the detail abstraction results from the CDAC so that staff may determine the types of errors and take appropriate action.

In support of our goal of obtaining complete, timely and accurate data, the chart audit validation process will be applied to all data submitted to the clinical data warehouse. Several commenters argued that the validation in support of section 501(b) should only apply to the 10 quality measures required to be submitted. While such a restriction would not be in support of our policy on the integrity of the data in the clinical warehouse, we understand that receiving the full annual payment update is only subject to submission of the 10 required measures. To varying degrees, all of the data contained in the clinical warehouse are used to inform different parties on the quality of care delivered to patients. Therefore, we plan to apply the validation results in a two-step process. For purposes of the annual payment update, the validation will be restricted to the 10 measures. For purposes related to publishing data, we will apply the validation results to all of the measures submitted. This second validation will not affect the annual payment update.

Comment: Several commenters made suggestions on the quarterly sample size used to assess the percent agreement. One commenter recommended that we allow hospitals to submit additional records if the hospitals fail the initial validation. A second commenter suggested that we request a larger number of records and allow the hospital to select a subset to forward to the CDAC.

Response: In order to maintain the integrity of the chart audit validation process, the selection of records must be random and independent of the hospital's control to ensure that the records being reviewed are representative of the data submitted by the hospital. We do not believe we can compromise the validity of the audit procedure by giving up control of the cases selected.

Comment: Several commenters suggested that we consider optional standards for small volume hospitals. They contended that small differences in data validation can produce large percent differences that may adversely affect validation rates.

Response: Our plans call for calculating the percent agreement based upon the individual variables abstracted from each chart aggregated across all of the charts abstracted. That is, we will pool the variables to create a denominator and then calculate the percent agreement. This approach creates a percent agreement that is independent of the number of cases a hospital may treat. The problem for small volume hospitals is that they may

not generate enough cases to meet our minimum sample sizes. Our chart audit validation rules would have us then request all of the charts generated by these small volume hospitals and we would, in essence, be evaluating the "universe" of data for these hospitals. In such a case, we would be calculating the actual percent agreement for that hospital, rather than estimating this percent as in a hospital where we have sampled the cases. It is our intent to monitor the demands our processes will have on small volume hospitals and to consider modifications so as to not overburden these hospitals. However, we do believe that Medicare beneficiaries are entitled to the same high level of quality care in all hospitals providing services and that all hospitals should be subject to a similar level of assurance by CMS.

Comment: Several commenters requested that we engage in a series of training programs and briefings to educate the hospitals about the validation process and, in particular, provide information on the variables used in calculating the percent agreement.

Response: We agree that this is an important aspect of this process and we have instructed the QIOs to assist hospitals to understand the results of the chart audit validation as well as begin to educate the hospitals on the process itself. We have published on our QNet Exchange Web site all of the documentation that supports the chart audit validation process, including the list of variables included in our calculations. However, we will continue to explore better ways to educate hospitals, through our QIOs, on all of our processes.

Comment: Several commenters urged us to allow reasonable variation in abstracted data, especially for the variables containing continuous data such as the timing data. One commenter stated that our allowed variances seemed to be arbitrary.

Response: We note that we have published the variation allowed for each of these continuous data variables. Our decisions on how much variation to allow in calculating these timing measures are the result of input from our clinical experts. Each variable was carefully considered in this context. For example, the variation allowed for the pneumonia and surgical infection timing is based on the fact that the measures derived from those values are measured in hours. In contrast, the acute myocardial infarction indicators are measured in minutes so the timing variables need to be more accurate. We will conduct research on this issue as we collect data to test and refine our

theoretical expectations against the empirical data.

Comment: One commenter urged us to streamline and automate our registration and attestation processes so that potential administrative problems do not prevent eligible hospitals from receiving their annual payment update.

Response: We agree that this is an important issue. It is our policy to guard against just such a situation. We will be upgrading our systems, with input from the hospital community, to minimize this potential problem.

Comment: One commenter raised concerns about the accessibility of the clinical warehouse data through our QNet Exchange server. The commenter suggested that other users, such as corporate quality assurance staff employed by a hospital system and not necessarily the specific hospital, as well as staff from JCAHO accredited ORYX vendors should be able to see a hospital's data to assist that hospital in its data collection and reporting and quality assurance activities.

Response: Under current policy, only staff from a specific hospital are allowed to access that hospital's data through a system of user registration and password protections. This is a result of the laws and regulations that govern the data our QIOs maintain in the Clinical Warehouse. Specifically, regulations prohibit QIOs from releasing data that identifies individual hospitals without first notifying the hospitals and allowing a 30-day response period. In principle, we agree with the suggestion that other users, such as corporate quality assurance staff employed by a hospital system and not necessarily the specific hospital, as well as staff from JCAHO accredited ORYX vendors should be able to see a hospital's data (not patient-identified data) to assist that hospital in its data collection and reporting and quality assurance activities. We believe we can resolve the legal issues satisfactorily and we anticipate implementation of mechanisms to allow this type of access in the Fall of 2004.

Comment: Several commenters expressed a concern that the designation of the 10 quality indicators in section 501(b) fixes, by law, measures that in fact are subject to change depending upon medical science and the evolving field of quality measurement. While realizing that CMS cannot change the required data by regulation, the commenters nonetheless believed that some accommodation should be considered for allowing these measures to be modified or changed as the knowledge in the field of quality measurement changes.

Response: We agree that the field of quality measurement is a changing landscape and that, sometimes, accommodations need to be made. However, we would point out that section 501(b) contains a sunset clause for these 10 measures. Submission of the data on the 10 quality measures is only required for FYs 2005, 2006, and 2007 in order for a hospital to receive the full annual payment update. Otherwise, we are required to enforce the law as written.

Comment: Several commenters made note of our attempts to estimate the minimum number of cases that CMS expects from each hospital. They were particularly concerned that this number will not be an accurate representation of the number of cases a hospital may treat.

Response: The estimate of the minimum number of cases that we are providing is based upon the average number of Medicare discharges per quarter found in the administrative data for each hospital over the last 2 years. In contrast, section 501(b) requires that the submitted data include all payers and not just the Medicare beneficiaries. We recognize that this distinction is a shortcoming in our calculation of the minimum number of cases. However, we do not have any data from which to estimate how many non-Medicare patients a hospital treats. Our intent is to monitor the submissions from the hospitals and to update our estimates as we gain experience, taking into account sampling where appropriate.

Comment: One commenter believed it was important that its organization participate in the formulation of quality measures, given the importance attached to these measures.

Response: All of the measures CMS currently collects, as well as those measures collected by the JCAHO, are endorsed by the National Quality Forum (NQF). This organization uses a consensus process to develop quality measures for all health care settings. Its deliberations include all aspects of a quality measure, including current standards of practice, documentation requirements, and the scientific research supporting the measure. Membership is open to all interested parties. These organizations can contact the NQF and participate through this mechanism. The 10 measures are required by statute and have been endorsed by the NQF.

Comment: One commenter was concerned about new hospitals that are not able to meet the registration and reporting requirements simply because they were not in existence during the first quarter of calendar year 2004, but will be operating throughout FY 2005.

Response: We agree that new hospitals should not be disadvantaged by their inability to report data prior to opening. Therefore, we will hold these hospitals harmless with respect to the update. The instructions we have given the QIOs are to have these new hospitals register with QNet Exchange as soon as possible; complete the pledge to participate in the annual payment update; complete the form that tells CMS the hospital has zero discharges for the first quarter of calendar year 2004, and begin submitting the required data as it becomes available in the future.

Comment: Several commenters were concerned about our intent to publish the quality measure data that we receive through section 501(b). These commenters focused on the validation of the published data and on the use of composite hospital level scores, as opposed to individual measures.

Response: We have stated that we intend to use validation results as part of the criteria for publishing the hospital data. This is still our intent. However, we recognize that situations may change and we may have to modify this decision. It is our practice, in this situation, to notify the community should this decision change. As to the use of a composite score at the hospital level, we have not made our final decisions about the format for publishing these data, but we are considering the use of composite scores.

3. Submission of Hospital Data for FYs 2006 and 2007

For FYs 2006 and 2007, we will require hospitals to submit data quarterly, starting August 15, 2004. Eligibility for the full annual payment update will be based on the most recent four quarters of data. These data would be submitted on the same schedule for data transmission currently in force for CART data. That is, data must be submitted to the QIO Clinical warehouse no later than 15 calendar days after the fourth month following the end of the calendar quarter. This schedule is available at <http://www.qnetexchange.org>. We will establish validation requirements for submitted data for FYs 2006 and 2007. Submissions would, at a minimum, need to be accurate, timely, and complete. That is—

- The hospital-submitted data must meet minimum levels of reliability through chart audit re-abstractions over all topics. At the data element level, there must be an 80 percent agreement between the original abstraction and the re-abstraction using the CART tool.
- The submitted data must be on schedule, pass all warehouse edits, and

be successfully accepted into the warehouse.

- Completeness of submitted data will be assessed to ensure the number of submitted cases corresponds to the number of bills submitted by the hospital to CMS.

We are planning to publish the most recent 12 months of discharge data (4 quarters) for all data accepted into the warehouse and passing all validation requirements. For FY 2005, we will publish as much data as we have available. Hospitals will have the opportunity to review the information prior to posting on the CMS Web site. However, there will be no opportunity to withhold the publication of the information. The preview will only be to correct obvious errors. Comments regarding the requirements for the submission of quality data for FY 2006 and FY 2007 are presented above in conjunction with the comments regarding the general requirements for hospital reporting of quality data.

4. Regulation Change

In the May 18, 2004 proposed rule (69 FR 28279), we proposed to establish a new § 412.64(d)(2) to provide that, for FYs 2005, 2006, and 2007, the applicable percentage change is reduced by 0.4 percentage points in the case of any subsection (d) hospital that does not submit data to CMS on the 10 quality indicators established by the Secretary as of November 1, 2003. Any reduction will apply only to the fiscal year involved, and will not be taken into account in computing the applicable percentage increase for a subsequent fiscal year.

Comment: MedPAC reiterated its support of the concept of tying payment to quality performance. MedPAC did question the need to financially reward or penalize hospitals just for submitting data. It also noted that the statute requires hospitals to report on the quality measures that were a part of the NVHRI as of November 2003. MedPAC recommended that the Secretary should have the authority to update the measures on a regular basis, adding or retiring measures as clinical guidelines change or when providers reach high levels of performance in certain areas.

Response: While payment for performance may be an ultimate goal, the current law is specific in tying the annual payment update data to reporting only. We point out that hospitals, as a condition of participation and payment, are required to submit charts of Medicare patients for review upon the request of the program. The failure to do so may result in a denial of payment for that discharge. We

appreciate MedPAC's recommendation that the Secretary should have the authority to update the measures that are reported. As MedPAC's comment implies, adoption of this recommendation would require a statutory change.

Comment: One commenter asked whether the Medicare intermediaries would receive specific instructions about how to implement this differential update for hospitals that do and do not submit quality data.

Response: As we indicated in the proposed rule, we will be modifying our payment software to apply the correct updates to hospitals, depending on whether they submit the requisite data on the 10 quality indicators. The software will automatically provide payment based on the fully updated rate to hospitals that have submitted data on the requisite quality measures.

In this final rule, we are adopting, as final, the new § 412.64(d)(2) as proposed. This new section of the regulations provides that, for FYs 2005, 2006, and 2007, the applicable percentage change is reduced by 0.4 percentage points in the case of any subsection (d) hospital that does not submit data to CMS on the 10 quality indicators established by the Secretary as of November 1, 2003. Any reduction will apply only to the fiscal year involved, and will not be taken into account in computing the applicable percentage increase for a subsequent fiscal year.

We show the different standardized amounts that apply to hospitals that submit the requisite quality data, and to hospitals that do not, in the Addendum to this final rule.

F. Revision of the Labor-Related Share for the Hospital Wage Index (§ 412.64(h))

As discussed in section III. of the preamble of this final rule, section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related. The portion of hospital costs attributable to wages and wage-related costs is referred to as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index. In the past, we have defined the labor-related share for prospective payment

acute care hospitals as the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share for the acute care hospital inpatient prospective payment system has been calculated as the sum of the weights for wages and salaries, fringe benefits, nonmedical professional fees, contract labor, postage, and labor-intensive services. For FY 2004, the labor share of the hospital wage index was established at 71.066 percent.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must use 62 percent as the labor-related share unless application of this percentage “would result in lower payments than would otherwise be made.” However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate “from time to time” the proportion of hospitals’ costs that are “attributable to wages and wage-related costs.” In fact, section 404 of Public Law 108–173 requires the Secretary to develop a frequency for revising the weights used in the hospital market basket, including the labor share, to reflect the most current data more frequently than once every 5 years. Section 404 further requires us to include in the final IPPS rule for FY 2006 an explanation of the reasons for, and options considered, in determining such frequency.

Under section III. of this final rule (and in the May 18, 2004 proposed rule), we discuss our implementation of section 1886(d)(3)(E) of the Act, as amended by section 403, as it applies to the development of the FY 2005 wage index. In this section IV.F. of the preamble, we are incorporating the provisions of section 403 of Public Law 108–173 under a new § 412.64(h). Specifically, we are specifying that CMS will adjust the proportion of the Federal rate for inpatient operating costs that are attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS based on survey data) reflecting the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined by the regulations) of the hospital compared to the national average level of hospital wages and wage-related costs. The wage index will continue to be updated annually. In addition, we are specifying that CMS will determine the proportion of the Federal rate that is attributable to wages and labor-related costs from time to time, employing a methodology that is described in the annual regulation updating the system of payment for

inpatient hospital operating costs. However, CMS will employ 62 percent as the proportion of the rate that is adjusted for the relative level of hospital wages and wage-related costs, unless employing that percentage would result in lower payments for the hospital than employing the proportion determined under the methodology described in the preceding sentence.

We did not receive any public comments on our proposed implementation of section 403 of Public Law 108–173. Therefore, we are adopting as final, the proposed addition of the section 403 provisions in § 412.64(h) of the regulations.

G. Wage Index Adjustment for Commuting Patterns of Hospital Employees (§ 412.64(i))

As discussed in section III.H.3.e. of this final rule (and in the May 18, 2004 proposed rule), section 505 of Public Law 108–173 established new section 1886(d)(13) of the Act. We refer readers to section III.H.3.e for a discussion of this adjustment.

We are incorporating the provisions of section 505 of Public Law 108–173 in the regulations by adding a new § 412.64(i).

To identify “qualifying counties,” we use commuting data compiled by the U.S. Census Bureau based on a special tabulation of Census 2000 journey-to-work data. This information is gathered from responses to the Census long-form (sample) questions on where people worked. The resulting county-of-residence by county-of-work commuter flow file uses 108 Industrial Structure codes, developed by the Bureau of Economic Analysis. We limited the data set to those employees working in the category designated “hospitals.” (BEA code 622000).

In order to be considered a qualifying county, the hospitals in such county must meet the criteria listed § 412.64(i). First, the difference between the county’s wage index and the weighted wage index of the surrounding higher wage index areas to which hospital workers commute must be greater than zero. Thus, any increase in the wage index resulting from this provision that is greater than zero percent would be recognized for meeting this criterion. Second, the county must meet the minimum out-migration threshold of 10 percent (the minimum out-migration percentage permitted by statute). Third, the average hourly wage of the hospitals located in the county must equal or exceed the wage index of the labor market area in which the county is located.

As stated in section III.H.3.e. of this preamble, for this third criterion, we will use the average of hospitals’ 3-year average hourly wage for all hospitals in a given county. We compared this county average hourly wage to the 3-year average hourly wage for the labor market area where the county is located. We are using the 3-year average hourly wage because we believe it gives a better estimate for the wages paid by a given hospital over a period of time.

In addition, as stated in section III.H.3.e of this preamble that we will apply the out-migration adjustment in an automatic manner. All hospitals located in qualifying counties will automatically receive the increase in wage index, unless the hospital has already been reclassified to another geographic area, including reclassifications under section 508 of Public Law 108–173. If a hospital has been redesignated under section 1886(d)(8)(B) of the Act, reclassified under section 1886(d)(10) of the Act, or reclassified under section 508 of Public Law 108–173, we assume that the hospital wishes to remain reclassified/re-designated and does not want to receive the out-migration adjustment. This wage index increase will be effective for a period of 3 fiscal years, FY 2005 through FY 2007.

Hospitals receiving this wage index increase under section 1886(d)(13)(F) of the Act are not eligible for reclassification under section 1886(d)(8)(B) or section 1886(d)(10) of the Act, or under section 508 of Public Law 108–173. Therefore, in the proposed rule, consistent with § 412.273, we stated that hospitals that were reclassified by the MGCRRB were permitted to terminate their reclassifications or redesignations within 45 days of the publication of the proposed rule in the **Federal Register** (that is, by July 2, 2004).

In this final rule, we have allowed for a one time rule for FY 2005 that would allow hospitals a 30-day period after publication of this final rule when they can decide if they would rather take advantage of their redesignation/reclassification or the out-migration adjustment. Hospitals will have 30 days after the publication of this rule in the **Federal Register** to either— (1) submit to us a request to terminate their reclassifications under section 1886(d)(10) of the Act (or under section 508 of Public Law 108–173) or redesignated status under section 1886(d)(8)(B) of the Act and receive the out-migration adjustment instead; or (2) reactivate a hospital’s reclassification/re-designation if a hospital withdrew its reclassification/re-designation within 45

days of publication of the May 18, 2004 proposed rule. (Only one hospital requested waiver of its redesignation.) If we do not receive a request for termination or reactivation within this 30-day period, we will assume that hospitals that have been redesignated under section 1886(d)(8)(B) of the Act or reclassified under section 1886(d)(10) of the Act or under section 508 of Public Law 108–173 would prefer to keep their redesignation/reclassification. In addition, if within 30 days of publication of this final rule, we do not receive a request from the one hospital that withdrew its redesignation to reactivate such redesignation, we will assume that the hospital wishes to receive the out-migration adjustment. Finally, we wish to clarify that (except for the one hospital that has already withdrawn its redesignation) hospitals that wish to retain their redesignation/reclassification (instead of receiving the out-migration adjustment) for FY 2005 did not and do not have to submit a formal request to CMS, and will automatically retain their reclassification/redesignation status for FY 2005.

H. Additional Payments for New Medical Services and Technology: Policy Changes (§§ 412.87 and 412.88)

As discussed in section II.D. of the preamble of this final rule (and in the preamble of the May 18, 2004 proposed rule), sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies under the IPPS, effective for discharges beginning on or after October 1, 2001. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that the process must apply to a new medical service or technology if, “based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.” Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered “new” if it meets criteria established by the Secretary after notice and opportunity for public comment.

Sections 1886(d)(5)(K)(ii) through (d)(5)(K)(vi) of the Act further provide—

- For an additional payment for new medical services and technology in an amount beyond the DRG prospective payment system payment rate that adequately reflects the estimated average costs of the service or technology.

- That the requirement for an additional payment for a new service or technology may be satisfied by means of

a new technology group (described in section 1886(d)(5)(L) of the Act), an add-on payment, a payment adjustment, or any other similar mechanism for increasing the amount otherwise payable with respect to a discharge.

- For the collection of data relating to the cost of a new medical service or technology for not less than 2 years and no more than 3 years after an appropriate inpatient hospital services code is issued. The statute further provides that discharges involving new services or technology that occur after the collection of these data will be classified within a new or existing DRG group with a weighting factor derived from cost data collected for discharges occurring during such period.

Section 412.87(b)(1) of our existing regulations provides that a new technology will be an appropriate candidate for an additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries (see the September 7, 2001 final rule (66 FR 46902)). Section 412.87(b)(3) provides that, to receive special payment treatment, new technologies meeting this clinical definition must be demonstrated to be inadequately paid otherwise under the DRG system.

In the August 1, 2003 final IPPS rule, we revised the threshold amount for determining if payment for a new technology or medical service is inadequate, effective for FY 2005 and subsequent fiscal years (68 FR 45392). We lowered the previously established threshold of 1 standard deviation to 75 percent of 1 standard deviation (based on the logarithmic values of the charges) beyond the geometric mean standardized charges for all cases in the DRG to which the new technology is assigned (or the case-weighted average of all relevant DRGs, if the new technology occurs in many different DRGs), transformed back to charges.

Section 503(b) of Public Law 108–173 amended section 1886(d)(5)(K)(ii)(I) of the Act to specify that in determining whether payments for a new technology or medical service are inadequate, the Secretary is to determine and apply a threshold amount that is the “lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of 1 standard deviation for the DRG involved.” As a result of enactment of section 503(b), as we proposed in the May 18, 2004 proposed rule, we are revising our regulations at § 412.87(b)(3) to incorporate the revised threshold amount.

The report language accompanying section 533 of Public Law 106–554 indicated Congressional intent that the Secretary implement the new mechanism on a budget neutral basis (H.R. Conf. Rep. No. 106–1033, 106th Cong., 2nd Sess., at 897 (2000)). Section 1886(d)(4)(C)(iii) of the Act requires that the adjustments to annual DRG classifications and relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. Therefore, in the past, we accounted for projected payments under the new medical service and technology provision during the upcoming fiscal year at the same time we estimated the payment effect of changes to the DRG classifications and recalibration. The impact of additional payments under this provision was then included in the budget neutrality factor, which was applied to the standardized amounts and the hospital-specific amounts.

To balance appropriately the Congressional intent to increase Medicare payments for eligible new technologies with concern that the total size of those payments not result in significantly reduced payments for other cases, we set a target limit for estimated add-on payments for new technology under the provisions of sections 1886(d)(5)(K) and (L) of the Act at 1.0 percent of estimated total operating prospective payments. In accordance with § 412.88(c) of the regulations, if the target limit was exceeded, we would reduce the level of payments for approved technologies across the board, to ensure estimated payments did not exceed the limit.

Section 503(d)(1) of Public Law 108–173 amended section 1886(d)(5)(K)(ii)(III) of the Act to remove the budget neutrality provision for add-on payments for a new medical service or technology. Section 503(d)(2) specifies that “There shall be no reduction or other adjustment to payments under section 1886 of the Social Security Act because an additional payment is provided” for new technology. Accordingly, as a result of the enactment of section 503(d) of Public Law 108–173, we will no longer include the impact of additional payments for new medical services and technologies in the budget neutrality factor. In addition, as we proposed in the May 18, 2004 proposed rule, we are deleting § 412.88(c) of the regulations. All the comments that we received on add-on payments for new technologies are addressed in section II.E. of the preamble to this final rule.

I. Rural Referral Centers (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center. For discharges occurring before October 1, 1994, rural referral centers received the benefit of payment based on the other urban standardized amount rather than the rural standardized amount. Although the other urban and rural standardized amounts are the same for discharges occurring on or after October 1, 1994, rural referral centers continue to receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108-173 raised the DSH adjustment for other rural hospitals with less than 500 beds and rural referral centers. Other rural hospitals with less than 500 beds are subject to a 12-percent cap on DSH payments. Rural referral centers are not subject to the 12.0 percent cap on DSH payments that is applicable to other rural hospitals (with the exception of rural hospitals with 500 or more beds). Rural referral centers are not subject to the proximity criteria when applying for geographic reclassification, and they do not have to meet the requirement that a hospital's average hourly wage must exceed 106 percent of the average hourly wage of the labor market area where the hospital is located.

Section 4202(b) of Public Law 105-33 states, in part, "[a]ny hospital classified as a rural referral center by the Secretary * * * for fiscal year 1991 shall be classified as such a rural referral center for fiscal year 1998 and each subsequent year." In the August 29, 1997 final rule with comment period (62 FR 45999), we also reinstated rural referral center status for all hospitals that lost the status due to triennial review or MGCRB reclassification, but not to hospitals that lost rural referral center status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. However, subsequently, in the August 1, 2000 final rule (65 FR 47089), we indicated

that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as a rural referral center and lost their status due to OMB redesignation of the county in which they are located from rural to urban to be reinstated as a rural referral center. Otherwise, a hospital seeking rural referral center status must satisfy the applicable criteria.

One of the criteria under which a hospital may qualify as a rural referral center is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as a rural referral center if the hospital meets two mandatory prerequisites (a minimum case-mix index and a minimum number of discharges) and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume) (§ 412.96(c)(1) through (c)(5)). (See also the September 30, 1988 **Federal Register** (53 FR 38513)). With respect to the two mandatory prerequisites, a hospital may be classified as a rural referral center if—

- The hospital's case-mix index is at least equal to the lower of the median case-mix index for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median case-mix index for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. (The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.)

1. Case-Mix Index

Section 412.96(c)(1) provides that CMS will establish updated national and regional case-mix index values in each year's annual notice of prospective payment rates for purposes of determining rural referral center status. The methodology we use to determine the proposed national and regional case-mix index values is set forth in

regulations at § 412.96(c)(1)(ii). The proposed national median case-mix index value for FY 2005 includes all urban hospitals nationwide, and the proposed regional values for FY 2005 are the median values of urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals receiving indirect medical education payments as provided in § 412.105). These proposed values are based on discharges occurring during FY 2003 (October 1, 2002 through September 30, 2003) and include bills posted to CMS' records through March 2004.

In the May 18, 2004 proposed rule (69 FR 28281), we proposed that, in addition to meeting other criteria, if they are to qualify for initial rural referral center status for cost reporting periods beginning on or after October 1, 2004, rural hospitals with fewer than 275 beds must have a case-mix index value for FY 2003 that is at least—

- 1.3550; or
- The median case-mix index value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 412.105) calculated by CMS for the census region in which the hospital is located. (See the table set forth in the May 18, 2004 proposed rule at 69 FR 28282.)

Based on the latest data available (FY 2003 bills received through March 2004), in addition to meeting other criteria, hospitals with fewer than 275 beds, if they are to qualify for initial rural referral center status for cost reporting periods beginning on or after October 1, 2004, must have a case-mix index value for FY 2004 that is at least—

- 1.2496; or
- The median case-mix index value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 412.105) calculated by CMS for the census region in which the hospital is located.

The final median case-mix index values by region are set forth in the following table:

Region	Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.2157
2. Middle Atlantic (PA, NJ, NY)	1.2118
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.2365
4. East North Central (IL, IN, MI, OH, WI)	1.1957
5. East South Central (AL, KY, MS, TN)	1.0901
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.0855
7. West South Central (AR, LA, OK, TX)	1.1371
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.1696
9. Pacific (AK, CA, HI, OR, WA)	1.2698

Hospitals seeking to qualify as rural referral centers or those wishing to know how their case-mix index value compares to the criteria should obtain hospital-specific case-mix index values (not transfer-adjusted) from their fiscal intermediaries. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, these case-mix index values are computed based on all Medicare patient discharges subject to DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS will set forth the national and regional numbers of discharges in each year's annual notice of prospective payment rates for purposes of determining rural referral center status.

As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. In the May 18, 2004 proposed rule, we proposed to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2001 (that is, October 1, 2000 through September 30, 2001), which is the latest available cost report data we had at that time. In last year's final rule we inadvertently indicated that we relied upon data regarding discharges occurring during FY 2002. However, we have now determined that our values for FY 2004 were based upon data regarding discharges occurring during FY 2000.

Therefore, in the May 18, 2004 proposed rule (69 FR 28282), we proposed that, in addition to meeting

other criteria, a hospital, if it is to qualify for initial rural referral center status for cost reporting periods beginning on or after October 1, 2004, must have as the number of discharges for its cost reporting period that began during FY 2001 a figure that is at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located. (See the table set forth in the May 18, 2004 proposed rule at 69 FR 28282.)

Based on the latest discharge data available at this time, that is, for cost reporting periods that began during FY 2002, the final median number of discharges for urban hospitals by census region area are as follows:

Region	Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	7,557
2. Middle Atlantic (PA, NJ, NY)	9,466
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	9,602
4. East North Central (IL, IN, MI, OH, WI)	8,323
5. East South Central (AL, KY, MS, TN)	6,986
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	6,576
7. West South Central (AR, LA, OK, TX)	6,307
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	9,367
9. Pacific (AK, CA, HI, OR, WA)	6,954

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, 5,000 discharges is the minimum criterion for all hospitals.

We reiterate that if an osteopathic hospital is to qualify for rural referral center status for cost reporting periods beginning on or after October 1, 2004, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2002.

We note that in section IV.N.3 of this preamble, we discuss public comments that we received on the effects on RRCs of the new geographical area designations for wage index purposes.

J. Additional Payments to Hospitals With High Percentage of End-Stage Renal Disease (ESRD) Discharges (§ 412.104)

Under existing regulations at § 412.104(a), CMS provides for additional Medicare payments to a hospital for inpatient dialysis provided to Medicare beneficiaries with end-stage renal disease (ESRD) if the hospital's ESRD Medicare beneficiary discharges are 10 percent or more of its total Medicare discharges. This provision states that discharges classified into DRG 302 (Kidney Transplant), DRG 316 (Renal Failure), or DRG 317 (Admit for Renal Dialysis) are excluded for purposes of determining a hospital's eligibility for this special payment. We have been informed that, under this provision, hospitals may be counting all discharges of ESRD Medicare beneficiaries towards determining the 10 percent factor rather than counting only those discharges where the ESRD beneficiary received inpatient dialysis.

When we established this regulation in the August 31, 1984 final rule (49 FR 34747), we stated that this special payment was intended to ameliorate those circumstances in which the concentration of ESRD beneficiaries receiving inpatient dialysis may be such that the hospital would not be able to absorb the entire expense with revenue from other less costly cases. We further stated that we believed those few hospitals most extremely impacted by the ESRD beneficiary population should be afforded some protection against the chance of encountering inpatient dialysis expenses that could not be offset by revenue from cases in which the DRG payment was greater than the hospital's cost. Because this special payment is intended to limit the adverse impact on hospitals delivering inpatient dialysis services to ESRD beneficiaries, we firmly believe that only those

discharges of beneficiaries who receive dialysis services during an inpatient stay should be counted in determining a hospital's eligibility for the additional payment. After a careful review of § 412.104(a), we acknowledge that hospitals may require additional guidance in appropriately determining their eligibility for this special payment. Therefore, in the May 18, 2004 proposed rule (69 FR 28282), we proposed to revise § 412.104(a) to make it clear that, in determining a hospital's eligibility for the additional Medicare payment, only discharges involving ESRD Medicare beneficiaries who have received a dialysis treatment during an inpatient hospital stay are to be counted. We indicated that this proposed change would be applied prospectively, effective for cost reporting periods beginning on or after October 1, 2004.

Comment: One commenter requested clarification as to whether the proposed change to § 412.104, which provides for an additional payment to hospitals with a high percentage of ESRD discharges, applies to LTCHs.

Response: The additional payment to hospitals with a high percentage of ESRD discharges provided at § 412.104 is applicable only to short-term, acute care hospitals paid under the IPPS. It does not apply to LTCHs paid under the LTCH PPS.

Comment: Some commenters opposed the proposed revisions to the regulation because they believe this regulation was intended to compensate hospitals for higher costs of treating all ESRD patients, not just those receiving inpatient dialysis treatment.

Response: Section 412.104 specifically provides for an additional payment to a hospital for inpatient dialysis provided to ESRD beneficiaries. This payment is based on the estimated weekly cost of dialysis and the average length of stay of ESRD beneficiaries for the hospital. Therefore, we believe it is entirely consistent with the regulations to provide this additional payment only when dialysis is actually provided during the inpatient stay.

Comment: Several commenters expressed concern that a revision of the regulation would place an undue financial burden on hospitals that treat a significant number of ESRD beneficiaries, and that hospitals may discontinue these services in the future.

Response: Our data indicate that approximately 41 hospitals are currently receiving approximately \$15 million dollars through this add-on payment. While we cannot precisely quantify the impact of this revision, we believe that the impact will be modest because ESRD patients admitted to the hospital will

typically require dialysis during their hospital stay.

Comment: Some commenters believed that, because hospitals and fiscal intermediaries are currently counting all ESRD beneficiaries, the proposed change would lead to confusion. The commenter also indicated that, in the cost report, there is no way to indicate only discharges of ESRD beneficiary who are receiving dialysis.

Response: We do not believe that this policy will create confusion. The cost report instructions will be amended to reflect the policy in the final rule. As we stated earlier, we believe this revision to the regulation will have little effect on additional hospitals with respect to the add-on payment.

Comment: Several commenters expressed concern that the proposed revision would distort the existing formula to compute the add-on payment and would under compensate those hospitals that now treat a large number of African-American patients who seem to be those affected largely by ESRD.

Response: The formula is now based on several factors; the most significant is the cost of inpatient dialysis. We are not revising the formula. Therefore, we do not agree that the revision would distort the formula. Further, we do not believe this revision would adversely affect any specific group of beneficiaries.

Comment: Several commenters expressed concern that CMS did not comply with the Regulatory Flexibility Act (RFA), in proposing this revision.

Response: As we indicated in the proposed rule (69 FR 28807), our impact analysis identified those hospitals currently receiving compensation through the add-on payment, as well as the amount paid to each hospital. Currently, there are approximately 41 hospitals receiving approximately \$15 million. As we stated in the proposed rule, we are unable to quantify the impact more precisely.

Comment: One commenter objected to the exclusion of DRGs 316 and 317 from the add-on payment. The commenter believed the exclusion places an unfair burden on hospitals.

Response: We do not believe that the exclusion of these DRGs is inappropriate, because their weights already include a payment amount for inpatient dialysis.

Comment: One commenter recommended that the add-on payment for inpatients receiving dialysis be updated. Specifically, the commenter recommended that the average weekly cost of dialysis be increased from the current \$335.

Response: Under § 412.104(b)(3), the average cost of dialysis includes only those costs that are determined to be directly related to the dialysis services. These costs include salary, employee health and welfare, drugs, supplies, and laboratory services. We will review these costs and consider the commenter's recommendation to update the average weekly cost of dialysis as part of our next annual IPPS rulemaking.

Comment: One comment referenced correspondence that CMS had written with instructions to include all ESRD beneficiaries when considering the add-on payment.

Response: The correspondence cited reflected our policy at the time the correspondence was issued. However, we have further evaluated that policy and, as we stated in the proposed rule, believe that a revision is necessary to ensure that the add-on payment is made in accordance with the intent of the law.

K. Indirect Medical Education (IME) Adjustment (§ 412.105)

1. IME Adjustment Factor Formula Multipliers (Section 502(a) of Public Law 108–173 and § 412.105(d)(3)(vii) and § 412.105(d)(3)(viii) Through (d)(3)(xii) of the Regulations)

Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals that have residents in an approved graduate medical education (GME) program receive an additional payment to reflect the higher indirect costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment, known as the indirect medical education (IME) adjustment, are located at § 412.105. The IME adjustment is based in part on the applicable IME adjustment factor. The IME adjustment factor is calculated using a hospital's ratio of residents to beds, which is represented as r , and a formula multiplier, which is represented as c , in the following equation: $c \times \{ [1 + r]^{.405} - 1 \}$. The formula is traditionally described in terms of a certain percentage increase in payment for every 10-percent increase in the resident-to-bed ratio.

Section 502(a) of Public Law 108–173 modified the formula multiplier c to be used in the calculation of the IME adjustment. Prior to enactment of Public Law 108–173, the formula multiplier was fixed at 1.35 for discharges occurring during FY 2003 and thereafter. Section 502(a) modifies the formula multiplier beginning midway through FY 2004 and provides for a new

schedule of formula multipliers for FYs 2005 and thereafter as follows:

- For discharges occurring on or after April 1, 2004, and before October 1, 2004, the formula multiplier is 1.47.
- For discharges occurring during FY 2005, the formula multiplier is 1.42.
- For discharges occurring during FY 2006, the formula multiplier is 1.37.
- For discharges occurring during FY 2007, the formula multiplier is 1.32.
- For discharges occurring during FY 2008 and fiscal years thereafter, the formula multiplier is 1.35.

In the May 18, 2004 proposed rule (69 FR 28283), we proposed to revise § 412.105(d)(3)(vii) and add § 412.105(d)(3)(viii) through (d)(3)(xii) to incorporate these changes in the formula multipliers.

Comment: One commenter opposed decreases in the IME adjustment factor. The commenter asserted that hospitals are already being taxed beyond their ability to shoulder the costs of graduate medical education and that further decreases in payment for such costs will threaten important educational programs.

Response: The proposed regulatory changes to the IME adjustment factor are mandated by section 502(a) of Public Law 108–173. We do not have the discretion to change the IME adjustment factor that is mandated by statute. However, the changes to the IME factor provided by section 502(a) of Public Law 108–173 generally constitute increases, not decreases as indicated by the commenter. As stated above, prior to enactment of Public Law 108–173, the formula multiplier was fixed at 1.35 for discharges occurring during FY 2003 and thereafter. Section 502(a) modified the formula multiplier beginning midway through FY 2004 and provided for a new schedule of formula multipliers for FYs 2005 and thereafter, as previously noted.

We are adopting, as final without modification, the proposed revision of § 412.105(d)(3)(vii) and the proposed addition of § 412.105(d)(3)(viii) through (d)(3)(xii) to incorporate changes in the formula multipliers.

2. IME Adjustment Formula Multiplier for Redistributed FTE Resident Slots (Section 422(b)(1)(C) of Public Law 108–173)

Under new section 1886(h)(7)(B) of the Act, added by section 422(a) of Public Law 108–173, a hospital may receive an increase in its FTE resident cap as a result of the agency's redistribution of unused resident positions. (This provision is discussed in detail in section IV.J.2. of the preamble of this final rule.) Section

422(b)(1)(C) of Public Law 108–173 amended section 1886(d)(5)(B) of the Act to add a new subclause (ix) to provide that, for discharges occurring on or after July 1, 2005, for a hospital whose FTE resident cap is increased as a result of a redistribution of unused resident positions, the IME adjustment factor is to be calculated using a formula multiplier of 0.66 with respect to any additional residents counted by the hospital as a result of that increase in the hospital's FTE resident cap. Thus, in the May 18, 2004 proposed rule (69 FR 28283), we proposed that a hospital that counts additional residents as a result of an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act would receive IME payments based on the sum of two different IME adjustment factors: (1) An IME adjustment factor that is calculated using the schedule of formula multipliers described in section IV.G.1. of this preamble established by section 502(a) of Public Law 108–173, and which also uses the hospital's number of FTE residents, not including residents attributable to an FTE cap increase under section 1886(h)(7)(B) of the Act, in the numerator of the resident-to-bed ratio; and (2) an IME adjustment factor that is calculated using the formula multiplier of 0.66, and the additional number of FTE residents that is attributable to the increase in the hospital's FTE resident cap under section 1886(h)(7)(B) of the Act in the numerator of the resident-to-bed ratio. (The number of available beds used in the denominator would be the same for both IME adjustments.)

We note that section 422(b) of Public Law 108–173, which addresses the application of the IME adjustment to the residents counted as a result of an increase in a hospital's FTE resident cap under section 422(a), makes no reference to section 1886(d)(5)(B)(vi) of the Act. That is, the statute does not provide for an exclusion from application of the cap on the resident-to-bed ratio at section 1886(d)(5)(B)(vi)(I) of the Act or from application of the rolling average count at section 1886(d)(5)(B)(vi)(II) of the Act for residents added as a result of FTE cap increases under section 1886(h)(7)(B). There is no specific pronouncement in section 422 exempting residents counted as a result of the FTE resident cap increases under section 422(a) from the cap on the resident-to-bed ratio and the rolling average, and we see no apparent reason to treat those residents differently for purposes of these two provisions. Therefore, in the May 18, 2004 proposed rule, we proposed to require that if a

hospital increases its IME FTE count of residents as a result of section 1886(h)(7)(B) of the Act, those FTE residents are immediately subject to the cap on the resident-to-bed ratio and the rolling average calculation. We explained further that, given potentially significant shifts of FTE positions among hospitals as a result of the new section 1886(h)(7) of the Act, the inclusion of FTE residents added as a result of section 1886(h)(7)(B) of the Act in the cap on the resident-to-bed ratio and in the rolling average introduces a measure of stability and predictability, and mitigates radical shifts in IME payments from period to period. Thus, a hospital's increase in IME payment may be delayed for one year to the extent that the resident-to-bed ratio for the current cost reporting period is capped by the resident-to-bed ratio for the previous cost reporting period. Further, the additional FTE residents would be phased in over a 3-year period in the hospital's FTE count because they are immediately included in the rolling average calculation.

The following illustrates how we proposed to calculate the IME payment for a hospital that receives an increase to its FTE resident cap as a result of section 1886(h)(7)(B) of the Act. For example, Hospital A has a fiscal year end (FYE) of September 30, and a 1996 IME FTE cap of 20 FTEs. During its FYEs September 30, 2003, September 30, 2004, and September 30, 2005, Hospital A trains 25 FTE residents. Effective July 1, 2005, under section 1886(h)(7)(B) of the Act, Hospital A receives an increase to its IME 1996 cap of 5 FTEs, for a total adjusted IME cap of 25 FTEs. Hospital A has maintained an available bed count of 200 beds in FYE September 30, 2004 and throughout FYE September 30, 2005. For the FYE September 30, 2005 cost report, the IME adjustment factor is calculated as follows:

Step 1. For discharges occurring on October 1, 2004, through September 30, 2005 for residents NOT counted pursuant to section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: $20+20+20/3 = 20$.
- Current year resident-to-bed ratio: $20/200 = .10$
- Cap on resident-to-bed ratio (from prior year): $20/200 = .10$
- Compare, and use the lower of, prior year resident-to-bed ratio and current year resident-to-bed ratio: $.10 = .10$.
- Compute IME adjustment factor: $1.42 \times \{[1 + .10]^{.405} - 1\} = 0.0559$.

Step 2. For discharges occurring on July 1, 2005 through September 30, 2005

for residents counted pursuant to section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: $25+20+20/3 = 21.7$.
- Resident-to-bed ratio for 7/1/05–9/30/05: $21.7/200 = .11$
- Cap on resident-to-bed ratio (from prior year): $20/200 = .10$
- Compare, and use the lower of, prior year resident-to-bed ratio and resident-to-bed ratio for 7/1/05–9/30/05: $.10 < .11$. Capped by prior year ratio of $.10$.
- Compute IME adjustment factor: $0.66 \times \{[1 + 0]^{.405} - 1\} = 0.0$.

In this example, the addition of 5 FTE residents under section 1886(h)(7)(B) caused Hospital A's resident-to-bed ratio for discharges occurring on July 1, 2005, through September 30, 2005, to exceed the resident-to-bed ratio of $.10$ from the prior year. Since the multiplier of 0.66 is to be used for determining IME payment "insofar as an additional payment amount * * * is attributable to resident positions redistributed to a hospital * * *" under section 1886(d)(5)(B)(v) of the Act, as amended by section 422(b)(1)(C) of Public Law 108–173, Hospital A does not receive any IME payment attributable to the 5 FTE residents added as a result of section 1886(h)(7)(B) of the Act for discharges occurring on July 1, 2005, through September 30, 2005. As shown under the fifth bullet point in Step 2 of the example above, a resident-to-bed ratio of zero is used to compute the IME adjustment for FTE residents attributable to increases in the FTE resident cap under section 1886(h)(7)(B) of the Act for discharges occurring on or after July 1, 2005 and on or before September 30, 2005. The ratio of $.10$ would not be used to compute the IME adjustment for FTE residents attributable to an increase in the FTE resident cap under section 1886(h)(7)(B) because the ratio of $.10$ is attributable to the 20 FTE residents from the prior year, and is not related to residents added under section 1886(h)(7)(B) of the Act. (We noted that a hospital's resident-to-bed ratio in the current year might decrease despite residents added as a result of section 1886(h)(7)(B) of the Act, due to an increase in the number of available beds in the denominator of the current year resident-to-bed ratio. In such a case, because the current year ratio would be less than the prior year ratio, the hospital's resident-to-bed ratio would not be capped by the prior year resident-to-bed ratio, and, therefore, the hospital could receive an IME payment in the current year (that is, there would not be a 1-year delay) relating to residents added under section 1886(h)(7)(B) of the Act.)

However, an increase in the resident-to-bed ratio in the current period may establish a higher cap for the following period, and, all other things being equal, a hospital could then receive IME payment for FTE residents added as a result of section 1886(h)(7)(B) of the Act after a 1-year lag. In the example above, Hospital A would receive an IME payment for residents added as a result of section 1886(h)(7)(B) of the Act in its cost reporting period ending September 30, 2006, as follows:

Step 1. For residents NOT counted pursuant to section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: $20 + 20 + 20/3 = 20$.
- Current year resident-to-bed ratio: $20/200 = .10$
- Cap on resident-to-bed ratio (from prior year): $20/200 = .10$
- Compare, and use the lower of, prior year resident-to-bed ratio and current year resident-to-bed ratio: $.10 = .10$.
- Compute IME adjustment factor: $1.37 \times \{[1 + .10]^{.405} - 1\} = 0.0559$.

Step 2. For 5 FTE residents counted pursuant to with section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: $25 + 25 + 20/3 = 23.3$.
- Resident-to-bed ratio for FYE 9/30/06: $23.3/200 = .12$
- Cap on resident-to-bed ratio (from prior year): $25/200 = .13$
- Compare, and use the lower of, prior year resident-to-bed ratio and current year resident-to-bed ratio: $.13 > .12$. Current year ratio of $.12$ is the lower of the two.
- Take the difference between the rolling average count of FTE residents counted as a result of section 1886(h)(7)(B) of the Act, and the rolling average count of FTE residents *not* counted as a result of section 1886(h)(7)(B) of the Act, (rolling average count under step 2 minus rolling average count under step 1): $23.3 - 20 = 3.3$.

• Compute current year resident-to-bed ratio attributable to residents added under section 1886(h)(7)(B): $3.3/200 = 0.02$.

- Compute IME adjustment factor: $0.66 \times \{[1 + .02]^{.405} - 1\} = 0.0053$.

Step 3. Compute IME payment for FYE September 30, 2006: [Total DRG payments for discharges occurring on October 1, 2005 through September 30, 2006] \times $[0.0592]$ (that is, $0.0539 + 0.0053$).

In the May 18, 2004 proposed rule, we proposed to revise § 412.105 to incorporate these changes under proposed new paragraph (d)(4), proposed new paragraph (e)(2),

proposed new paragraph (f)(1)(iv)(B), and proposed added new last sentence of paragraph (f)(1)(v).

Comment: One commenter stated that the calculation of the IME payment relating to additional residents counted as a result of an increase in the hospital's FTE cap received under section 1886(h)(7)(B) of the Act is extremely cumbersome and will require difficult and extensive changes to the Medicare cost report, particularly if the additional residents are to be subject to the rolling average and the resident-to-bed ratio. The commenter suggested that instead of revising Worksheet E, Part A to include this calculation, CMS should consider including this calculation on a separate worksheet, with the results added to Worksheet E, Part A.

Response: First, we note that we are required by section 1886(d)(5)(B)(ix) to apply a different IME formula multiplier to calculate the IME payment relating to these residents. Therefore, some level of additional complexity is not avoidable. Additionally, we have stated in previous responses concerning the IME calculation relating to residents counted under section 1886(h)(7)(B) of the Act, under our final policy, we are not requiring that these residents be subject to the rolling average and resident-to-bed ratio calculations. Thus, we believe our final policy substantially reduces the complexity of the proposed calculations that concerned the commenter. Even so, we do realize that the presence of an additional calculation on Worksheet E, Part A for IME (and also on Worksheet E-3, Part IV for direct GME) further complicates an already difficult calculation. We will attempt to revise the worksheets in the simplest and least disruptive manner.

Comment: Several commenters noted that there is a mathematical error on page 28284 of the May 18, 2004 **Federal Register**. The second column on page 28284, in "Step 1", shows an IME computation of: $1.37 \times \{1 - .10\}^{.405} - 1 = 0.0559$. The result of this computation should be .053917, not the .0559 as indicated.

Response: We agree with the commenters that the computed result for "Step 1" of the example is 0.053917, not 0.0559.

Comment: One commenter noted that there appears to be an error on page 28284 of the May 18, 2004 **Federal Register**. On page 28284, third column, in "Step 3", shows an IME adjustment factor computation of: $0.0539 + 0.0053 = .0592$. The commenter believes the adjustment factor should be calculated as $0.0559 + 0.0053 = .0612$ since 0.0559 is the factor calculated in "Step 1" for

residents not counted as a result of cap redistribution.

Response: As noted previously, "Step 1" of the IME adjustment factor calculation (shown in the second column of page 28284) contains an error. The result of "Step 1" should read 0.0539, not the 0.0559 as indicated. With this change, "Step 3" shows the correct IME adjustment factor calculation ($0.0539 + 0.0053 = .0592$).

3. Counting Beds and Patient Days for Purposes of Calculating the IME Adjustment (§ 412.105(b)) and DSH Adjustment (§ 412.106(a)(1)(i))

As stated in section IV.K.1 of the preamble, § 412.105 of our existing regulations specifies that the calculation of the IME adjustment is based on the IME adjustment factor, which is calculated using hospitals' ratios of residents to beds. The determination of the number of beds is based on available bed days. This determination of the number of available beds is also applicable for other purposes, including the level of the disproportionate share hospital (DSH) adjustment payments under § 412.106(a)(1)(i).

In the FY 2004 IPPS proposed rule (68 FR 27201 through 27208, May 19, 2003), we proposed changes to our policy on determining the number of beds and patient days as it pertains to both the IME and DSH adjustments. In the FY 2004 IPPS final rule (68 FR 45415 through 45422), we indicated that, due to the nature and number of public comments we received on the proposed policies regarding unoccupied beds, observation beds for patients ultimately admitted as inpatients, dual-eligible patient days, and Medicare+Choice (M+C) days, we would address the comments in a separate document. In the May 18, 2004 proposed rule, we stated that we planned to respond to comments in this final rule. Under section IV.L.3. of this preamble, we are responding to public comments received on the proposals in the May 19, 2003 and the May 18, 2004 proposed rules as they relate to both the IME and DSH payment adjustments and finalizing our policies in these four areas.

4. Technical Changes

- In § 412.105(a)(1), introductory text, we include a cross-reference to "paragraph (f) and (h)" of § 412.105. Paragraph (h) no longer exists in this section. Therefore, in the May 18, 2004 proposed rule (69 FR 28284), we proposed to remove the cross-reference to paragraph (h).

- In § 412.105(f)(1)(i)(A), we reference national organizations listed in

§ 415.200(a). The cross-reference to § 415.200(a) is incorrect. In the May 18, 2004 proposed rule (69 FR 28284), we proposed to correct the cross-reference to read "§ 415.152."

We did not receive any comments on these two proposals for technical changes and, therefore, are adopting them as final.

- In section IV.O. of the preamble of this final rule (and in the May 18, 2004 proposed rule), we discuss our redesignation of existing § 413.86 governing payments for direct costs of GME to nine separate sections. Many of the paragraphs in the existing § 413.86 are cited in § 412.105 governing the IME adjustment. We proposed to make changes to the cross-reference in § 412.105 to conform them to these redesignated separate sections.

We did not receive any comments on this proposal; and therefore, are adopting this proposal as final.

L. Payment to Disproportionate Share Hospitals (DSHs) (Section 402 of Pub. L. 108-173 and § 412.106 of Existing Regulations)

1. Background

Section 1886(d)(5)(F) of the Act provides for additional payments to subsection (d) hospitals that serve a disproportionate share of low-income patients. The Act specifies two methods for a hospital to qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to indigent patients. These hospitals are commonly known as "Pickle hospitals." The second method, which is also the most commonly used method for a hospital to qualify, is based on a complex statutory formula under which payment adjustments are based on the level of the hospital's DSH patient percentage, which is the sum of two fractions: the "Medicare fraction and the Medicaid fraction." The Medicare fraction is computed by dividing the number of patient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the number of patient days furnished to patients who, for those

days, were eligible for Medicaid but were not entitled to benefits under Medicare Part A by the number of total

hospital patient days in the same period.

$$\text{DSH Patient Percentage} = \frac{\text{Medicare, SSI Days}}{\text{Total Medicare Days}} + \frac{\text{Medicaid, Non-Medicare Days}}{\text{Total Patient Days}}$$

2. Enhanced DSH Adjustment for Rural Hospitals and Urban Hospitals With Fewer Than 100 Beds

Hospitals whose DSH patient percentage exceeds 15 percent are eligible for a DSH payment adjustment (prior to April 1, 2001, the qualifying DSH patient percentage varied, in part, by the number of beds (66 FR 39882)). The DSH payment adjustment may vary based on the DSH patient percentage and the type of hospital. The statute provides for different payment adjustments for urban hospitals with 100 or more beds and rural hospitals with 500 or more beds, hospitals that qualify as RRCs or SCHs, and other hospitals.

Effective April 1, 2004, section 402 of Public Law 108-173 amended section 1886(d)(5)(F) of the Act to revise the formulae used to calculate DSH payment adjustments for certain hospitals that qualify for the adjustments under the second method. Specifically, under the new section 1886(d)(5)(F)(xiv), added by section 402, for hospitals that are not large urban or large rural hospitals, DSH payments are calculated using the same DSH adjustment formula used for large urban hospitals. However, the DSH payment adjustment for most of these categories of hospitals, except for hospitals classified as RRCs, including RRCs that are also SCHs, is capped at 12 percent. In addition, the formula for large urban hospitals with 100 beds or more, and large rural hospitals with 500 beds or more, has not been revised by section 402. Finally, Pickle hospitals are not affected by this change; they will continue to receive a DSH adjustment under the alternative formula.

Effective for discharges occurring on or after April 1, 2004, the following DSH payment adjustment formulae apply for the following specified categories of hospitals:

- For urban hospitals with fewer than 100 beds and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent:

$$\begin{aligned} & \text{(Disproportionate patient percentage} \\ & \text{– 15 percent) (65 percent) + 2.5} \\ & \text{percent.} \\ & \geq 15\% < 20.2\% \quad 2.5\% + [.65 \times (\text{DSH pct.} \\ & \text{– 15\%})] \end{aligned}$$

- For urban hospitals with fewer than 100 beds and whose disproportionate patient percentage is greater than 20.2 percent:

$$\begin{aligned} & \text{(Disproportionate patient percentage} \\ & \text{– 20.2 percent) (82.5 percent) + 5.88} \\ & \text{percent.} \\ & \geq 20.2\% \quad 5.88\% + [.825 \times (\text{DSH pct.} \\ & \text{– 20.2\%})] \end{aligned}$$

For urban hospitals with fewer than 100 beds, the maximum DSH payment adjustment is 12 percent.

- For rural hospitals that are SCHs and are not RRCs and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent:

$$\begin{aligned} & \text{(Disproportionate patient percentage} \\ & \text{– 15 percent) (65 percent) + 2.5} \\ & \text{percent.} \\ & \geq 15\% < 20.2\% \quad (2.5\% + [.65 \times (\text{DSH} \\ & \text{pt.} \% \text{– 15\%})]) \end{aligned}$$

- For rural hospitals that are SCHs and are not RRCs and whose disproportionate patient percentage is greater than 20.2 percent:

$$\begin{aligned} & \text{(Disproportionate patient percentage} \\ & \text{– 20.2 percent) (82.5 percent) + 5.88} \\ & \text{percent.} \\ & \geq 20.2\% \quad 5.88\% + [.825 \times (\text{DSH pct.} \\ & \text{– 20.2\%})] \end{aligned}$$

For rural hospitals that are SCHs and are not RRCs, the maximum DSH payment adjustment is 12 percent.

- For RRCs whose disproportionate patient percentage is greater than or equal to 15 percent and less than or equal to 20.2 percent:

$$\begin{aligned} & \text{(Disproportionate patient percentage} \\ & \text{– 15 percent) (65 percent) + 2.5} \\ & \text{percent.} \\ & \geq 15\% < 20.2\% \quad 2.5\% + [.65 \times (\text{DSH pct.} \\ & \text{– 15\%})] \end{aligned}$$

- For RRCs whose disproportionate patient percentage is greater than 20.2 percent:

$$\begin{aligned} & \text{(Disproportionate patient} \\ & \text{percentage—20.2 percent) (82.5 percent)} \\ & \text{+ 5.88 percent.} \\ & \geq 20.2\% \quad 5.88\% + [.825 \times (\text{DSH pct.} \\ & \text{– 20.2\%})] \end{aligned}$$

For rural referral centers there is no maximum DSH payment adjustment.

- For rural hospitals that are both RRCs and SCHs and whose disproportionate patient percentage is greater than or equal to 15 percent and less than or equal to 20.2 percent:

$$\begin{aligned} & \text{(Disproportionate patient percentage} \\ & \text{– 15 percent) (65 percent) + 2.5} \\ & \text{percent.} \\ & \geq 15\% < 20.2\% \quad 2.5\% + [.65 \times (\text{DSH pct.} \\ & \text{– 15\%})] \end{aligned}$$

- For rural hospitals that are both RRCs and SCHs whose disproportionate patient percentage is greater than 20.2 percent:

$$\begin{aligned} & \text{(Disproportionate patient percentage} \\ & \text{– 20.2 percent) (82.5 percent) + 5.88} \\ & \text{percent.} \\ & \geq 20.2\% \quad 5.88\% + [.825 \times (\text{DSH pct.} \\ & \text{– 20.2\%})] \end{aligned}$$

For rural hospitals that are both RRCs and SCHs there is no maximum DSH payment adjustment.

- For rural hospitals with fewer than 500 beds and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent:

$$\begin{aligned} & \text{(Disproportionate patient percentage} \\ & \text{– 15 percent) (65 percent) + 2.5} \\ & \text{percent.} \\ & \geq 15\% < 20.2\% \quad 2.5\% + [.65 \times (\text{DSH pct.} \\ & \text{– 15\%})] \end{aligned}$$

- For rural hospitals with fewer than 500 beds and whose disproportionate patient percentage is greater than 20.2 percent:

$$\begin{aligned} & \text{(Disproportionate patient percentage} \\ & \text{– 20.2 percent) (82.5 percent) + 5.88} \\ & \text{percent.} \\ & \geq 20.2\% \quad 5.88\% + [.825 \times (\text{DSH pct.} \\ & \text{– 20.2\%})] \end{aligned}$$

For rural hospitals with fewer than 500 beds, the maximum DSH payment adjustment is 12 percent.

These revised formulae, which became effective for discharges occurring on or after April 1, 2004, were implemented through a CMS One-Time Notification (CR 3158), issued on March 26, 2004. The notice describes the changes required by section 402 of Public Law 108-173. In the May 18, 2004 proposed rule (69 FR 28284 through 28286) we described the changes to the DSH adjustment calculations required under section 402 of Public Law 108-173 as well as the required modifications to its regulations to implement section 402 of Public Law 108-173.

The following DSH formulae were not affected by the changes made by section

402 of Public Law 108–173 and remain in effect:

- For urban hospitals with 100 beds or more and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent:

(Disproportionate patient percentage – 15 percent) (65 percent) + 2.5 percent.

$\geq 15\% \leq 20.2\% \quad 2.5\% + [.65 \times (\text{DSH pct.} - 15\%)]$

- For urban hospitals with 100 beds or more and whose disproportionate patient percentage is greater than 20.2 percent:

(Disproportionate patient percentage – 20.2 percent) (82.5 percent) + 5.88 percent.

$\geq 20.2\% \quad 5.88\% + [.825 \times (\text{DSH pct.} - 20.2\%)]$

For urban hospitals with 100 beds or more there is no maximum DSH payment adjustment.

- For rural hospitals with 500 beds or more and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent:

(Disproportionate patient percentage – 15 percent) (65 percent) + 2.5 percent.

$\geq 15\% < 20.2\% \quad 2.5\% + [.65 \times (\text{DSH pct.} - 15\%)]$

- For rural hospitals with 500 beds or more and whose disproportionate patient percentage is greater than 20.2 percent:

[(Disproportionate patient percentage – 20.2 percent) (82.5 percent)] + 5.88 percent.

$\geq 20.2\% \quad 5.88\% + [.825 \times (\text{DSH pct.} - 20.2\%)]$

For rural hospitals with 500 beds or more there is no maximum DSH payment adjustment.

Comment: We received several comments in regard to section 402 of Public Law 108–173. One commenter requested that CMS clarify how the DSH percentage will be computed to implement these provisions for a provider whose year-end period overlaps with the April 1, 2004 date. Another commenter stated that when the DSH policy was developed, consideration was given to the financial condition of the hospitals providing a high level of care to low-income patients, and as a result of that consideration, a cap was placed on the size of DSH payments to rural hospitals. Additionally, the commenters believe that without any publicly articulated policy basis, Congress has called for raising this cap and increasing DSH payments, but only increasing them for

rural hospitals, even though these hospitals are not treating more low-income patients and have not seen their financial condition deteriorate. The commenter believes that urban hospitals are in far worse and declining financial condition, and are to receive comparable benefit.

Response: As we stated in the May 18, 2004 proposed rule (69 FR 28285) hospitals whose DSH patient percentage exceeds 15 percent are eligible for a DSH payment adjustment (prior to April 1, 2001, the qualifying DSH patient percentage varied, in part, by the number of beds (66 FR 39882)). The DSH payment adjustment may vary based on the DSH patient percentage and the type of hospital. The revised formula increases the DSH add-on payment that a hospital receives because the cap has been increased. For example, effective for discharges occurring on or after April 1, 2004, a hospital that is not a large urban hospital that qualifies for a DSH adjustment will receive its DSH payments using the current DSH adjustment formula for large urban hospitals, subject to a limit. The DSH adjustment for these hospitals, except RRCs will be capped at 12 percent instead of the 5.25 percent used prior to discharges occurring before April 1, 2004. We have determined that the revised formulae used to calculate the DSH payment adjustments for certain hospitals will result in making a change in the Medicare cost report. We will make two separate computations of the DSH percentage on the Medicare cost report for discharges occurring before April 1, 2004 and one after April 1, 2004.

In response to the comment regarding rural hospitals receiving a higher cap and DSH payment, as we stated previously, the statute allows a hospital that is not a large urban hospital that qualifies for a DSH adjustment to receive its DSH payments using the current DSH adjustment formula for large urban hospitals, subject to a limit. Like large urban hospitals with 100 beds or more and rural hospitals with 500 beds or more, the revised formula removes the cap for RRCs and SCHs that are also RRCs.

Therefore, in this final rule, we are adopting as final the policy expressed in the May 18, 2004 proposed rule to revise the formulae used to calculate the DSH payment adjustment for certain hospitals that qualify for the adjustments, and amending our regulations at § 412.106 accordingly. This policy is effective for discharges occurring on or after April 1, 2004.

3. Counting Beds and Patient Days for the IME and DSH Adjustments

In the May 19, 2003 IPPS proposed rule for FY 2004 (68 FR 27201), we proposed changes to our policy on counting beds and patient days for the purposes of the DSH and IME adjustments. We proposed changes to the way unoccupied beds are counted. We also proposed to clarify how observation beds and swing-beds are counted, as well as our policy regarding nonacute care (that is, a level of care that would not generally be payable under the IPPS) beds and days. In regard to patient days, we proposed changes to the way observation days, dual-eligible days and M+C days are counted. We recognize that section 101 of Public Law 108–173 changed the title of Medicare+Choice to Medicare Advantage. However, throughout this preamble and our regulations, we are continuing to use the title, Medicare+Choice (M+C). We will make a global change of this reference in a separate regulatory document.

As discussed earlier under section IV.N.1. of this preamble, the IME adjustment provided for under section 1886(d)(5)(B) of the Act applies to prospective payment hospitals that have residents in an approved GME program. These hospitals receive an additional payment to reflect the higher indirect costs of teaching hospitals relative to nonteaching hospitals and the level of the payment varies based in part on the applicable IME adjustment factor. The IME adjustment factor is calculated using a hospital's ratio of residents to beds. As in the May 19, 2003 proposed rule (68 FR 45415), we are combining in this final rule our discussion of changes to the policies for counting beds and patient days in relation to the regulations at §§ 412.105(b) and 412.106(a)(1)(ii) because the underlying concepts are similar, and we believe they generally should be interpreted in a consistent manner for both purposes.

Due to the number and nature of the public comments received on the proposals regarding the counting of available beds and patient days in the May 19, 2003 proposed rule, we did not respond to the public comments on some of the proposals in the final rule for FY 2004 (August 1, 2003 final rule (68 FR 45415)). We indicated in that final rule that we would address public comments regarding unoccupied beds, observation beds, dual-eligible days, and M+C days in a separate document. In the May 18, 2004 proposed rule, we indicated that we planned to address the comments in this IPPS final rule for FY 2005.

a. Provisions of the FY 2004 Proposed Rule, Responses to Public Comments, and Provisions of the FY 2005 Final Rule

In the May 19, 2003, FY 2004 IPPS proposed rule (68 FR 27205), we discussed proposed changes to our policies for counting beds and patient days in relation to the IME and DSH adjustments. Specifically, we proposed to amend § 412.105(b) and § 412.106(a)(1)(ii) as they pertain to the counting of beds and patients days for determination of the IME adjustment and DSH payment adjustment. We proposed to amend § 412.105(b) to indicate that the bed days in a unit that is unoccupied by patients receiving a level of care that would be generally payable under the IPPS (IPPS level of care) for the 3 preceding months are to be excluded from the available bed day count for the current month. In addition, we proposed that the beds in a unit that was occupied by a patient(s) receiving an IPPS level of care during the 3 preceding months should be counted unless they could not be made available for patient occupancy within 24 hours, or they are used to provide outpatient observation services or swing-bed skilled nursing care (68 FR 27204). Regarding nonacute care beds and days, we proposed to revise § 412.105(b) to clarify that beds in units or wards established or used to provide a level of care that is not consistent with what would be payable under the IPPS cannot be counted. We also proposed to revise the DSH regulations at § 412.106(a)(1)(ii) to clarify that the number of patient days includes only those days attributable to patients that receive care in units or wards that furnish a level of care that would generally be payable under the IPPS (68 FR 27205).

In the May 19, 2003 proposed rule, we proposed to revise our regulations to specify our policy that observation and skilled nursing swing-bed days are to be excluded from the counts of both available beds and patient days, unless a patient treated in an observation bed is ultimately admitted, in which case the bed and patient days would be included in those counts.

The final categories of patient days addressed in the proposed rule of May 19, 2003 were the dual-eligible patient days and the Medicare+Choice (M+C) days. We proposed in the rule that the days of patients who are dually-eligible, (that is, Medicare beneficiaries who are also eligible for Medicaid) and have exhausted their Medicare Part A coverage will not be included in the Medicare fraction. Instead, we proposed

that these days should be included in the Medicaid fraction of the DSH calculation. In regard to M+C days, we proposed that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary should not be included in the Medicare fraction of the DSH patient percentage. The patient days should be included in the count of total patient days in the denominator of the Medicaid fraction, and if the M+C beneficiary is also eligible for Medicaid, the patient's days would be included in the numerator of the Medicaid fraction as well.

In the August 1, 2003 final rule (68 FR 45346), we finalized some of these proposals. For the proposals we did not finalize, we indicated that we would address the comments in a separate document. The proposals for nonacute care beds and days, observation and swing-bed days, LDP beds and days, and days for 1115 demonstration projects were finalized in the August 1, 2003 final rule. However, due to the large number of comments we received on our proposals for unoccupied beds, observation beds for patients ultimately admitted as inpatients, dual-eligible patient days, and M+C days, we decided to address the comments on these proposed policies in a separate final document. In this IPPS final rule, we are addressing those comments, as well as some additional comments that we received in response to the May 18, 2004 proposed rule, and finalizing the policies.

As we did in the IPPS proposed rule of May 19, 2003 and the August 1, 2003 IPPS final rule, we are combining our discussion of policies for counting beds and patient days in relation to the calculations at §§ 412.105(b) and 412.106(a)(1) which relate to the IME and DSH payment adjustments, because the underlying concepts are similar, and we believe they should generally be interpreted in a consistent manner for both purposes. Specifically, we clarified that beds and patient days that are counted for these purposes should be limited to beds or patient days in hospital units or wards that would be directly included in determining the allowable costs of inpatient hospital care payable under the IPPS on the Medicare cost reports. As a preliminary matter, beds, and patient days associated with these beds, that are located in units or wards that are excluded from the IPPS (for example, psychiatric or rehabilitation units, or outpatient areas), and thus from the determination of allowable costs of inpatient hospital care under the IPPS on the Medicare cost report, are not to

be counted for purposes of §§ 412.105(b) and 412.106(a)(1)(ii).

The remainder of this discussion pertains to beds and patient days in units or wards that are not excluded from the IPPS and for which costs are included in determining the allowable costs of inpatient hospital care under the IPPS on the Medicare cost report.

As we noted in our FY 2004 proposed and final rules, our policies on counting beds are applied consistently for both IME and DSH although the incentives for hospitals can be different for IME and DSH. For purposes of IME, teaching hospitals have an incentive to minimize their number of available beds in order to increase the resident-to-bed ratio and maximize the IME adjustment. On the other hand, for DSH purposes, urban hospitals with under 100 beds and rural hospitals with under 500 beds may have an incentive to increase their bed count in order to qualify for the higher DSH payments for urban hospitals with over 100 beds or rural hospitals with over 500 beds (although we recognize that, as a result of section 402 of Public Law 108-173, the DSH payment adjustment no longer varies based upon the hospital's number of beds effective for discharges on or after April 1, 2004). However, under section 402 of Public Law 108-173, urban hospitals under 100 beds and rural hospitals under 500 beds are subject to a 12 percent cap on the DSH payment adjustment.

While some of the topics discussed below pertain only to counting available beds (unoccupied beds) and some only to counting patient days (dual-eligible days and Medicare+Choice days), other topics are applicable to both bed-counting and day-counting policies (observation beds and days and swing-beds and days). Therefore, for ease of discussion, we have combined all topics pertaining to counting available beds and patient days together in the following discussion.

We received numerous comments on our May 19, 2003 and May 18, 2004 proposals and our responses and final policies are included in this preamble.

1. Unoccupied Beds

The existing regulations for counting hospital beds for IME and DSH are at § 412.105(b). The bed count is based on total available bed days during the hospital's cost reporting period, divided by the number of days in the cost reporting period. The regulations specify certain types of beds to be excluded from this count (for example, beds or bassinets in the healthy newborn nursery, custodial care beds, and beds in excluded distinct part hospital units).

Further instructions for counting beds are detailed in section 2405.3, Part I, of the Medicare Provider Reimbursement Manual (PRM). That section states that a bed must be permanently maintained for lodging inpatients and it must be available for use and housed in patient rooms or wards. Thus, beds in a completely or partially closed wing of the facility are considered available only if the hospital can put the beds into use when they are needed.

Currently, if a bed can be staffed for inpatient care either by nurses on staff or from a nurse registry within 24 to 48 hours, the unoccupied bed is determined available.⁶ In most cases, it is a straightforward matter to determine whether unoccupied beds can be staffed within this timeframe because they are located in a unit that is otherwise staffed and occupied (an unoccupied bed is available for patient care but it is not occupied by a patient on a particular day). The determination is not as simple in situations where a room in an otherwise occupied unit has been altered for other purposes, such as for a staff lounge or for storage.

Beds in unoccupied rooms or wards are to be excluded from the bed count if the associated costs are excluded from depreciable plant assets because the area is not available for patient use.⁷ However, issues continue to arise with regard to how to treat entire units or even entire floors that are unoccupied over a period of time. For example, in a Provider Reimbursement Review Board (PRRB) decision, the hospital acknowledged that an entire floor was temporarily unoccupied for approximately 2 years. Rooms on the floor were used for office space, storage, and outpatient services. The PRRB held that current rules allowed these beds to be counted. Specifically, the PRRB found the beds could reasonably be made ready for inpatient use within 24 to 48 hours, the rooms were counted on the hospital's cost report as depreciable plant assets available for patient care, and the hospital could adequately provide patient care in the beds using staff nurses or nurses from a nurse registry. Upon review, the Administrator also ultimately upheld this decision based on existing policies and instructions.

We do not believe that an accurate bed count should include beds that are essentially hypothetical in nature; for example, when the beds are on a floor

that is not used for inpatient care throughout the entire cost reporting period (and, indeed, may have been used for other purposes). Followed to the extreme, a hospital could count every bed in its facility, even if it had no intention of ever using a bed for inpatient care, as long as it would be theoretically possible to place an inpatient in the bed. We do not believe such a result would accurately reflect a hospital's capacity to provide inpatient services. Although teaching hospitals have an incentive to minimize the bed count for IME payment purposes, some DSH hospitals have had an incentive to maximize the bed count for the same reason. Our current policy is intended to reflect a hospital's available bed count as accurately as possible, achieving a balance between capturing short-term shifts in occupancy and long-term changes in capacity. Therefore, we believe further clarification and refinement of our policies relating to counting available beds is necessary.

In the FY 2003 IPPS proposed rule published on May 9, 2002 (67 FR 31462), we proposed that, if a hospital's reported bed count results in an occupancy rate (average daily census of patients divided by the number of beds) below 35 percent, the applicable bed count, for purposes of establishing the number of available beds for that hospital, would exclude beds that would result in an average annual occupancy rate below 35 percent. However, at the time the FY 2003 IPPS final rule was published on August 1, 2002 (67 FR 50060), we decided not to proceed with the proposed changes as final and to reconsider the issue as part of a future comprehensive analysis of our bed and patient day counting policies.

In the May 19, 2003 proposed rule, we proposed to determine whether beds in a unit or ward are available based upon whether the unit or ward was used to provide patient care of a level generally payable under the IPPS ("IPPS level of care") at any time during the 3 preceding months, rather than propose to establish a minimum standard occupancy rate. If any of the beds in the unit or ward were used to provide an IPPS level of care at any time during the preceding 3 months, all of the beds in the unit or ward are considered available and are to be counted for purposes of determining available bed days during the current month. (However, individual bed days may be excluded from that count if the bed is used to provide other services such as observation bed or swing-bed service, as discussed below.) If no patient care of a type generally payable under the IPPS

was provided in that unit or ward during the 3 preceding months, the beds in the unit or ward are to be excluded from the determination of available bed days during the current month (proposed §§ 412.105(b)(2) and 412.106(a)(1)(ii)(C)).

Comment: Many commenters objected to our proposals to amend our policy for counting unoccupied beds. Some commenters believed we should not apply an occupancy test, regardless of how long a hospital's beds sit idle. Other commenters believed the proposed 3-month test to show that a unit is unoccupied was unreasonable, and suggested that our policy should recognize small-scale, short-term renovations that take individual rooms out of service for less than 3 months.

A few commenters recommended the threshold for excluding an unoccupied unit should be reduced from 3 months to 1 month. Several commenters requested tangible evidence to support a 3-month threshold for excluding unoccupied beds.

Response: We believe that our proposal to amend our policy for counting unoccupied beds would provide a clear standard for both hospitals and fiscal intermediaries to use to determine whether otherwise unoccupied beds are to be counted. We note that if the required time period for excluding the unoccupied beds were set too low, hospitals could potentially manipulate their available bed count by not admitting any patients to a unit or ward during low occupancy periods, thereby distorting the measure of hospital beds. We believe that, 3 months (one quarter of a hospital's fiscal year), represents a reasonable standard for determining whether beds in a unit or ward are not being used to provide patient care and should be excluded from the hospital's available bed count.

Comment: One commenter stated that we should include the beds in the determination of the available bed count if they are located in an area that is included in the determination of allowable costs on the Medicare cost report. One commenter suggested that a policy that does not recognize such beds for DSH payment purposes because they do not meet an occupancy standard contradicts the recognized allowable nature of the costs associated with those beds. This commenter also requested that we apply the same 24-hour availability standard, regardless of the reason a bed is unoccupied. The commenter expressed the opinion that, whether a bed is associated with an altered patient room or merely a bed in a unit housing unoccupied beds, if the bed can be staffed and readied to house

⁶ This policy was first articulated in correspondence to the Blue Cross and Blue Shield Association (BCBSA) on November 2, 1988, and published in BCBSA's Administrative Bulletin No. 1841, 88.01, on November 18, 1988.

⁷ Ibid.

a patient within a designated period of time, the bed should be counted for DSH payment calculations.

Another commenter stated that if a hospital can demonstrate its intent to remove beds from service, the beds should be excluded from the bed count on the first day they are removed from service without meeting the 3-month waiting period. Other commenters believed the proposal should allow hospitals to exclude specific rooms from the available bed count when the individual rooms are undergoing renovations (as opposed to the entire unit). Some commenters indicated that, instead of clarifying and simplifying our bed counting policy, our proposal would complicate the current policy.

Response: The range of comments on this proposal demonstrates the difficulty in administering our current policy, and the importance of a uniform bed-counting policy for purposes of determining the number of beds for IME and DSH.

We proposed to use a 3-month standard to determine whether beds in a unit or ward should be considered unoccupied and excluded from the count of available beds because we believed it would provide a clear standard for both hospitals and fiscal intermediaries to use to determine whether beds should be counted. We believed 3 months represents a reasonable timeframe to demonstrate whether beds within a unit or ward are or are not being used to provide an IPPS-level of patient care, and to determine whether beds in the unit or ward should be included in the determination of a hospital's available bed count.

We continue to believe that the 3 month standard is appropriate. As noted previously, there are conflicting views among hospitals over whether this timeframe is too long or too short. Some hospitals argue that there should be no limitation on a hospital's ability to count unoccupied beds. Others argue that hospitals should be able to exclude beds on a daily basis as they undertake renovations.

We believe our proposed policies generally provide a balance between these contrasting positions while establishing a clearer standard to follow. We also continue to believe our proposed policies will strike an appropriate balance between capturing short-term shifts in occupancy and reflecting long-term changes in capacity, which will result in a reasonable representation of the hospital's number of available beds. However, based on the comments, we recognize the need for some refinement and further elaboration

upon our proposal. For example, we stated in the proposed rule of May 19, 2003, that the proposed policy to exclude from the count of available beds only the beds in units or wards that were not occupied by a patient receiving an IPPS level of care at any time during the 3 preceding months would be also be applicable to rooms undergoing renovations. However, we understand that many renovations do not involve entire units or wards, but do make individual rooms unavailable for patient care during the course of the renovation. Therefore, we are specifying in this final rule that beds in individual rooms within units or wards that would otherwise be considered occupied and available, but that are actually unavailable due to renovations, will be excluded from the available bed count.

However, in order to avoid day-to-day fluctuations in available beds resulting from minor renovations, and to ensure consistent application of this policy, we continue to believe it is necessary to establish a uniform, minimum time period that a bed must be unavailable before it is excluded. Therefore, in order for any bed within a unit or ward that would otherwise be considered occupied to be excluded because it is unavailable, the bed must remain unavailable for 30 consecutive days. In other words, if an individual bed or group of beds within an otherwise occupied unit or ward could not be made available within a 24-hour period for whatever reason (for example, renovations, use as office space, use for provision of ancillary services) for 30 consecutive days, the beds should be excluded from the hospital's available bed count for those 30 consecutive days. This policy would apply to all situations that would render a bed unavailable, not just to the examples listed above. With respect to our proposal to exclude from the available bed count all of the beds in any unit or ward that is unoccupied for the 3 preceding months, we continue to believe that this is an appropriate standard to establish whether the beds in that unit or ward are available for use by the hospital for an IPPS level of care. At some point, the measure of a hospital's number of available beds must bear a relationship to its patient population. We believe the 3 month timeframe, which requires that the beds in a unit or ward are counted if an IPPS level of care is provided to even one patient every 3 months, is a reasonable threshold that affords a good deal of flexibility to the hospital to maintain as available some beds in low occupancy units or wards.

Comment: One commenter requested that we postpone the proposal to decrease a hospital's total number of beds for purposes of calculating the IME and DSH payments if the hospital's occupancy rate falls below a threshold of 35 percent. Specifically, the commenter requested that we perform further analysis of the bed count methodology and determine the impact on smaller hospitals in rural areas.

Response: In the May 19, 2003 proposed rule, we made reference to the proposed rule published on May 9, 2002 (67 FR 31462) in which we proposed that if a hospital's reported bed count results in an occupancy rate (average daily census of patients divided by the number of beds below 35 percent), we would exclude from beds that would result in an average annual occupancy rate below 35 percent. However, in the August 1, 2002 IPPS final rule (67 FR 50060), we decided not to proceed with the proposed change as final and to reconsider the issue as part of a future comprehensive analysis of our bed and patient day counting policies. In the proposed rule of May 19, 2003 (68 FR 27203), we proposed to determine whether beds in a unit or ward are available based upon whether any bed in the unit or ward was used to provide ("an IPPS level of care") at any time during the 3 preceding months rather than to establish a minimum standard occupancy rate.

Comment: One commenter asked whether if an entire ward has been closed for 4 months, the beds should be excluded only for the fourth month, or whether after the 3-month period has been met, the beds would be excluded from the date that the ward closed.

Response: If any of the beds in a unit or ward were used to provide an IPPS level of care at any time during the preceding 3 months, all of the beds in the unit or ward would be counted for purposes of determining available bed days during the current month. If no IPPS level of care was provided within that unit or ward during the 3 preceding months, the beds in the unit or ward are to be excluded from the count of available bed days during the current month.

In the example given by the commenter, if an entire ward had been used to provide an IPPS level of care during December, but closed for the months of January, February, and March, the beds would be excluded from the available bed count for the month of April. However, the beds would be counted for the months of January through March if a bed in the ward had been used to provide an IPPS level of care in December. If a bed in the

ward is occupied for even a portion of the month of April, all of the beds located in the ward would be considered available for the entire month of May. If no bed in the ward is occupied during the month of April, all of the beds would not be counted in the available bed count for May (because no IPPS level of care was provided in that ward for the months of February, March and April).

Comment: One commenter recommended that we reconsider our proposal to exclude unoccupied beds from the available bed count and rely on the hospital license as the definitive bed count for purposes of determining the applicable bed count.

Response: Our policy is not to rely on the hospital license as the definitive bed count for purposes of determining the applicable bed count. There are several reasons we do not believe it is appropriate to rely on a hospital's license to determine the applicable bed count. Hospitals often are licensed for many more beds than they currently occupy. Using a hospital's number of licensed beds as the measure of available beds would allow hospitals with excess capacity to show a higher number of beds which, could inappropriately allow some hospitals to meet the bed thresholds for DSH payment calculation purposes. We also note that the IME adjustment for teaching hospitals could be reduced significantly, and artificially, by including in a hospital's bed count the number of licensed beds that are not in use. In addition, individual states determine the number of licensed beds for hospitals. There is no consistent method from State to State on the requirements or standards for determining these licensed beds. Lack of a consistent method or standard for establishing the number of licensed beds could unfairly disadvantage hospitals in some states, and benefit hospitals in others; the inconsistency among States in bed-licensing methods or standards makes licensed beds an unreliable representation of a hospital's number of available beds.

Comment: Another commenter stated that, if the provider can document that a space is under evaluation as a future location for health care related services (although perhaps it is now only used for storage), the number of beds associated with these spaces should be considered allowable. If, in a year, the provider has not put beds into service or made the beds available by using them to provide an IPPS level of care, the fiscal intermediary could consider the space as non-allowable, for purposes of determining a hospital's bed count.

Response: The purpose of our policy change is to provide clearer guidance, and to be more consistent in determining which beds should be considered available and included in a hospital's bed count. We believe that allowing hospitals to identify or document that a space is under evaluation as a location for future health care related services, and considering some number of beds associated with the space to be available would add significant vagueness and imprecision to the policy.

In summary, in this final rule, we are revising our regulations at § 412.105(b) and § 412.106(a)(1)(ii) to specify that bed days in a unit that was occupied to provide an IPPS level of care for at least one day during the 3 preceding months are included in the available bed day count for a month. In addition, bed days for any bed within a unit that would otherwise be considered occupied should be excluded from the available bed day count for the current month if the bed has remained unavailable (could not be made available for patient occupancy within 24 hours) for 30 consecutive days, or if the bed is used to provide outpatient observation services or swing-bed skilled nursing care. This policy will be effective for discharges occurring on or after October 1, 2004.

2. Observation Services and Swing-bed Skilled Nursing Services

Observation services are those services furnished by a hospital on the hospital's premises that include use of a bed and periodic monitoring by a hospital's nursing or other staff in order to evaluate an outpatient's condition or to determine the need for a possible admission to the hospital as an inpatient. When a hospital places a patient under observation but has not formally admitted him or her as an inpatient, the patient is initially treated as an outpatient, and the services are reimbursed as outpatient services. Consequently, the observation days are not recognized under the IPPS as part of the inpatient operating costs of the hospital. However, if the patient is subsequently admitted as an inpatient, the observation services are reimbursed as inpatient services.

Observation services may be provided in a distinct outpatient observation bed area, (which is not a routine inpatient acute care unit or ward for which costs are included for purposes of the IPPS), but they may also be provided in a bed located within a routine inpatient care unit or ward. As we mentioned above, the discussion of our policies on counting beds and days in this final rule

pertains to beds and patient days that occur in units or wards that are not excluded from the IPPS and for which costs are included in determining the allowable costs of inpatient hospital care under the IPPS on the Medicare cost report. However, we note that whether the observation services are provided in a separate outpatient observation area or in a bed within an inpatient acute care unit or ward, our general policy is that the days attributable to beds used for observation services are excluded from the counts of available bed days and patient days at (§§ 412.105(b) and 412.106(a)(1)(ii)). This policy was clarified in a memorandum that was sent to all CMS Regional Offices (for distribution to fiscal intermediaries) dated February 27, 1997. This memorandum stated that if a hospital provides observation services in beds that are generally used to provide hospital inpatient services, the days that those beds are used for observation services are to be excluded from the available bed day count (even if the patient is ultimately admitted as an acute inpatient).

A swing-bed is a bed that is available for use to provide acute inpatient care and is also available for use to provide SNF-level care. The requirements for a hospital to be considered a swing-bed hospital are located under existing regulations at § 482.66, and for a swing-bed CAH, under existing regulations at § 485.645. Under existing § 413.114(a)(1), payment for posthospital SNF care furnished in swing-beds is made in accordance with the provisions of the SNF prospective payment system (effective for SNF services furnished in cost reporting periods beginning on and after July 1, 2002). Similar to beds and patient days, associated with observation services, when the swing-bed is used to furnish SNF care⁸ those beds and patient days are excluded from the counts of available bed days and patient days (§§ 412.105(b) and 412.106(a)(1)(ii)).

Observation services and swing-beds skilled nursing services are both special, frequently temporary, alternative uses of acute inpatient care beds. Thus, the days a bed in an (otherwise occupied) acute inpatient care unit or ward is used to provide outpatient observation services are to be deducted from the available bed count under § 412.105(b) and the patient day count under § 412.106(a)(1)(ii). Otherwise, the bed would be considered available for IPPS-level acute care services (as long as it meets the other criteria to be considered available). This same policy applies to

⁸ Ibid.

swing-beds for days the bed is used to provide SNF-level care. The policies to exclude observation days and SNF-level swing-bed days from the count of available bed days and patient days, as described above stem from the fact that although the services are provided in beds that would otherwise be available to provide an IPPS level of services, these days are not payable under the IPPS, except in the case of observation days when the patient is ultimately admitted as an inpatient).

In the proposed rule of May 19, 2003, we proposed to amend our policy with respect to observation days for patients who are ultimately admitted for inpatient acute care. As we noted previously, our current policy is that observation days are excluded from the available bed day and the patient day counts. (This policy was communicated in a memorandum to all CMS Regional Offices on February 27, 1997). Specifically, we proposed that, if a patient is admitted as an acute inpatient subsequent to receiving outpatient observation services, we would include the days associated with the observation services in the available bed day and patient day counts. We proposed this policy because it would be consistent with our policy generally to count beds and days when the costs associated with the beds and days would be considered inpatient operating costs under the IPPS.

In order to avoid any potential future misunderstandings about our policies regarding the exclusion of observation and swing-bed days under the regulations at § 412.105(b) and § 412.106(a)(1)(ii), we proposed to revise our regulations to specify our policy that observation and swing-bed days are to be excluded from the counts of both available beds and patient days, unless a patient, who receives outpatient observation services is ultimately admitted for acute inpatient care, in which case the beds and days would be included in those counts.

Comment: One commenter indicated that the proposed change does not seem unreasonable, although it will require administrative changes for hospitals to count these days as part of their reporting processes. However, the commenter suggested that, if the change is finalized, it should be included in all Medicare calculations of days and length of stay; for example, when determining the length of stay for patients subject to the per diem payment methodology for transfers.

Another commenter pointed out that the costs associated with these days would still be ancillary costs and treated as such on the Medicare cost report.

Thus, it would be necessary to report these days separately from other inpatient routine care days so that the costs can be appropriately allocated.

Some commenters noted that the proposed change would result in Medicare treating these days inconsistently from other payers and, therefore, it would require a significant amount of a hospital's time and resources to track observation patients that ultimately become inpatients. On the other hand, some commenters asserted that this change would result in Medicare's policy becoming consistent with other payers' treatment of observation patient days attributable to patients who are admitted as inpatients.

Response: We recognize the issues raised by the commenters with regard to treating these days consistently for purposes of determining the length of stay in calculating per diem payments and for cost allocation purposes. We have determined that these days are similar to those days for patients who go to the emergency room and are ultimately admitted to the hospitals. Once a patient has been admitted into the hospital, the time and costs they incurred in the emergency room are also included in the inpatient stay. Including observation patients in the available bed and patient day count once they are admitted as inpatients requires making a change in the Medicare cost report. On Worksheet S-3, of CMS Form 2552-96, we will include a line to show observation days for patients subsequently admitted as inpatients and a separate line for observation days for patients not admitted.

Comment: Some commenters objected to the general exclusion of observation bed days from the available bed day count on the grounds that it is a flawed premise that the size of a hospital's bed complement should be impacted by the payment policy classification of the services provided to the patient. That is, the commenter believed a bed should not be excluded from the available bed day count because it is used to provide services not payable under the IPPS on a particular day.

Response: When the application of IPPS payment policy hinges on a determination of a hospital's bed size, it seems reasonable to determine bed size based on the portion of the hospital that generates the costs that those IPPS payments are designed to compensate. In addition, we use available bed days as the basis to determine a hospital's bed count for purposes of the IME adjustment. Therefore, we believe it is appropriate to consider how a bed is used on a given day. For example, if a bed is used for observation services on

a given day, it is not available for inpatient services. As stated above, our bed counting policies start with the premise that the treatment of beds should be generally consistent with the treatment of the patient days and the costs of those days on the Medicare cost report. Therefore, we continue to believe it is appropriate to exclude outpatient observation days, even when the beds used to provide that service are located in an otherwise available routine inpatient care unit or ward.

In determining whether a bed should be considered available, our policy has been to treat the bed in the same manner as we treat the patient days and costs associated with the bed. For example, we include intensive care unit beds in the available bed count because patient days in these units are included in total patient days and the costs are included in the calculation of allowable costs under the IPPS. If a patient is placed for observation in a bed generally used to provide inpatient services, and is then admitted to the hospital, the patient days that occurred before the inpatient admission are included in the inpatient stay, the costs prior to the admission are included in allowable inpatient costs, and the bed days are included in the available bed day count. However, if the patient placed for observation is released from the hospital without being admitted, then the observation days and costs are excluded from the calculation of inpatient days and costs, and the bed days are excluded from the available bed day count.

A change in the Medicare cost report is required in order to include observation days for patients that are subsequently admitted as inpatients in the available bed and patient day counts. Therefore, on Worksheet S-3, of CMS Form 2552-96, we will include a line, to show observation days for patients subsequently admitted as inpatients and a separate line for observation days for patients not admitted. This policy change will be applied to all cost reporting periods beginning on or after October 1, 2004.

In summary, in this final rule we are adopting the proposed changes to § 412.105(b) and § 412.106(a)(1)(ii), which specify that observation and swing-bed days are to be excluded from the counts of both available bed days and patient days unless a patient receiving outpatient observation services in a bed that is generally used to provide hospital inpatient acute care services is ultimately admitted, in which case the beds and days associated with the observation services would be included in those counts. This policy will be effective for cost reporting

periods beginning on or after October 1, 2004.

3. Dual-Eligible Patient Days

As described above, the DSH patient percentage is equal to the sum of the percentage of Medicare inpatient days attributable to patients entitled to both Medicare Part A and SSI benefits, and the percentage of total inpatient days attributable to patients eligible for Medicaid but not entitled to Medicare Part A benefits. If a patient is a Medicare beneficiary who is also eligible for Medicaid, the patient is considered dual-eligible and the patient days are included in the Medicare fraction of the DSH patient percentage but not the Medicaid fraction. This is consistent with the language of section 1886(d)(5)(F)(vi)(II) of the Act, which specifies that patients entitled to benefits under Part A are excluded from the Medicaid fraction.

It has come to our attention that we inadvertently misstated our current policy with regard to the treatment of certain inpatient days for dual-eligibles in the proposed rule of May 19, 2003 (68 FR 27207). In that proposed rule, we indicated that a dual-eligible beneficiary is included in the Medicare fraction even after the patient's Medicare Part A hospital coverage is exhausted. That is, we stated that if a dual-eligible patient is admitted without any Medicare Part A hospital coverage remaining, or the patient exhausts Medicare Part A hospital coverage while an inpatient, the non-covered patient days are counted in the Medicare fraction. This statement was not accurate. Our policy has been that only covered patient days are included in the Medicare fraction (§ 412.106(b)(2)(i)). A notice to this effect was posted on CMS's Web site (<http://www.cms.hhs.gov/providers/hpps/dual.asp>) on July 9, 2004.

Comment: We received numerous comments that commenters were disturbed and confused by our recent Web site posting regarding our policy on dual-eligible patient days. The commenters believed that this posting was a modification or change in our current policy to include patient days of dual-eligible Medicare beneficiaries whose Medicare Part A coverage has expired in the Medicaid fraction of the DSH calculation. In addition, the commenters believed that the information in this notice appeared with no formal notification by CMS and without the opportunity for providers to comment.

Response: The notice that was posted on our Web site was not a change in our current policy. Our current policy is, if a patient is a Medicare beneficiary who

is also eligible for Medicaid, the patient is considered dual-eligible and the patient days are included in the Medicare fraction of the DSH patient percentage but not the Medicaid fraction. This is consistent with the language of section 1886(d)(5)(F)(vi)(II) of the Act, which specifies that patients entitled to benefits under Medicare Part A are excluded from the Medicaid fraction.

The Web site posting is a correction of an inadvertent misstatement made in the May 19, 2003 proposed rule (68 FR 27207). This Web site posting was not a new proposal or policy change. As a result, we do not believe it is necessary to utilize the rule making process in correcting a misstatement that was made in the May 19, 2003 proposed rule regarding this policy.

In the proposed rule of May 19, 2003 (68 FR 27207), we proposed to change our policy to begin to count in the Medicaid fraction of the DSH patient percentage the patient days of dual-eligible Medicare beneficiaries whose Medicare coverage has expired. We note that the statutory provision referenced above stipulates that the Medicaid fraction is to include patients who are eligible for Medicaid. However, the statute also requires that patient days attributable to patients entitled to benefits under Medicare Part A are to be excluded from the Medicaid fraction.

Comment: Numerous commenters opposed our proposal to begin to count in the numerator of the Medicaid fraction of the DSH patient percentage, the patient days of dual-eligible Medicare beneficiaries whose Medicare inpatient coverage has expired. They objected that the proposal would result in a reduction of DSH payments when the exhausted coverage days are removed from the Medicare fraction and included in the Medicaid fraction. According to these commenters, any transfer of a particular patient day from the Medicare fraction (based on total Medicare patient days) to the Medicaid fraction (based on total patient days) would dilute the value of that day and, therefore, reduce the overall patient percentage and the resulting DSH payment adjustment.

One commenter observed that a patient who exhausts coverage for inpatient hospital services still remains entitled to other Medicare Part A benefits. This commenter found it difficult to reconcile the position that these patients are not entitled to Medicare Part A benefits when they can receive other covered Part A services, such as SNF services.

In addition, some commenters stated that these days should not be included

in either the Medicare or Medicaid fraction. They indicated that the days should not be included in the Medicare fraction because that computation includes the number of patient days actually furnished to patients who were entitled to both Medicare Part A and SSI benefits. The commenters stated that the days should also be excluded from the Medicaid fraction because that computation excludes hospital patient days for patients who, for those days, were entitled to benefits under Medicare Part A.

Commenters also indicated that the proposal would put an increased administrative burden on the hospitals to support including these patient days in the Medicaid fraction. They recommended that if we finalize this policy, the requirement that hospitals submit documentation justifying the inclusion of the days in the Medicaid fraction should be removed.

Response: We proposed this change to facilitate consistent handling of these days across all hospitals, in recognition of the reality that, in some States, fiscal intermediaries are reliant upon hospitals to identify days attributable to dual-eligible patients whose Medicare Part A hospitalization benefits have expired. We believe it is important that all IPPS policies be applied consistently for all hospitals around the country.

However, we acknowledge the point raised by the commenter that beneficiaries who have exhausted their Medicare Part A inpatient coverage may still be entitled to other Part A benefits. We also agree with the commenter that including the days in the Medicare fraction has a greater impact on a hospital's DSH patient percentage than including the days in the Medicaid fraction. This is necessarily so because the denominator of the Medicare fraction (total Medicare inpatient days) is smaller than the denominator of the Medicaid fraction (total inpatient days). However, we note that we disagree with the commenter's assertion that including days in the Medicaid fraction instead of the Medicare fraction always results in a reduction in DSH payments. For instance, if a dual-eligible beneficiary has not exhausted Medicare Part A inpatient benefits, and is not entitled to SSI benefits, the patient days for that beneficiary are included in the Medicare fraction, but only in the denominator of the Medicare fraction (because the patient is not entitled to SSI benefits). The inclusion of such patient days in the Medicare fraction has the result of decreasing the Medicare fraction in the DSH patient percentage.

For these reasons, we have decided not to finalize our proposal stated in the May 19, 2003 proposed rule to include dual-eligible beneficiaries who have exhausted their Part A hospital coverage in the Medicaid fraction. Instead, we are adopting a policy to include the days associated with dual-eligible beneficiaries in the Medicare fraction, whether or not the beneficiary has exhausted Medicare Part A hospital coverage. If the patient is entitled to Medicare Part A and SSI, the patient days will be included in both the numerator and denominator of the Medicare fraction. This policy will be effective for discharges occurring on or after October 1, 2004. We are revising our regulations at § 412.106(b)(2)(i) to include the days associated with dual-eligible beneficiaries in the Medicare fraction of the DSH calculation.

4. Medicare+Choice (M+C) Days

Under existing § 422.1, an M+C plan means "health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan." Generally, each M+C plan must provide coverage of all services that are covered by Medicare Part A and Part B (or just Part B if the M+C plan enrollee is only entitled to Part B).

We have received questions whether the patient days associated with patients enrolled in an M+C Plan should be counted in the Medicare fraction or the Medicaid fraction of the DSH patient percentage calculation. The question stems from whether M+C plan enrollees are entitled to benefits under Medicare Part A since M+C plans are administered through Medicare Part C.

We note that, under existing regulations at § 422.50, an individual is eligible to elect an M+C plan if he or she is entitled to Medicare Part A and enrolled in Part B. However, once a beneficiary has elected to join an M+C plan, that beneficiary's benefits are no longer administered under Part A. In the proposed rule of May 19, 2003 (68 FR 27208), we proposed that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary would not be included in the Medicare fraction of the DSH patient percentage. Under our proposal, these patient days would be included in the Medicaid fraction. The patient days of dual-eligible M+C beneficiaries (that is, those also eligible for Medicaid) would be included in the count of total patient days in both the numerator and denominator of the Medicaid fraction.

Comment: Several commenters indicated that they appreciated CMS's attention to this issue in the proposed rule. The commenters also indicated that there has been insufficient guidance on how to handle these days in the DSH calculation. However, several commenters disagreed with excluding these days from the Medicare fraction and pointed out that these patients are just as much Medicare beneficiaries as those beneficiaries in the traditional fee-for-service program.

Response: Although there are differences between the status of these beneficiaries and those in the traditional fee-for-service program, we do agree that once Medicare beneficiaries elect Medicare Part C coverage, they are still, in some sense, entitled to benefits under Medicare Part A. We agree with the commenter that these days should be included in the Medicare fraction of the DSH calculation. Therefore, we are not adopting as final our proposal stated in the May 19, 2003 proposed rule to include the days associated with M+C beneficiaries in the Medicaid fraction. Instead, we are adopting a policy to include the patient days for M+C beneficiaries in the Medicare fraction. As noted previously, if the beneficiary is also an SSI recipient, the patient days will be included in the numerator of the Medicare fraction. We are revising our regulations at § 412.106(b)(2)(i) to include the days associated with M+C beneficiaries in the Medicare fraction of the DSH calculation.

M. Payment Adjustments for Low-Volume Hospitals (§ 412.101)

Section 406 of Public Law 108-173 amended section 1886(d) of the Act to add a new subclause (12) to provide for a new payment adjustment to account for the higher costs per discharge of low-volume hospitals under the IPPS. Section 1886(d)(12)(C)(i) of the Act, as added by section 406, defines a low-volume hospital as a "subsection (d) hospital * * * that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year." Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term "discharge" refers to total discharges, and not merely to Medicare discharges. Specifically, the term refers to the "inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under part A." Finally, the provision requires the Secretary to determine an applicable percentage increase for these low-volume hospitals based on the "empirical relationship" between "the

standardized cost-per-case for such hospitals and the total number of discharges of these hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges." The statute thus mandates the Secretary to develop an empirically justifiable adjustment formula based on the relationship between costs and discharges for these low-volume hospitals. The statute also limits the adjustment to no more than 25 percent.

MedPAC has published an analysis of the financial performance and cost profiles of low-volume hospitals (MedPAC June 2001 Report to Congress, page 66). Its analysis indicated that hospitals with 500 discharges or less generally have negative Medicare margins. Specifically, hospitals with 200 discharges or less have margins of -16.4 percent, and hospitals with 201 to 500 discharges have margins of -2.1 percent. MedPAC's analysis further revealed that hospitals with a small volume of discharges have higher costs per discharge than larger facilities, after controlling for the other cost factors recognized in the payment system. MedPAC's analysis thus indicates that low-volume providers are disadvantaged by payment rates based on average volume. In analyzing the relationship between costs per case and discharges, MedPAC also found that this relationship begins to level off and reaches zero variation at around 500 discharges. Therefore, MedPAC recommended an adjustment formula in the form of:

$$1.25 - (.0005 * D), \text{ if } D < 500 \text{ discharges}$$

Where 1.25 represents the maximum 25-percent add-on, .0005 is the payment adjustment per case (derived by dividing .25 by 500 discharges) and "D" is the number of discharges.

Using FY 2001 cost report data, we found an even larger disparity than MedPAC found between low-volume providers and their higher-volume counterparts. Although Medicare margins remain healthy overall at 9.32 percent, the Medicare margin for providers with 200 or less discharges is -46.26 percent, and the margin for providers with 201 to 500 discharges is -11.74 percent. For the May 18, 2004 proposed rule, we employed a bivariate regression analysis to determine the fit between total hospital discharges and operating costs from FY 2001.

As discussed in the proposed rule, we found a very strong correlation between costs and the total number of discharges. We then examined the variation in cost-per-case among subsection (d) hospitals, using both log

and nonlog functions. When the analysis was limited to hospitals with fewer than 1,000 discharges, we found a strong relationship between cost per case and low volume. We found that the greatest variation from the mean costs per case exists between 1 and 150 discharges, indicating (as MedPAC also found) that hospitals with the lowest case volume generally experience greater costs per case than hospitals with higher volume. However, after about 150 discharges, the trend line begins to level off rapidly. The trend line reaches zero variation from mean cost per case at approximately 450 discharges (cost per case in log form) or 500 discharges (nonlog form). Immediately after that point, the trend line in both forms becomes negative, while still maintaining a very smooth line. Both because of where the trend line crosses zero and because there is very little variation from the mean after this point, we believed that 500 discharges was the appropriate cutoff for an add-on payment under this provision.

Based on these results, we proposed to adopt a slightly revised version of MedPAC's recommended formula for an add-on payment to low-volume hospitals:

$$\text{Adjustment} = 1.25 - (.0005 * D), \text{ if } 0 < D \leq 500 \text{ discharges}$$

Where 1.25 represents the maximum 25 percent add-on, .0005 is the payment adjustment per case (derived by dividing .25 by 500 discharges) and "D" is the number of discharges. We proposed to revise the MedPAC recommended formula by adding the condition that "D>0" in order to avoid the anomalous result that a hospital without any discharges would qualify for the maximum 25-percent adjustment.

However, these proposals were based only on our univariate analysis conducted before publication of the proposed rule. In the proposed rule, we indicated our concerns about whether we had sufficient information (for example, total hospital case-mix) to support valid multivariate analyses. We also noted our plan to conduct more detailed multivariate analyses for the final rule.

We also noted that, under our proposed formula, some hospitals that meet the statutory definition of low-volume hospital would receive no adjustment. Specifically, hospitals with more than 500 but fewer than 800 total discharges for the fiscal year would receive no adjustment under this formula. Despite the statutory definition of a low-volume hospital as a subsection

(d) hospital that has less than 800 discharges during the fiscal year, the statutory provision mandating this adjustment also requires the Secretary to determine the empirical relationship between the standardized cost-per-case, the total number of discharges, and the amount of incremental costs associated with the number of discharges. In addition, the provision requires that the applicable percentage increase shall be "based upon such relationship in a manner that reflects * * * such incremental costs." We believe that the statutory language thus gives the Secretary the flexibility to set the percentage increase at zero for a given number of discharges if the empirical evidence shows that hospitals experience no higher incremental costs when they reach that number of discharges. In other words, the statute does not require the Secretary to provide an adjustment in the absence of empirical evidence that an adjustment is warranted by higher incremental costs.

Comment: Many commenters objected to our proposal to provide an adjustment for only some hospitals that meet the statutory definition of a low-volume hospital. Some of these commenters contended that such a proposal was contrary to the statute. Other commenters stated that the proposal neglected to provide additional payments for many small hospitals that may be struggling financially.

Response: We continue to believe that the statutory language gives the Secretary the flexibility to set the percentage increase at zero for a given number of discharges if the empirical evidence shows that hospitals experience no higher incremental costs when they reach that number of discharges. In other words, the statute does not require the Secretary to provide an adjustment in the absence of empirical evidence that an adjustment is warranted by higher incremental costs. Indeed, we believe that the statutory language implies that no adjustment would be warranted for any hospitals that meet the definition of "low-volume hospital" if the requisite empirical analysis of the "relationship between the standardized cost-per-case, the total number of discharges, and the amount of incremental costs associated with the number of discharges" does not support an adjustment. We also note MedPAC's agreement with our proposal to limit the adjustment to the level supported by the empirical analysis.

While the statute defines low-volume hospitals in terms of total inpatient acute care discharges and mandates that the adjustment be based upon the amount of incremental costs associated

with the number of discharges, it does not specify whether the count of discharges, either for purposes of the definition or the payment adjustment formula, should be based on the payment year or some previous year. Specifically, the statute defines low-volume hospital as "for a *fiscal year*, a subsection (d) hospital * * * [that] has less than 800 discharges during the *fiscal year*" (emphasis added).

As we indicated in the proposed rule, we believe that this statutory language gives us the flexibility to define which fiscal year to use in determining the number of discharges, both for purposes of the definition of "low-volume hospital" and the payment adjustment formula. Prospective payment systems place substantial value on providing hospitals with predictability regarding payments. If the determination of whether hospitals qualify for low-volume payment adjustments and the computation of the payment adjustment amount are based on the number of discharges in the current fiscal year, neither CMS nor the hospital will know with certainty whether a hospital qualifies for the adjustment, or what the amount of the adjustment would be, until after the end of the payment year (probably not until the time of final cost report settlement for the year). In such circumstances, CMS could be faced with the prospect of recouping large overpayments in some cases or reimbursing for large underpayments in others. Hospitals would face similar uncertainties. On the other hand, if these determinations are based on discharge counts from a prior fiscal year, hospitals will know in advance whether they will be receiving a payment adjustment and what the size of the adjustment will be. Both hospitals and CMS will be able to plan accordingly.

Therefore, in the proposed rule, we proposed to base the count of discharges, for purposes both of meeting the qualifying definition and determining the amount of the payment adjustment, on the number of inpatient acute care discharges occurring during the cost reporting period for the most recent submitted cost report. We recognize that this policy may temporarily disadvantage certain hospitals. For example, a hospital that had more than 500 discharges in its most recent submitted cost report may have fewer than 500 discharges during the first fiscal year in which this low-volume payment adjustment is available. Such a hospital would not qualify for the low-volume adjustment during the first fiscal year of the adjustment under the proposed policy,

but it would qualify under an alternative policy of basing the discharge count on the fiscal year for which payment is made. However, even in such cases, the hospital would not be certain about whether it would receive an adjustment until its cost report for the payment year is settled. In addition, under the proposed policy, the hospital would still be certain of receiving a low-volume adjustment for any fiscal year in which it had 500 or fewer discharges. The hospital would receive the adjustment during the fiscal year after the cost report is submitted for any fiscal year in which the hospital had 500 discharges or less.

Comment: MedPAC recommended that we consider employing a 3-year moving average of discharges in determining the adjustment and they noted that a 3-year moving average would better track a hospital's underlying patient volume.

Response: We appreciate and understand the basis for this recommendation. However, we believe that the text of the statute, which defines a low-volume hospital as one that has "less than 800 discharges during the fiscal year," precludes taking a multiyear approach to the number of discharges.

Comment: MedPAC recommended that we revise this proposed policy, and consider basing the adjustment on the actual number of discharges in the payment year, rather than relying on 2-year old cost report data. MedPAC noted that our proposed approach would delay recognition of changes to a hospital's actual volume in determining the adjustment, and that reconciliation of the final discharge count for the payment year could be carried out less than a year from the end of the cost reporting period.

Response: We appreciate MedPAC's recommendation and will take it into consideration for future years. However, we are not adopting the recommendation at this time for several reasons. The recommendation to employ the current year count of discharges would require establishment of a reconciliation process, which would probably be implemented by means of revisions to the Medicare cost report form. As we discuss later in this section of the preamble, we are significantly modifying the proposed low volume adjustment on the basis of the empirical analysis that we have conducted since the proposed rule. In the light of this analysis, we will be reanalyzing the empirical data in the FY 2006 rulemaking process and reexamining whether an adjustment is warranted based on the statutory

requirement that the adjustment be empirically justified. Until we have determined whether a low-volume adjustment is warranted by the empirical data over the long term, we do not believe that it would be prudent to establish a new reconciliation process and revise the Medicare cost report form.

A further implication of our proposed policy was that a new hospital would not receive an adjustment during its first year of operation, even if it has fewer than 500 total discharges during that year. While this approach is somewhat disadvantageous for hospitals in their first year of existence, we believe that it is justified in order to avoid establishing a settlement process to finalize payments under this new proposed adjustment. Therefore, we proposed that new hospitals that meet the distance requirement would not be eligible for the adjustment until data become available to determine that the annual number of discharges is 500 or less. Under this approach, new hospitals would not receive a low-volume adjustment during at least the first 2 years of their existence. (This is generally the amount of time that elapses before submission of a cost report.) This policy is consistent with the treatment of some existing hospitals, for example, hospitals that have declining numbers of discharges, and would not be eligible for the adjustment until their data show 500 or fewer discharges.

Comment: Several commenters encouraged us to provide a mechanism for new hospitals to qualify to receive an adjustment without waiting for settlement of the hospital's first cost report.

Response: Providing for new hospitals to receive an adjustment during the first year of operation would require establishment of a reconciliation process, probably through revision of the Medicare cost report. For the reasons discussed previously, we do not believe that it would be prudent to revise the cost report and establish a reconciliation process at this time.

As we noted previously, the statute defines a low-volume hospital as a subsection (d) hospital that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year. In order to enforce the requirement that a qualifying hospital be located more than 25 miles from another subsection (d) hospital, we proposed that a hospital that wishes to qualify for the adjustment must provide its fiscal intermediary with evidence that it meets

this distance requirement. The intermediary will then certify, on the basis of the evidence presented by the hospital and any other relevant evidence that it may be able to develop, that the hospital meets this requirement. Other relevant evidence may include maps, mapping software, and inquiries to State and local police, transportation officials, or other government officials.

As discussed previously, we indicated in the proposed rule that for the final rule we planned to conduct more detailed multivariate analysis on the empirical basis for a low-volume adjustment. We have expanded and refined our analysis in several significant ways and, as a result, are revising our proposal in this final rule.

In order to further evaluate the low volume proposal, we empirically modeled the relationship between hospital costs-per-case and total discharges in several ways. We used both regression analysis and straight-line statistics to examine this relationship.

We conducted three different regression analyses. For all of the analyses, we simulated the FY 2005 cost environment because the low-volume policies would be applied during that year. We also analyzed the relationship between costs and discharges based purely on FY 2001 and FY 2002 data. The FY 2005 models were given the most weight in our conclusions as payments have undergone several changes between FY 2001 and FY 2005, making the results of the earlier data less relevant. Furthermore, many of these policy changes may already have helped increase payments to low-volume hospitals.

In the first regression analysis, we used a dummy variable approach to model the relationship between standardized costs and total discharges. We standardized costs to remove the effects of differences in area wage levels, case-mix, outliers, and, for hospitals in Alaska and Hawaii, the applicable cost-of-living adjustment. This model was similar to that used by MedPAC on 1997 data. The results of these regression models on the earlier years of data, FY 2001 and FY 2002, provided support for giving hospitals with less than 200 total discharges positive payment adjustments, as they were found to have higher Medicare costs per Medicare discharge in comparison to high-volume hospitals. These results are somewhat consistent with the similar analysis performed by MedPAC, as MedPAC found that hospitals with up to 200 discharges were in most need of a payment adjustment. However, MedPAC also found evidence for

providing an adjustment to hospitals with up to 500 discharges, which the data for FYs 2001 and 2002 do not show. Furthermore, the analysis revealed no statistically significant relationship between standardized costs and total discharges when modeling under the FY 2005 environment. These results suggest that the relationship between standardized costs and total discharges is becoming less significant over time, which may indicate that changes to the payment structure (for example, changes in the labor share, and the equalization of standardized amounts) over time have already had some positive impact on low-volume hospital payments.

We also used a descriptive analysis approach to understand the empirical relationship between costs and total discharges. We grouped all hospitals by their total discharges and compared the mean Medicare per discharge payment-to-Medicare per discharge cost ratios. Hospitals with less than 800 total discharges were split into 24 cohorts based on increments of 25 discharges. For the most part, the mean payment-to-cost ratios were below one (implying that Medicare per discharge costs exceeded Medicare per discharge payments), for cohorts of hospitals with less than 200 discharges. However, consistent with the regression findings, the point at which the ratio seemed to transition from consistently being below 1 to above 1 decreased over time from approximately 225 discharges in 2001 to 150 discharges in 2005. There was also no obvious increasing trend in the ratios, from which it would be possible to infer a formula to generate adjustments for hospitals based upon the number of discharges. Because nearly 70 percent of hospitals with less than 200 discharges had ratios below 0.80, this analysis supports applying the highest payment adjustment to all providers with less than 200 discharges that are eligible for the low volume adjustment. This finding also raises concerns that the large variation in costs relative to payments and the low sample sizes for low-volume hospitals may bias the regressions toward insignificant results.

The second regression analysis modeled the Medicare per discharge cost-to-Medicare per discharge payment ratio as a function of total discharges. The cost-to-payment ratio model more explicitly accounts for the relative values of per discharge costs and per discharge payments. These models provided some evidence for a statistically significant negative relationship between the cost-to-

payment ratio and total discharges. However, that result was limited to FY 2001 and FY 2002 data and no significant relationship between the cost-to-payment ratio and total discharges was found with simulated FY 2005 data. These results also lend support to the notion that the relationship between the cost-to-payment ratio and total discharges has become less significant over time, and that changes to the payment structure have had some positive impact on low-volume hospital payments.

The third regression analysis employed per discharge costs minus per discharge payments as the dependent variable and total discharges as an explanatory variable. The results of this analysis were similar to the other regression analyses: some evidence was provided for an adjustment with the FY 2001 and FY 2002 data, but not with the simulated FY 2005 data. In fact, the 2005 results suggest (with a positive intercept and positive coefficient on total discharges) that payments are greater than costs for all hospitals, including the low-volume hospitals. Again, these results are consistent with the notion of previous changes to the payment structure having already had positive impacts on low-volume hospital payments.

In conjunction with this third regression analysis, we also examined the straight-line statistical relationship between per discharge costs minus per discharge payments and total discharges. The results of this analysis indicate that this relationship is negative for the majority of hospitals with less than 200 discharges.

The declining trend in the significance of the relationship between hospital costs and discharges and, in particular, the statistically insignificant relationship with the simulated FY 2005 results may provide some case for not making a low-volume adjustment. However, we are persuaded by the earlier data and the descriptive statistics that hospitals with less than 200 discharges have sufficiently higher costs relative to payments to justify an adjustment, although more modest in scope than the adjustment we proposed. Therefore, in this final rule we are providing a low-volume adjustment for hospitals with less than 200 discharges. As noted above, the descriptive data do not reveal any pattern that could provide a formula for calculating an adjustment in relation to the number of discharges. However, the descriptive analysis of the data does indicate that, for a large majority of the hospitals with less than 200 discharges, the maximum

adjustment of 25 percent would be appropriate. This is because, for example, the payment-to-cost ratios for more than 70 percent of these hospitals are 0.80 or less. The maximum adjustment of 25 percent would therefore leave most of these hospitals with payment-to-cost ratios still below 1.00. Because a large majority of hospitals with less than 200 discharges have payment-to-cost ratios below 1.00, we are providing that hospitals with less than 200 total discharges in the most recent submitted cost report will receive an adjustment of 25 percent on each Medicare discharge. Therefore, we are revising § 412.101(a) and (b) to implement these changes.

We believe that, in the light of all the analysis that we have conducted, extending a 25 percent low-volume adjustment to all hospitals with less than 200 discharges is most consistent at this time with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of discharges. However, we acknowledge that the empirical evidence does not provide robust support for this conclusion. Therefore, we will thoroughly reexamine the empirical evidence next year, and propose to modify or even eliminate the adjustment if the empirical evidence indicates that it is appropriate to do so at that time. Our analysis indicates that there are fewer than 100 hospitals with less than 200 total discharges. We are unable to determine how many of these hospitals also meet the requirement that a low-volume hospital be more than 25 road miles from the nearest subsection (d) hospital in order to qualify for the adjustment. However, the majority of the low-volume hospitals that we have been able to identify are located in urban areas. Some indications suggest that a number of these hospitals may be specialty hospitals, which are generally small institutions concentrating in one area of surgical practice, such as orthopedics or heart surgery. It is not entirely clear that it is the intent of this statutory provision to provide additional payment to this type of hospital. Others may be eligible to apply to become CAHs. We will monitor the numbers and types of hospitals that receive the low-volume adjustment as the intermediaries make determinations concerning which facilities meet all the requirements for the adjustment.

N. Medicare Geographic Classification Review Board (MGCRB) Reclassifications (§§ 412.230, 412.234, and 412.236)

1. Background

With the creation of the MGCRB, beginning in FY 1991, under section 1886(d)(10) of the Act, hospitals could request reclassification from one geographic location to another for the purpose of using the other area's standardized amount for inpatient operating costs or the wage index value, or both (September 6, 1990 interim final rule with comment period (55 FR 36754), June 4, 1991 final rule with comment period (56 FR 25458), and June 4, 1992 proposed rule (57 FR 23631)). Implementing regulations in Subpart L of Part 412 (§§ 412.230 *et seq.*) set forth criteria and conditions for redesignations for purposes of the wage index or the average standardized amount, or both, from rural to urban, rural to rural, or from an urban area to another urban area, with special rules for SCHs and rural referral centers.

Effective with reclassifications for FY 2003, section 1886(d)(10)(D)(vi)(II) of the Act provides that the MGCRB must use the average of the 3 years of hourly wage data from the most recently published data for the hospital when evaluating a hospital's request for reclassification. The regulations at § 412.230(e)(2)(ii) stipulate that the wage data are taken from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes. To evaluate applications for wage index reclassifications for FY 2005, the MGCRB used the 3-year average hourly wages published in Table 2 of the August 1, 2003 IPPS final rule (68 FR 50135). These average hourly wages are taken from data used to calculate the wage indexes for FY 2002, FY 2003, and FY 2004, based on cost reporting periods beginning during FY 1998, FY 1999, and FY 2000, respectively.

2. Standardized Amount Reclassification Provisions

As specified in § 412.230(d)(1), to be reclassified to an adjacent area for the purpose of using that area's standardized amount, an individual hospital seeking redesignation must demonstrate that its incurred costs are comparable to hospital costs in the adjacent area (that is, hospitals must demonstrate that their costs exceed their current payments by 75 percent of the additional payments they would receive through reclassification) and that it has the necessary close proximity to that area (that is, an urban hospital must be

no more than 15 miles and a rural hospital no more than 35 miles from the adjacent area; or at least 50 percent of the hospital's employees must reside in the adjacent area).

Under section 402(b) of Public Law 108-7, Congress provided that all inpatient PPS hospitals be paid at the large urban average standardized amount for discharges occurring on or after April 1, 2003 and before October 1, 2003. Under Public Law 108-89, Congress extended section 402(b) of Public Law 108-7 to discharges occurring through March 31, 2004. Section 401 of Public Law 108-173 further extended the equalization of urban and rural operating standardized payment amounts. (See section IV.B. of this preamble for a more detailed discussion.) Section 401 also equalized the Puerto Rico-specific urban and other area rates by requiring that the Puerto Rico-specific urban and other area rates be made retroactive to October 1, 2003. The Puerto Rico-specific equalization of the urban and rural operating standardized amounts became effective for discharges beginning on or after April 1, 2004.

As a result of these legislative changes, the standardized amount reclassification criterion is no longer necessary or appropriate. Therefore, in the May 18, 2004 proposed rule (69 Fr 28288), we proposed to revise § 412.230 and § 412.234 to remove all standardized amount criteria provisions. We proposed to remove the provisions of § 412.230(d) (existing paragraph (e) would be redesignated as paragraph (d)), and to remove § 412.234(c) and (d)(2) (existing paragraph (d)(1) would be redesignated as paragraph (c) and revised), which contain the criterion requiring individual hospitals and urban hospital groups to demonstrate that their costs are more comparable to the average amount they would be paid if they were reclassified than the amount they would be paid under their current classification.

With the implementation of the equalization of the national adjusted operating standardized amount for large urban and other areas provision of Public Law 108-173, we also proposed the following technical revisions to several sections under Subpart L of Part 412, which set forth the criteria and conditions for redesignations.

- We proposed to delete the cross-reference to “§ 412.230(d)(2)” cited in § 412.230(a)(4) and to make redesignation changes for the existing cross-reference changes to paragraph (e), which was proposed to be redesignated as paragraph (d).

- We proposed to delete § 412.230(a)(5)(ii) (the existing paragraphs (a)(5)(iii), (a)(5)(iv), and (a)(5)(v) was proposed to be redesignated as paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(5)(iv), respectively. Under existing § 412.230(a)(5)(ii), we defined, for fiscal years 1997, 1998, and 2002, the limitation for redesignation for purposes of the standardized amount. Our policy has been that a hospital may not be redesignated for purposes of the standardized amount to an area that does not have a higher standardized amount than the standardized amount the hospital currently receives.

Comment: Many commenters agreed with our proposed revisions. One commenter stated that, as a RRC approved for reclassification, the hospital should be allowed to retain its reclassification to the MSA with which it competes, as opposed to assignment to an area that does not include any other “academic tertiary care hospitals”. The commenter also stated that by allowing hospitals to maintain reclassification to the selected MSA, CMS would be adhering to the original intent of the geographic reclassification provision. In addition, the commenter advises that through CMS's recognition that “rural hospital's continued financial viability is necessary in order to preserve access to needed services for Medicare beneficiaries in these providers' service areas” and acknowledgement of the “need to maintain access to tertiary care for Medicare beneficiaries in relatively isolated areas,” rural referral centers and other similar teaching hospitals have in the past been insulated from the adverse financial consequences that result from changes in rules and regulations. In light of its concerns, the commenter recommends that CMS establish a separate exception for major rural teaching hospitals by revising § 412.230 to add two provisions. The commenter believes that adoption of the suggested rules would allow a major teaching hospital to reclassify to an MSA where a substantial number of its competing hospitals are located within the same census region, thus affording them the flexibility to reclassify to an appropriate MSA.

The first revision recommended by the commenter is to revise § 412.230(a)(4) to add a new title, “Special Rule for Major Rural Teaching Hospital,” to revise the text to read as follows:

“A hospital that is a major teaching hospital located in a rural area does not have to demonstrate a close proximity to the area to which it seeks redesignation. The hospital may seek redesignation to

a large urban area (as defined in § 412.63(c)(6)) that includes five or more major teaching hospitals and that is located in the same census region as the applicant. For purposes of this section, a major teaching hospital is a hospital that (i) has a documented affiliation agreement with a medical school accredited by the Liaison Committee on Medical Education ("LCME"), and (ii) sponsors, or participates significantly in residency programs in Medicine, Surgery, Obstetrics/Gynecology, Pediatrics, Family Practice, or Psychiatry."

The second recommendation is that § 412.230(e)(4) be retitled, "Major Rural Teaching Hospital Exception, and revised to read "If a hospital was a major teaching hospital in a rural area as of September 30, 2004, it does not have to demonstrate that it meets the criterion set forth in paragraph (e)(1)(iii) of this section concerning its average hourly wage."

Response: We appreciate the opportunity to consider the revisions recommended by the commenter. In response to the commenter's concern regarding the proposal to assign reclassified hospitals to the nearest county, because we have addressed similar concerns in this final rule, we are not readdressing that response here. We encourage the commenter to refer to section III.H of this final rule for a more detailed response to this issue.

With respect to the recommendation that § 412.230 be revised to establish a separate exception for major rural teaching hospitals we are not persuaded that there is a need to establish the suggested exception for several reasons. First, this hospital, while defined as a major rural teaching hospital, is also a rural referral center. Given its status as a rural referral center, it is not subject to the proximity criteria because it already has a special status as a rural referral center. As a result of this special status the hospital has an advantage over other reclassifying hospitals in that it can utilize a larger radius in seeking reclassification opportunities (§ 412.230(a)(3)). In addition, rural referral centers (and SCHs) may also reclassify to any MSA to which they qualify under § 412.230(b). With respect to the hospitals ability to reclassify based on its status as a rural referral center, we believe these criteria provide adequate opportunity for reclassification.

Second, while we understand the commenter's point about its competitors, we do not believe that this justifies establishing such broad exceptions as exempting a specific type of rural hospital from meeting the

proximity requirement or from having to demonstrate that it meets any wage comparability test for reclassification purposes. Therefore, we are not adopting either of the recommended revisions.

In the May 18, 2004 proposed rule, we proposed to delete existing § 412.236. Section 412.236 sets forth the redesignation criteria for hospitals in a NECMA. Under the new CBSAs, OMB has defined the MSAs and Micropolitan areas in New England on the basis of counties. As discussed in section III.B. of the May 18, 2004 proposed rule, to maintain consistency in the definition of labor market areas between New England and the rest of the country, we proposed to use the New England MSAs under the new CBSA definition. Proposing to adopt the New England MSAs requires not only that we delete the reference to NECMAs in existing definitions, but that we also delete reference to criteria applicable to hospitals located in a NECMA that apply for reclassification. In keeping with the proposal to define labor market areas as MSAs, including those in New England, the criteria and conditions for redesignation set forth in § 412.230 will be applicable to New England hospitals seeking to reclassify.

In an effort to refine the reclassification guidelines, we established §§ 412.234 and 412.236 in the existing guidelines to allow for reclassification of urban groups and New England groups, respectively (56 FR 25458). Under § 412.232(a) and § 412.234(a), we set forth similar criteria for rural and urban hospitals to be reclassified as a group, respectively. Prior to the implementation of legislation to eliminate the differential in the standardized amount, urban county groups that were interested in applying for purposes of the wage index submitted applications to the MGCRB for consideration. Many urban county group applications were unable to reclassify solely because they failed to meet the standardized amount criteria. In light of the fact that the standardized amount criteria are no longer appropriate, we believe it would be appropriate to make an adjustment to the hospital's wage index by assigning, to hospitals that were unable to reclassify in applications for both FY 2004 and FY 2005, the wage index for the MSA requested in the FY 2004 and FY 2005 group application. Section 1886(d)(5)(I)(i) of the Act provides the Secretary with broad authority to make adjustments and exceptions under the IPPS. Specifically, the section provides that the "Secretary shall provide by regulation for such other exceptions and

adjustments to such payment amounts under this subsection as the Secretary deems appropriate." Under this unique circumstance, in the May 18, 2004 proposed rule, we proposed to exercise the broad authority under section 1886(d)(5)(I)(i) of the Act, to make an exception to the assignment of wage index value for certain hospitals that failed to reclassify as a group under § 412.234 for FY 2004 and FY 2005. Specifically, effective with discharges occurring during the 3-year period beginning October 1, 2004 through September 30, 2007, any hospital whose urban county group application under § 412.234 would have been approved by the MGCRB but for the failure to meet the requirements in § 412.234 (c), would be assigned the wage index for the MSA identified in the FY 2004 and FY 2005 group application (in cases where the group identified more than one preference, the hospital would be assigned the wage index that is most advantageous). In the proposed rule, we indicated that hospitals that wish to receive the wage index of the area identified in their FY 2004 and FY 2005 group applications under this provision would need to only notify CMS in writing, at the address provided under the ADDRESSES section of the proposed rule, before the close of the comment period. We further stated that the notification should only contain:

- The hospital's name and street address.
- The hospital's provider number.
- The name, title, and telephone number of a contact person for communications.
- The area (name and MSA number) identified in their FY 2005 group application.
- Copies of any and all MGCRB decision notification letters for FY 2004 and FY 2005.

Comment: Several commenters stated that the requirement that hospitals needed to have failed to reclassify as an urban group under § 412.234 for "FY 2004 and FY 2005" is "unreasonable and arbitrary." The commenters recommended that the criteria be modified to provide relief to all urban group hospitals that applied in FY 2005, irrespective of whether they applied for consideration in FY 2004.

Response: We proposed to exercise the Secretary's authority to provide for "exceptions and adjustments" to payments under the IPPS. To assign a different wage index to a group of hospitals that were unable to reclassify because of a reclassification criterion that is no longer appropriate due to a statutory change. We do not believe it was "unreasonable and arbitrary" to

restrict the extraordinary exercise of this exceptions authority to a small group of hospitals that had persisted in seeking reclassification as an urban county group over two consecutive years. Several hospitals notified us that they have met the requirements that we announced in the proposed rule. In this final rule, we are providing for these hospitals to be assigned to the wage index of the MSA identified in their FY 2004 and FY 2005 group applications.

We do not agree with the commenters that we should extend this exception to all hospitals that were unable to reclassify as a group solely because they failed to meet the standardized amount criterion in either FY 2004 or FY 2005. However, we have been persuaded by the factual situations described by several commenters to extend this exception modestly beyond what we proposed. In several cases, some hospitals that were parties to group reclassification applications in FY 2004 or FY 2005 have been able to reclassify as individual hospitals, either through the regular MGCRB process or through the special one-time wage index appeal process under section 508 of MMA. In cases where a significant proportion of the group applicants have been able to reclassify otherwise, the remaining hospitals in the group can be placed at a significant competitive disadvantage. Therefore, we are providing in this final rule, to provide for an adjustment to the wage index of the hospitals that meet the following criteria:

- The hospital was part of an urban county group reclassification application for FY 2004 or FY 2005 that failed solely on the basis of the standardized amount criterion;
- At least one-third of the hospitals that had been parties to the urban county group reclassification application have subsequently been reclassified for FY 2005 either through the regular MGCRB reclassification process or the special one-time wage index appeal process under section 508 of MMA;
- The hospitals can demonstrate that the hospitals that have since reclassified to another area, have a wage index at least 10 percent higher than the wage index of the MSA where the hospital is located.

A hospital that meets all of these criteria will be assigned the wage index of the area identified in their FY 2004 or FY 2005 urban county group reclassification application.

Hospitals will have 30 days after the publication date of this final rule to notify us of their eligibility on the basis of the criteria described above.

Comment: Several commenters expressed concern that the proposed adoption of CBSA designations will require urban hospital groups seeking reclassification to be located within a CBSA, and to seek reclassification to another area within that CBSA (that is, another Metropolitan Division). They stated that if the proposal is implemented the opportunity for reclassification will not be available to urban hospital groups located in states such as California, Connecticut, New Hampshire, North Carolina, and New York. In other words, the proposal limits hospital group reclassification to hospitals located in CBSAs with multiple Metropolitan Divisions. Several of the commenters recommended that if CMS adopts the new CBSAs, it should modify the urban group proximity criteria to require that hospitals that are located in counties located in the same CSA under the new MSAs would meet the proximity requirement. Other commenters expanded on this recommendation by recommending that CMS “grandfather” counties where a group reclassification is in place and “deem” those counties as eligible for future group reclassifications to contiguous Metropolitan Divisions included in the same CSA.

Response: Section 1886(d)(10)(D)(i)(II) of the Act requires the Secretary to publish guidelines “for determining whether the county in which the hospital is located should be treated as being a part of a particular Metropolitan Statistical Area.” The statute does not specify the particular criteria to be used, but instead confers broad authority on the Secretary in establishing guidelines. Under current regulations, hospitals seeking group reclassification must be located within a CMSA, and they may seek reclassification only to another area within that CMSA. As we stated in the May 18, 2004 proposed rule, we proposed to adopt the new CBSA designations as announced by OMB to define labor market areas, specifically, the MSA category as defined by the standards. Given that the implications of implementing the new labor market areas as proposed result in the unintended restriction of reclassifications for some urban county groups, we have been persuaded that there is a need to modify our urban group reclassification policy so as to preserve the reclassification opportunities for these urban county groups. Therefore, in this final rule we are modifying the urban county group reclassification criteria set forth in § 412.234(a)(3) to specify that “hospitals

located in counties that are, under the new MSA designations, in the same CSA under the new MSA designations and the same CMSA under the former MSA designations qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation.” We thank the commenters for bringing this issue to our attention.

3. Reclassification of Urban Rural Referral Centers

Under existing regulations at § 412.230(e)(3), rural referral centers (RRCs) (including hospitals that were ever RRCs) are exempt from one of the average hourly wage criteria that apply to other hospitals seeking reclassification. Specifically, an RRC is exempt from the requirement under § 412.230(e)(1)(iii) that the hospital’s 3-year average hourly wage meet a threshold percentage in relation to the average hourly wage of all the hospitals in the area in which the hospital is located. These threshold percentages are 108 percent for hospitals located in urban areas, and 106 percent for hospitals located in rural areas. However, an RRC is not exempt from another threshold requirement, namely the requirement under § 412.230(e)(1)(iv) that the hospital’s 3-year average hourly wage must meet a threshold percentage of the 3-year average hourly wage of the hospitals located in the area to which the hospital seeks reclassification. As in the case of the first threshold, this threshold percentage is different for urban and rural hospitals. An urban hospital’s 3-year average hourly wage must be at least 84 percent of the average hourly wage of the hospitals located in the area to which the hospital seeks reclassification, while a rural hospital’s 3-year average hourly wage must be at least 82 percent of the average hourly wage of the hospitals located in the area to which the hospital seeks reclassification.

In the May 18, 2004 proposed rule (69 FR 28289), we indicated that it had come to our attention that the requirement of § 412.230(e)(1)(iv) places RRCs located in urban areas on a different footing than RRCs located in rural areas. In some cases, urban RRCs that have been denied reclassification because they failed to meet the 84-percent threshold would have been able to meet the 82-percent threshold that would have applied if they were located in a rural area. RRCs play a significant role in treating Medicare beneficiaries from rural areas, whether or not a particular RRC is physically located in a rural area or an urban area. Thus, we

believe that it would be more appropriate for all RRCs, whether they are actually located in urban or rural areas, to be treated on an equal basis with respect to the qualifications for geographic reclassification. Therefore, we proposed to revise § 412.230(e)(1)(iii) of the regulations to provide that RRCs, including RRCs located in urban areas, must meet the 82-percent threshold that applies to rural hospitals rather than the 84-percent threshold that applies to urban hospitals.

Furthermore, we had become aware of at least one case in which an RRC was reclassified by the MGCRB for FY 2004, but upon applying to the MGCRB for FY 2005, was found to be ineligible for reclassification because its 3-year average hourly wage was now less than 84 percent of the hospitals located in the MSA to which it applied for reclassification. In this case, the hospital's 3-year average hourly wage was still greater than 82 percent of the MSA to which it had applied for reclassification. In such a case, we believe that it would be appropriate to make an accommodation for one year, so that the hospital is not subjected to the financial strain that may be caused by receiving a lower wage index for one year until it qualifies to apply for reclassification under the revised threshold criterion that we are proposing here. Therefore, we proposed that, in such a case, we would exercise our authority under section 1886(d)(5)(I)(i) of the Act to make an exception by assigning to the hospitals for one additional year the wage index that applied to the hospital in FY 2004 through FY 2005. We proposed to use this authority to provide, under this unique circumstance, special protection to a small number of hospitals that would otherwise be subject to a temporary, but serious, disadvantage. Specifically, we would assign an RRC that meets the conditions described above, the wage index value of the MSA to which it was reclassified by the MGCRB in FY 2004. In order to be eligible for this exception, the hospital may not qualify for any geographic reclassification for discharges effective October 1, 2004 (under the regular rules or the special one-time appeal provision). This assignment would be valid only for FY 2005, after which the hospital would have the opportunity to apply for reclassification under the proposed new threshold for all RRCs in the proposed rule.

We proposed to revise proposed redesignated § 412.230(d)(3) and add a new § 412.64(j) to incorporate this proposal.

Comment: A number of commenters expressed support for our proposal to revise § 412.230(e)(1)(iii) of the regulations to require that the 3-year AHW of RRCs, including those located in urban areas, must be at least 82 percent of the AHW of the hospitals in the targeted area and to allow an urban RRC which did not qualify for reclassification for FY 2005 to receive the wage index of the MSA to which it was reclassified in FY 2004. One commenter, questioned the rationale for extending the reclassification exception for only 1 year while other hospitals qualifying for reclassification are reclassified for 3 fiscal years. The commenter stated that the proposed 1-year extension impairs the hospital's ability to make plans regarding financial status more than 1 year in advance. The commenter recommended that the exception allowing qualifying urban RRCs to be reclassified be applicable for 3 years. Other commenters recommended that "CMS continue to allow a 35 mile proximity requirement for urban RRCs."

Response: We appreciate the commenter's support for our proposal that RRCs, including those located in urban areas must, meet the 82 percent threshold that applies to rural hospitals rather than the 84 percent threshold applicable to urban hospitals. The premise behind the development of the proposal and the exception was to put urban RRCs on an equal footing with RRCs located in rural areas. As the commenter noted, a 1-year exception, even in light of their ability to apply for reclassification in FY 2006, does not provide the equal footing they would realize if the exception were extended for 3 years. We agree with the commenter and, in this final rule, we are modifying the reclassification exception for urban RRCs and therefore will allow qualifying urban RRCs to be reclassified for 3 years.

With respect to the recommendation that "CMS continue to allow a 35 mile proximity requirement for urban RRCs", it is important to note that under the special access guidelines at § 412.230(a)(3), we exempt RRCs and SCHs from the adjacency and proximity requirements in § 412.230(a)(2), therefore, RRCs and SCHs are not required to demonstrate a close proximity to the area to which it seeks to reclassify.

Comment: A commenter recommended that CMS consider, for purposes of geographic reclassification, designating as RRCs these urban hospitals that reflect characteristics similar to urban RRCs. The commenter advised that failure to do so will

continue to "significantly disadvantage" urban hospitals that play a significant role in treating Medicare rural beneficiary populations. As one way to accomplish this, the commenter recommended that CMS designate any hospital as an urban RRC if it meets the criteria of § 412.103(a)(3) as it relates to RRCs.

Response: Under Medicare law, the location of a hospital can affect its payment as well as whether the facility qualifies for special treatment both for operating and capital payments. The commenter recommends that CMS designate urban hospitals that reflect characteristics similar to urban RRCs and advises that § 412.103 provides the means to accomplish this. Section 401(a) of Public Law 106-113, which amended section 1886(d)(8) by adding paragraph (E), directs the Secretary to treat any subsection (d) hospital located in urban areas as being located in the rural area of the State in which it is located if the hospital files an application and if it meets one of the established criteria set forth on § 412.103. (We provided a detailed discussion of this policy in the August 1, 2000 interim final rule with comment period (65 FR 47029) and the August 1, 2001 final rule (FR 66 39884).) Because there are several provisions of the Social Security Act that provide procedures under which a hospital can apply for reclassification from one geographic area to another, we still do not believe, as we stated in the aforementioned final rules, that there is a need to specify further qualifying criteria for reclassifications governed by § 412.103 guidelines. Therefore, as discussed above, we are adopting the change requiring all RRCs, regardless of location in an urban or rural area, to meet the 82-percent threshold. In addition, we are modifying our proposal for those RRCs that were reclassified to an urban area in FY 2004 and that failed to be reclassified in FY 2005 in order to provide a reclassification for 3 years using our authority under section 1886(d)(5)(i)(I) of the Act.

4. Special Circumstances of Sole Community Hospitals (SCHs) in Low Population Density States

Medicare program policy has long provided special treatment for hospitals in rural areas. For many years, rural hospitals have experienced lower margins than other hospitals, and Congress has created several special measures to address the unique issues of hospitals in rural areas. For example, Congress created the CAH program in 1997 to ensure that beneficiaries in isolated areas had access to emergency

services and certain essential inpatient services. To qualify for CAH designation, a hospital must be located more than 35 miles from the nearest similar hospital and have an average length of stay not exceeding 4 days. A CAH must provide 24-hour emergency care services and have no more than 25 acute care beds. CAHs are currently paid 101 percent of their current Medicare allowable costs for inpatient and outpatient services. Similarly, the SCH program has long served to maintain access to needed health services for beneficiaries in isolated communities. SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; or the updated hospital-specific rate based on FY 1996 costs per discharge.

Many rural hospitals have taken advantage of the opportunity to participate in the CAH program in recent years. We expect the number of hospitals to increase because of the changes made to the CAH program under recently enacted Public Law 108-173 (for example, increasing the reasonable cost payment rate from 100 percent to 101 percent and increasing the qualifying bed size limitation from 15 to 25). Because CAHs are paid on the basis of their reasonable costs, the wage index is not a factor in their payments, and geographic reclassification is thus not an issue for these hospitals. However, for many rural hospitals that cannot qualify for CAH status, the wage index remains an important factor in their payment, even in the case of SCHs paid on their hospital-specific rate, for which the only impact of the wage index may be on their inpatient capital and outpatient payments. The regulations governing reclassifications by the MGCRB provide special treatment for SCHs by exempting them from the normal rules that require hospitals to demonstrate a close proximity (15 miles in the case of urban hospitals; 35 miles for rural hospitals), and allowing these hospitals to reclassify to the urban area or the rural area that is the closest to the hospital.

Wage index assignment is an especially pressing issue for hospitals in States with low population densities. In such States, employees are likely to commute greater distances to work. More distant areas are thus likely to compete for labor than is the case in more densely populated States. Because of this concern, and the program's longstanding recognition of these

hospitals, we exercised our discretion in implementing the special one-time wage index reclassification appeal provision of section 508 of Public Law 108-173 to provide special consideration for SCHs in States with fewer than 10 people per square mile, based on 2000 census data (Alaska, Montana, North Dakota, South Dakota, and Wyoming). Specifically, we provided that SCHs in such a State could reclassify to an MSA within its State. More than 20 SCHs in those States were able to reclassify under this provision.

However, a number of SCHs from those States were precluded from reclassifying under the terms of section 508. In the May 18, 2004 proposed rule (69 FR 28289), we indicated that we were concerned that these hospitals could now be placed at a serious disadvantage in comparison to other SCHs in their States and regions. Under the authority of section 1886(d)(5)(I)(i) of the Act, we proposed to provide, under these unique and temporary circumstances, special protection to a small number of hospitals that would otherwise be subject to a temporary, but serious, disadvantage. Specifically, we proposed to allow an SCH in one of the States with fewer than 10 people per square mile (Alaska, Montana, North Dakota, South Dakota, and Wyoming) to adopt the wage index of another geographic area within its State for 3 years.

Under the proposal, such wage index assignments would become effective for FY 2005 through FY 2007. Because the wage index assignments would be made in order to remedy a temporary disadvantage, the assignments would be for the 3-year period only and would not be available thereafter. In order to receive the wage index of another area under this proposal, we proposed that a SCH may not qualify for reclassification (under the regular rules or the special one-time appeal provision) effective for discharges on or after October 1, 2004. SCHs in the identified States will not be required to meet proximity or access requirements similar to those required for reclassification in order to qualify for change in wage index under this provision. Under this proposal, SCHs that wished to receive the wage index of another area within their State under this provision needed only to notify CMS in writing, at the address in the "Addresses" section provided for comments on the proposed rule, before the close of the comment period. The notification should have contained:

- The hospital's name and street address.
- The hospital's provider number.

- The name, title, and telephone number of a contact person for communications.

- A statement certifying the SCH status.

- The name of the area within the State whose wage index the hospital wishes to adopt.

Comment: Many commenters expressed their support of our proposal and providing us with notification that they meet the conditions for receiving this exception.

Response: We will adjust the wage indexes of these hospitals accordingly. We have listed these hospitals, and their wage index assignments, in Table 9B of the Addendum to this final rule.

Comment: One commenter expressed support for the provision and noted that it would have qualified for the exception, except that it had been designated as a CAH effective July 1, 2004. This hospital requested that we provide the exception retroactively back to April 1, 2004, the date on which the commenter would have begun to receive an adjustment under section 508 of the MMA if it had been able to qualify.

Response: We do not believe that it would be appropriate to provide this adjustment retroactively. Doing so runs counter to the basis for payment in a prospective payment system. We would note that the hospital is now receiving payment on a favorable basis at 101 percent of cost as a CAH.

Comment: One commenter expressed concern regarding CMS's proposal to allow an SCH located in one of 5 identified low-population density States to adopt the wage index of another geographic area within its State for 3 years. The commenter objected to the proposal on the basis that because CMS is not proposing a broader exception, hospitals such as the SCHs and other hospitals who met criteria under section 508 in the commenter's State, are being disadvantaged given the fact that hospitals in neighboring States will be reclassified.

Response: As we noted in the proposed rule, we believe that given the pressing issues associated with wage index assignment issues for hospitals in States with low population densities, the likelihood that, in such States, employees are likely to commute greater distances to work, and the fact that more distant areas are thus likely to compete for labor than is the case in more densely populated States. Given these circumstances, we continue to believe that such an exception for these SCHs is warranted. Therefore, in this final rule, we are finalizing the special exception provision, as proposed, by adjusting the wage indexes of those

SCHs that provided notification that they met the conditions for receiving this exception.

5. Possible Reclassifications for Dominant Hospitals and Hospitals in Single-Hospital MSAs

In the May 18, 2004 proposed rule (69 FR 28290), we indicated that representatives of individual hospitals had expressed concern about the special circumstances of dominant hospitals and hospitals in single-hospital MSAs in relation to the wage index and the rules governing geographic reclassification. The term "dominant hospital" generally refers to a hospital that pays a substantial proportion of all the wages paid by hospitals geographically located in the hospital's area. A dominant hospital necessarily has a preponderate influence on the wage index calculation for the area in which it is located. As a result, dominant hospitals find it difficult to meet the threshold requirements for wage index reclassification; for example, the requirement that an urban hospital's average hourly wage is at least 108 percent of the average hourly wage of hospitals in the area in which the hospital is located (§ 412.230(e)(1)(iii)(B)). Indeed, a dominant hospital would find it difficult to meet any threshold based on the ratio of the hospital's average hourly wage to the average hourly wage of hospitals in the area, unless the dominant hospital's wage data were removed from the denominator for purposes of the comparison. Dominant hospitals have argued that this places them in an unfair situation. While the lower wages of other, smaller hospitals in the area can still have the effect of holding down their wage index, their dominant position makes it difficult, or even impossible, to reclassify to another area where the wage index may more closely reflect their costs.

Hospitals in single-hospital MSAs face a situation that is similar in certain respects, but quite different in others. By definition, the wage index for the sole hospital in an MSA is based completely on that hospital's wage data. Such a hospital receives, in effect, its own unique wage index, reflecting the hospital's exact position in relation to the national average hourly wage. As a result, these hospitals cannot qualify for reclassification, unless they are exempt from the wage threshold requirements due to rural referral center status. By definition, the ratio of such a hospital's average hourly wages to the area average hourly wage is always 100 percent, and these hospitals thus cannot meet either the 108 percent threshold for urban

hospitals or the 106 percent threshold for rural hospitals (§ 412.230(e)(1)(iii)(B)). Unlike dominant hospitals, hospitals in single-hospital MSAs cannot argue that they are disadvantaged by the effect that lower wage hospitals can have on the area wage index. However, these hospitals have contended that they are sometimes in the position of competing for labor with hospitals in nearby MSAs with higher wage indexes. Under these circumstances, these hospitals cannot reclassify to the higher wage index area even if they meet the relevant distance requirements. These hospitals also contend that they cannot afford to compete with hospitals that are paid under a higher wage index, and the 3-year lag in the data used to compute the wage index can place them in a permanent position of playing catch up. On the other hand, it is also true that such a disadvantage may be only temporary because increasing wages may eventually equalize wage index values despite the temporary financial disadvantage that would accrue to these hospitals during the 3-year lag period.

In the proposed rule, we invited comment on the concerns raised by hospitals in these two situations and on possible methods of addressing these concerns. We indicated that a number of measures might be considered to address the concerns of these hospitals. In the case of dominant hospitals, the threshold requirements for reclassification could be revised to provide that a hospital's average hourly wage is at least 108 percent (in the case of urban hospitals) or 106 percent (in the case of rural hospitals) of the average hourly wages of all other hospitals in the area. Removing a dominant hospital's wages from the denominator of the ratio would remove the current disadvantage imposed by their dominant status, and make it more realistic for a dominant hospital to meet the threshold requirement. An existing provision under § 412.230(e)(4) provides this treatment for certain dominant hospitals, specifically those that were approved for reclassification each year from 1992 through 1997. We could develop a parallel provision that applies to dominant hospitals generally. The use of this revised ratio could be restricted to the special circumstances of dominant hospitals, or extended to all hospitals. We could also adopt a revised threshold for dominant hospitals, as we did in the notice setting forth the criteria for reclassification under the one-time wage index appeal provision of section 508 of Public Law 108-173 (69 FR 7342). Consistent with the

criteria from that notice, a dominant hospital might be defined for this purpose as a hospital that pays at least 40 percent of all the wages paid by hospitals geographically located in the hospital's area. We indicated that we were considering adopting one of these measures in the final rule, and invited comments on the advisability of doing so.

In the case of hospitals in single-hospital MSAs, we cited one new provision that we had proposed to implement in this proposed rule that might address some of their concerns (see section III.G.3.2. of the preamble of the proposed rule). Section 505 of Public Law 108-173 provides for a new wage index adjustment for hospitals in lower wage areas in cases where significant numbers of hospital workers commute from the lower wage area to higher wage areas nearby. The statute requires that at least 10 percent of the hospital workers in a county must be commuting to a higher wage area, or areas, in order for the hospitals in the county to receive the adjustment. The adjustment formula provides for an increase to the wage index for hospitals in the county, based on the differences between the wage index that applies to the county and the higher wage indexes of nearby areas, in proportion to the percentages of hospital workers commuting to the higher wage index areas. To the degree that hospitals in single-hospital MSAs experience disadvantages in competing for hospital workers with hospitals in higher wage index areas, we expect that the counties in which these hospitals are located would qualify for this adjustment. We also indicated that we were actively considering whether to address the concerns of these hospitals more directly. At the same time, we intended to analyze the extent to which this provision would alleviate the concerns of these hospitals. We welcomed comments on the special circumstances of hospitals in single-hospital MSAs and whether their special circumstances should be addressed by revisions to the regulations governing reclassification, or other measures.

Comment: A number of commenters expressed support for adopting a provision to address the concerns of dominant hospitals. Several commenters supported defining a dominant hospital as a hospital that pays at least 40 percent of all wages paid by hospitals geographically located in the hospital's MSA, and providing that any hospital so defined should be "given the same reclassification options as rural and urban rural referral centers." One of these commenters

further recommended that dominant hospitals should be entitled to the full implementation of the occupational mix adjustment. Other commenters recommended that we consider revising § 412.230(e)(4) to eliminate the requirement that the applicant hospital “was approved for redesignation * * * for each year from fiscal year 1992 through fiscal year 1997.” The effect of this revision would be that the test for dominant hospitals would be that the three-year AHW be at least 108 percent (106 percent for rural hospitals) of the three-year AHW of all the other hospitals in the area. Other commenters supported the idea that, for purposes of determining the AHW of the area where the hospital is located, the 108/106 percent test should be revised for all hospitals so that applicant hospitals are required to compare their AHWs to all the other hospitals in the area. One of these commenters argued that including a hospital’s own AHW in the equation does not support the underlying purpose of the 108/106 percent test, which is for the hospital to demonstrate that its wage costs are disproportionately high when compared to its neighbors. Other commenters recommended that we exempt dominant hospitals altogether from the 108/106 percent threshold requirement or consider a new threshold requirement for reclassification that would be at least 110 percent of all other hospitals in the MSA. One commenter recommended that CMS consider establishing criteria that would give special consideration to these hospitals by, for example, allowing a dominant hospital to reclassify to MSAs that are “less than 55 miles” from the MSA where the hospital is located. Finally, some commenters expressed opposition or hesitation about providing any special provision to address the concerns of the dominant hospitals. MedPAC, for example, suggested that the new out-commuting adjustment is a promising approach, observing that the blended formulation of that adjustment, which generally yields a lower wage index than traditional reclassification, might be appropriate since these hospitals have an above-average degree of influence on the wage indexes of the areas where they are located.

Response: We are persuaded that it is equitable, as a matter of general policy for all hospitals, to revise the wage comparison formula for all hospitals in the manner recommended by some of the commenters. Specifically, in this final rule we are revising the regulations at § 412.230(e)(1)(iii)(B) to provide that, in order to qualify for reclassification,

the hospital’s average hourly wage is at least 106 percent (in the case of a hospital located in a rural area) or at least 108 percent (in the case of a hospital located in an urban area), of the average hourly wage of all other hospitals in the area in which the hospital is located. While this revision addresses, at least in part, the concerns of the dominant hospitals, and while it will allow some dominant hospitals to qualify for reclassification, this is not the primary consideration in favor of this revision to the regulations. The predominant consideration is rather the general point that the purpose of the comparison test is to distinguish whether a hospital is sufficiently different in terms of the wages it pays from other hospitals in its geographic region. Defining the ratio in terms of all other hospitals in the area captures the appropriate comparison more precisely. Therefore, we are also not adopting any of the other alternatives suggested.

Comment: A number of commenters also expressed support for adopting a provision to address the concerns of hospitals that are the only hospitals in an MSA. Several commenters recommended that CMS consider exempting hospitals in single hospital MSAs from the 108/106 percent threshold requirement. One commenter suggested that CMS consider using its discretion to either eliminate or significantly reduce the number of single hospital MSAs by, merging into the nearest MSA only those single hospital MSAs whose hospitals meet the 84 percent threshold requirement, merging all single hospital MSAs into the closest MSA, for purposes of the wage index, or allowing hospitals in single hospital MSAs to reclassify to the closest MSA if they satisfy all of the RRC criteria except for the rural location requirement. One commenter recommends that CMS exercise its discretion to implement a 4-year transition period for hospitals in single hospital MSAs. The transition period would, in addition to protecting these hospitals from financial hardship, allow them the opportunity to equalize their wage index without experiencing any temporary adverse financial impact. The commenter further suggests that during the transition period these hospitals should be afforded the same exemption as RRCs under § 412.230(e)(3). The commenter argued that, by allowing these providers to be paid at a higher wage index they will, in turn, be in a better position to raise wage levels and compete with neighboring urban hospitals. As in the case of the dominant hospitals, MedPAC suggested

that the new out-commuting adjustment is a promising approach for addressing this issue.

Response: We have decided not to adopt any of the policy changes proposed by commenters concerning the issue of single hospital MSAs at this time. We agree with MedPAC that the new out-commuting provision is a promising vehicle for addressing the concerns raised by hospitals in single-hospital MSAs. To the degree that hospitals in single-hospital MSAs experience disadvantages in competing for hospital workers with hospitals in higher wage index areas, we would expect that the counties in which these hospitals are located would exhibit rates of commuting by hospital workers to the higher wage index areas that might meet the threshold for receiving the adjustment. We also agree with MedPAC that the adjustment under this provision, which generally yields a lower wage index than traditional reclassification, may be appropriate since the wage indexes for these hospitals are calculated solely on the basis of the hospitals’ own wage data. Although certain of the hospitals in single-hospital MSAs that have contacted us about their situations do not qualify for the adjustment this year, we believe that it is appropriate to gain more experience with the workings of this new provision before we adopt any policy revisions designed to address separately reclassification by these hospitals.

6. Special Circumstances of Hospitals in All-Urban States

Section 4410 of Public Law 105–33 (BBA) provides that, for the purposes of section 1886(d)(3)(E) of the Act, for discharges occurring on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in the State. This provision, commonly referred to as the “rural floor,” affects the payments received by 150 hospitals in 49 MSAs in FY 2004. For these 150 hospitals, the applicable wage index and overall payment amounts under the IPPS are higher than they would be if their wage indexes were computed solely on the basis of the wage data from their MSAs. The wage index floor is applied in a budget neutral manner, so that aggregate IPPS payments each year are not greater or less than those that would have been made in the absence of this provision.

In the May 18, 2004 proposed rule (69 FR 28291), we discussed the fact that the “rural floor” under section 4410 of

Public Law 105–33 does not apply in the two States that have no rural areas under the labor market definitions that apply within the IPPS. In the past, hospitals in those two States had commented that the absence of a rural floor disadvantages them for wage index purposes compared to hospitals in States where the “rural floor” provision can apply. Specifically, some hospitals contend that they would have higher wage indexes, and higher payments overall, if there were a rural area in their State to set a floor under the wage indexes within the State.

In the proposed rule, we indicated that we were considering whether it would be appropriate to adopt some measure to address the concerns of these hospitals. For example, we indicated that we were examining the ratios between the lowest and highest wage index values in States where the “rural floor” affects the wage indexes of some hospitals. We further indicated that we might consider employing the average ratio of highest-to-lowest wage indexes in those States to set an imputed “rural floor” for all-urban States. For example, assume the average “lowest-to-highest” ratio of States with rural floors is 0.9500. Assume further that the lowest wage index in an all-urban State is 1.0000, and the highest is 1.1000. The “lowest-to-highest” ratio for that State is 0.9091. If we apply the average “lowest-to-highest” ratio to the highest wage index in the all-urban State, we would multiply 0.9500 by 1.1000, which yields 1.0450. The imputed analogue to the “rural floor” for the all-urban State would then be 1.0450. Any hospital with a regular wage index value less than 1.0450 would then receive the new imputed floor.

In the proposed rule, we welcomed comments on the position of hospitals in all-urban States relative to hospitals that receive the “rural floor” in other States. We also welcomed comments on whether it would be advisable to adopt an imputed floor measure or some alternative measure to address the concerns of hospitals in these States. We noted that, in order to be consistent with the statutory provision establishing the rural floor, we would apply any such measure in budget neutral manner, that is, we would adjust the standardized amount so that aggregate IPPS payments each year are not greater or less than those that would have been made in the absence of this provision.

Comment: We received a number of comments in favor of proceeding with a provision to establish an imputed floor in all-urban states. These commenters asserted that the absence of a rural floor

does disadvantage them for wage index purposes compared to hospitals in States where the “rural floor” provision can apply.

While generally supportive of our proposal, these commenters offered alternative suggestions to the example we had provided about how the formula for determining such an imputed floor might work. For example, one commenter suggested using the median, instead of the average, ratio of the highest to lowest wage indexes in the States where a rural floor could potentially affect the wage indexes of some hospitals. This formulation, according to the commenter, would provide more predictability and would be subject to less distortion as situations change in the States with rural floors. Other commenters recommended expanding any provision for an imputed rural floor to at least one additional State, which has geographic rural areas, but no hospitals actually classified as rural.

Response: We agree with the commenters that any provision to provide an imputed floor for States without rural areas should also apply to any State which has geographic rural areas but no hospitals actually classified as rural. Using this definition, there are three States that can be considered all-urban for the purposes of this provision. As discussed in more detail below, we also agree with the commenters that a variation of the methodology that we suggested in the final rule is more appropriate for determining the level of the imputed floor. Specifically, we believe that the most appropriate methodology is to compare the average ratio of lowest-to-highest wage indexes of the three all-urban States to the ratio of the lowest-to-highest wage index of each of those States individually. For each State, we would base the imputed floor on the higher of these two ratios. Therefore, in this final rule, we are revising the regulations at § 412.64(h) to describe the methodology for computing the minimum wage index value for all-urban states and to define an all-urban State.

Comment: Some commenters objected to the establishment of an imputed floor in all-urban States. These commenters contended that any special provision for urban-only States should be subject to legislative action.

Response: Although we appreciate the commenters’ observation, we would note that the Secretary has broad authority under section 1886(d)(3)(E) of the Act to “adjust the proportion (as estimated by the Secretary from time to time) of hospitals’ costs which are attributable to wages and wage-related

costs of the DRG prospective payment rates *—*—* for area differences in hospital wage levels by a factor (established by the Secretary) * * *” (Emphasis added). Therefore, we believe that we do have the discretion to adopt a policy that would adjust wage areas in the stated manner.

Comment: Some commenters also pointed out that other States, including those with rural floors, face various inequities in the wage index system, and recommended that a more general solution would be preferable to piecemeal approaches such as an imputed floor for only a few States. Finally, some commenters objected because they were not persuaded that the problem described was sufficiently serious to justify a special protection for a few States that would require a reduction in the rates paid to all hospitals.

Response: We appreciate the reservations expressed by the commenters opposing the policy that we discussed in the May 18, 2004 proposed rule. While we are adopting a policy that establishes an imputed floor for the three all-urban States in this final rule, we are limiting this policy change to 3 years (that is, FYs 2005, 2006, and 2007). During that time, we will monitor the operation of this policy in these all-urban States and determine whether to make additional changes to the policy or eliminate it.

In this final rule, we are adopting a variation of the policy that we discussed in the May 18, 2004 proposed rule. We note first that there are similarities among the three States that are not impacted by the rural floor. Obviously, they are urban States. In addition, each of the three States has one predominant labor market area. That, in turn, forces hospitals that are not located in the predominant labor market area to compete for labor with hospitals that are located in that area. However, because there is no “floor” to protect those hospitals not located in the predominant labor market area from facing continued declines in their wage index, it becomes increasingly difficult for those hospitals to continue to compete for labor. In the BBA, Congress spoke of an “anomaly” in States where hospitals located in urban areas had a wage index that was below the wage index applicable for hospitals located in rural areas. (See H.R. Rep. No. 149, 105th Cong., 1st Sess. At 1305.) We think it is also an anomaly that hospitals in all-urban States with predominant labor market areas do not have any type of protection, or “floor,” from declines in their wage index. Therefore, we are adopting the logic similar to that

articulated by Congress in the BBA and are adopting an imputed rural policy for a 3-year period.

In the proposed rule, we suggested a policy option that would have developed a ratio of the lowest-to-highest wage index for all States that had a rural wage index and therefore, had the potential to be impacted by the rural floor. Based on the comments that we have received, and based on the similarities between the three all-urban States, we think that it is more appropriate to compare the three individual all-urban States to those three States as a class. Under the proposed rule, we suggested that we would analyze the average ratio of the lowest-to-highest wage indexes of all States potentially affected by the rural floor. Under the policy we are adopting in this final rule, we compare the average ratio of the lowest-to-highest wage indexes (occupational mix-adjusted, both prereclassification and postreclassification) of the three all-urban States to the ratio of the lowest-to-highest wage index (occupational-mix adjusted, both prereclassification and postreclassification) of each of those States individually. We note that in doing so, we consider only the wage indexes of all-urban States in the mainland United States. The Commonwealth of Puerto Rico is also an urban area that does not benefit from the rural floor because there are no hospitals located in rural areas in Puerto Rico. However, there are sufficient differences between Puerto Rico and the three mainland all-urban states. For example, the highest area wage index in the Commonwealth of Puerto Rico is 0.5230; by contrast, the lowest wage index in the three mainland all-urban States is almost twice as high. Moreover, the lowest-to-highest ratio of wage indexes in Puerto Rico is significantly less than the lowest-to-highest ratio of wage indexes of any State on the mainland United States. Moreover, Puerto Rico hospitals are paid on a blended Federal/Commonwealth-specific rate. We therefore, do not believe that it is appropriate to consider the wage indexes of Puerto Rico hospitals in the development of this policy.

Under our final rule, we would then take the higher of those two numbers (that is, the State-specific ratio and the average ratio of the three all-urban States) and multiply it by the highest area wage index applicable in a State (again, we would look at the postreclassification wage indexes). The product is the imputed "floor," below which no wage index in the State could fall. In order to account for the fact that

some hospitals receive a blended wage index (see section III.B.3.d. of this final rule), we computed these ratios, and the corresponding imputed floors, separately using the old labor market definitions and the new labor market definitions. We then compared the blended wage indexes (that is, the wage index determined on the basis of the old labor market areas, and the wage index determined on the basis of the new labor market areas) separately with the corresponding imputed floors.

As a result, hospitals receiving a blended wage index could be at the floor for neither wage index, for their old labor market wage index alone, for their new labor market wage index alone, or for both wage indexes. After this determination, we blended the two wage indexes (including the effects of the imputed floor on each side): 50 percent of the wage index determined on the basis of the old labor market areas (whether at the floor level or above), and 50 percent of the wage index determined on the basis of the new labor market areas (whether at the floor level or above).

7. Geographic Reclassifications for SNFs

Several SNFs indicated support for our proposal to implement the new CBSA designations for IPPS hospitals. They also commented that our continued delay in implementing a reclassification system for SNFs, as authorized by section 315 of BIPA, places Medicare SNFs at an unfair disadvantage in competing with reclassified hospitals for professional staff.

We appreciate the commenters' support for our proposed adoption of the new CBSA designations for IPPS hospitals. With respect to the comment regarding the implementation of a SNF reclassification system, section 1888(e)(4)(G)(ii) of the Act requires that we adjust the Federal rates for SNFs to account for differences in area wage levels using a wage index that we find appropriate. Since the inception of a PPS for SNFs, we have used hospital wage data in developing a wage index to be applied to SNFs. Section 315 of the BIPA does authorize us to establish a reclassification system for SNFs, similar to the hospital methodology. However, the statute makes this change contingent upon the collection of the data necessary to establish an area wage index for SNFs based on SNF wage data. As part of our ongoing program analysis, we periodically reevaluate the suitability of establishing an SNF-specific wage index and a provider reclassification methodology. However, we note that, in order to effect such

changes, we must first be able to provide reasonable assurance as to the accuracy of the underlying cost report data and the equitable distribution of funds under the new methodology.

O. Payment for Direct Graduate Medical Education (Existing § 413.86)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99-272) and implemented in regulations at existing § 413.86, establishes a methodology for determining payments to hospitals for the costs of approved GME programs. Section 1886(h)(2) of the Act, as added by COBRA, sets forth a payment methodology for the determination of a hospital-specific, base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable costs of GME for a base period by its number of residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, the period of October 1, 1983 through September 30, 1984). The PRA is multiplied by the weighted number of full-time equivalent (FTE) residents working in all areas of the hospital (and nonhospital sites, when applicable), and the hospital's Medicare share of total inpatient days to determine Medicare's direct GME payments. In addition, as specified in section 1886(h)(2)(D)(ii) of the Act, for cost reporting periods beginning on or after October 1, 1993, through September 30, 1995, each hospital-specific PRA for the previous cost reporting period is not updated for inflation for any FTE residents who are not either a primary care or an obstetrics and gynecology resident. As a result, hospitals that train primary care and obstetrics and gynecology residents, as well as nonprimary care residents in FY 1994 or FY 1995, have two separate PRAs: one for primary care and obstetrics and gynecology and one for nonprimary care.

The BBRA (Pub. L. 106-113) amended section 1886(h)(2) of the Act to establish a methodology for the use of a national average PRA in computing direct GME payments for cost reporting periods beginning on or after October 1, 2000, and on or before September 30, 2005. The BBRA established a "floor" for hospital-specific PRAs equal to 70 percent of the locality-adjusted national average PRA. In addition, the BBRA established a "ceiling" that limited the annual adjustment to a hospital-specific PRA if the PRA exceeded 140 percent of the locality-adjusted national average

PRA. Section 511 of the BIPA (Pub. L. 106–554) increased the floor established by the BBRA to equal 85 percent of the locality-adjusted national average PRA. Existing regulations at § 413.86(e)(4) specify that, for purposes of calculating direct GME payments, each hospital-specific PRA is compared to the floor and the ceiling to determine whether a hospital-specific PRA should be revised.

Section 1886(h)(4)(F) of the Act established caps on the number of allopathic and osteopathic residents that hospitals may count for purposes of calculating direct GME payments. For most hospitals, the caps were the number of allopathic and osteopathic FTE residents training in the most recent cost reporting period ending on or before December 31, 1996.

Comment: Several commenters noted that policy experts are beginning to forecast shortages in physician supply in the near future. One commenter stated: “[a]s presented at the Federal [Council on Graduate Medical Education] meeting, the physician workforce analysis indicated that while the supply of physicians is expected to increase over the next two decades, demand for services is likely to grow even more rapidly. According to the analysis, the three major factors driving the increase in demand will be the projected U.S. population growth of 18 percent between 2000 and 2020, the aging of the population as the number of Americans over 65 increases from 35 million in 2000 to 54 million in 2020, and the changing age-specific per capita physician utilization rates, with those under age 45 using fewer services and those over age 45 using more services. The analysis notes that changing work patterns of physicians, such as decreases in working hours, could lead to greater shortfalls, while increases in productivity could moderate any shortfalls.”

In response to the projected physician shortfall, one commenter urged CMS to work with Congress “to explore expansion of physician training opportunities if research demonstrates a need for more U.S. medical school graduates.” These commenters argued that Congress should lift the statutorily mandated 1996 FTE caps for direct GME and IME. Stated another commenter: “[i]t is time for the Medicare resident caps to be lifted. While Medicare has periodically imposed other types of regulatory ‘freezes,’ these have always been temporary. The current caps have been in place for over six years—far exceeding what typically would be viewed as reasonable.”

Response: We appreciate the commenters’ concern about the

statutory 1996 caps on the count of FTE residents for purposes of direct GME and IME payments, particularly in light of the alleged national physician shortage. If the Congress considers further legislation regarding the cap on the number of residents that may be counted for Medicare payment purposes, CMS would provide assistance to Congress and the provider industry on this issue.

Note to Readers: This final rule includes a major redesignation of the contents of § 413.86. As a result of the numerous amendments we have made over the years, the size of § 413.86 has become voluminous and difficult to follow because of the multiple levels of coding. We are taking a first step to split the one section (§ 413.86) into nine individual sections (§§ 413.75 through 413.83). We are designating each first level paragraph under existing § 413.86 as a separate new section and vacate § 413.86. At this time, we are not making any changes in the language of these new redesignated sections, except for the changes that are discussed in section IV.O. of this preamble (which conform to the existing language of § 413.86) and any appropriate cross-reference and conforming changes. We are providing a detailed crosswalk of the existing paragraphs of § 413.86 to the new §§ 413.75 through 413.83. In addition, in any discussion of changes we are making, we are providing both the existing citation under § 413.86 and the redesignated section and paragraph. At a later date, we may further refine the contents of the redesignated sections to improve readability.

2. Reductions of and Increases in Hospitals’ FTE Resident Caps for GME Payment Purposes Under Section 422 of Public Law 108–173 (Redesignated § 413.79 (a Redesignation of § 413.86(g))

a. General Background on Methodology for Determining the FTE Resident Count

As we explain earlier in this preamble, Medicare makes both direct and indirect GME payments to hospitals that train residents in approved medical residency training programs. Direct GME payments are made in accordance with section 1886(h) of the Act, based generally on hospital-specific PRAs, the number of FTE residents a hospital trains, and the hospital’s Medicare patient share. IME payments are made in accordance with section 1886(d)(5)(B) of the Act, based generally on the ratio of the hospital’s FTE residents to the number of hospital beds. Accordingly, the calculation of both direct GME and IME payments is affected by the number of FTE residents that a hospital is allowed to count; generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt

to end the implicit incentive for hospitals to increase the number of FTE residents, Congress instituted a cap on the number of allopathic and osteopathic residents a hospital is allowed to count for direct GME and IME purposes under the provisions of section 1886(h)(4)(F) of the Act for direct GME and section 1886(d)(5)(B)(v) of the Act for IME. Dental and podiatric residents were not included in this statutorily mandated cap.

b. Reduction of Hospitals’ FTE Resident Caps Under the Provisions of Section 422 of Public Law 108–173

Medicare makes direct GME and IME payments based only on the number of FTE residents that is within a hospital’s FTE resident cap. Some hospitals have trained a number of allopathic and osteopathic residents in excess of their FTE resident caps. Other hospitals have reduced their resident counts to some level below their FTE resident caps. Section 422 of Public Law 108–173 added a new section 1886(h)(7) to the Act to provide for reductions in the statutory resident caps under Medicare for certain hospitals and authorize a “redistribution” of the FTE resident slots resulting from the reduction in the FTE resident caps to other hospitals.

The new section 1886(h)(7)(A) of the Act provides that a hospital’s FTE resident cap will be reduced if its reference resident level, as described below, is less than its otherwise applicable FTE resident cap. Rural hospitals with less than 250 acute care inpatient beds are exempt from these reductions. For other hospitals, any such reduction will be equal to 75 percent of the difference between the hospital’s otherwise applicable FTE resident cap and its reference resident level.

Under the new section 1886(h)(7)(B) of the Act, the Secretary is authorized to increase the otherwise applicable FTE resident caps for certain categories of hospitals for portions of cost reporting periods occurring on or after July 1, 2005, by an aggregate number that does not exceed the estimated overall reduction in FTE resident caps for all hospitals under section 1886(h)(7)(A). A single hospital may receive an increase in its FTE resident cap of no more than 25 additional FTEs. In determining which hospitals would receive an increase in their FTE resident caps, section 1886(h)(7)(B) of the Act directs us to—

- Take into account the demonstrated likelihood of the hospital filling the additional positions within the first three cost reporting periods beginning on or after July 1, 2005.

- Establish a priority order to distribute resident slots first to programs in hospitals located in rural areas; second, to urban hospitals that are not in large urban areas; and third, to other hospitals operating a training program in a State where there is no other training program for a particular specialty in the State.

In summary, section 422 of Public Law 108–173 added a new section 1886(h)(7) of the Act that prescribes a methodology for determining reductions to certain hospitals' FTE resident caps based on unused FTE resident slots, provides for certain exceptions to the FTE resident cap reductions, and includes general criteria that CMS must consider in making a "redistribution" to other hospitals of the estimated number of FTE resident positions resulting from the reductions in the FTE resident caps. In this final rule, we are establishing procedures for determining whether, and by what amount, a hospital's FTE resident cap is subject to a reduction under section 1886(h)(7) of the Act. We also are specifying an application process for hospitals that seek to receive increases in their FTE resident caps and the specific criteria that we will use to determine which hospitals will receive the increases in their FTE resident caps under section 1886(h)(7)(B) of the Act.

c. Hospitals Subject to the FTE Resident Cap Reduction

As indicated earlier, section 1886(h)(7)(A) of the Act, as added by section 422 of Public Law 108–173, provides that if a hospital's "reference resident level" is less than its "otherwise applicable resident limit," its "otherwise applicable resident limit" will be reduced by 75 percent of the difference between its "otherwise applicable resident limit" and its "reference resident level." Under the amendments made by section 422, the "reference resident level" generally refers to the number of unweighted allopathic and osteopathic FTE residents who are training at a hospital in a given cost reporting period. The "otherwise applicable resident limit" refers to a hospital's FTE resident cap established under sections 1886(h)(4)(F)(i) and (h)(4)(H) of the Act. A hospital's permanent FTE cap under section 1886(h)(4)(F)(i) of the Act is based on (1) for an urban hospital, the number of unweighted allopathic or osteopathic FTE residents in the hospital's most recent cost reporting period ending on or before December 31, 1996 (the "1996 cap"), adjusted as specified under existing regulations at § 413.86(g)(4) (redesignated § 413.79(c)(2)), and, if applicable, the

1996 cap adjusted for new programs as specified under existing § 413.86(g)(6) (redesignated § 413.79(e)); or (2) for a rural hospital, 130 percent of the 1996 cap, adjusted as specified under existing § 413.86(g)(4) and, if applicable, 130 percent of the 1996 cap adjusted for new programs as specified under § 413.86(g)(6), or 130 percent of the 1996 cap with both adjustments. We also note that a hospital's 1996 cap may be adjusted in other instances (such as temporary adjustments for program or hospital closure) if the hospital is a member of a Medicare GME affiliated group under existing § 413.86(b) (redesignated § 413.75(b)), but we will discuss the applicability of affiliations under section 1886(h)(7)(A) of the Act in more detail at section IV.O.2.f.(5) of this preamble.

In our discussion of the provisions of section 422 of Public Law 108–173 under this section of this final rule, we will generally refer to a hospital's number of unweighted allopathic and osteopathic FTE residents in a particular period as a hospital's "resident level." We will also refer to a hospital's resident level in the applicable "reference period," as explained further below, as the hospital's "reference resident level." In addition, we will refer to the "otherwise applicable resident cap" as the hospital's FTE resident cap that is applicable during a particular cost reporting period. Thus, as we proposed in the May 18, 2004 proposed rule (69 FR 28293), we are providing that if a hospital's resident level is less than the hospital's otherwise applicable resident cap in the "reference period" (as explained below), effective for portions of cost reporting periods occurring on or after July 1, 2005, we will permanently reduce the hospital's FTE resident cap by 75 percent of the difference between the reference resident level and the otherwise applicable FTE resident cap. For example, if a hospital's otherwise applicable FTE resident cap for the reference period is 100, and its resident level for that period is 80 FTEs, we will reduce the hospital's FTE resident cap by 15 FTEs $[0.75 (100 - 80)] = 15$. (Redesignated § 413.79(c)(3)).

Comment: One commenter expressed concern that the reduction to the FTE resident cap of a hospital that has had trouble filling vacancies in certain specialty programs may jeopardize the funding available for residents training in programs that the hospital has been able to fill. The commenter asked that CMS further analyze the impact that "slot re-allocations" could have on other specialties at a particular hospital, and should consider the effect that such

reductions may have on the overall availability of services to patients.

Response: Although the commenter may be concerned about the impact that cap reductions may have on a hospital's ability to provide patient care and maintain its residency programs at historical levels, we do not believe we have the authority to design and implement a "re-allocation" process that considers such factors. Rather, as explained in response to other comments, under section 1886(h)(7)(A)(i), the Secretary is directed to reduce the FTE resident caps of hospitals in instances where the resident levels were below the FTE resident caps in the reference cost reporting period. There is no statutory provision that authorizes CMS to consider the overall impact on patient care delivery or on residency training in making reductions to FTE resident caps.

d. Exemption From FTE Resident Cap Reduction for Certain Rural Hospitals

Section 1886(h)(7)(A)(i)(II) of the Act, as added by section 422 of Public Law 108–173, specifically exempts rural hospitals (as defined in section 1886(d)(2)(D)(ii) of the Act) with less than 250 acute care inpatient beds from the possible 75 percent reduction to their FTE resident caps. Section 1886(d)(2)(D)(ii) of the Act defines a rural area as any area outside a Metropolitan Statistical Area (MSA). Under the existing regulations at § 413.62(f)(ii), an "urban area" means (1) a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA); or (2) the following New England counties: Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island. Under existing § 413.62(f)(iii), a "rural area" means any area outside an urban area. In addition, we note that under section III. of this preamble, which discusses wage areas, we are no longer recognizing NECMAs as a distinct category of wage areas. Thus, for purposes of the amendments made by section 422, we are providing that any hospital located in an area that is not in a MSA is a rural hospital, regardless of any reclassification under § 412.102 or § 412.103. We note that this definition of "rural" is consistent with our policy under section III. of this preamble concerning designation of wage index areas.

A hospital's bed size is based on its number of available beds, as determined for IME payment purposes under § 412.105 of the regulations. For purposes of determining whether a rural

hospital has less than 250 beds, in the May 18, 2004 proposed rule (69 FR 28293), we proposed to use data from the rural hospital's most recent cost reporting period ending on or before September 30, 2002. (This information may be found on Worksheet S-3, Part I of the Medicare cost report, CMS-2552-96, the sum of lines 1 and 6 through 10 in column 2, minus line 26 in column 6, divided by the number of days in the cost reporting period.) This is the cost reporting period under section 1886(h)(7)(A)(ii)(I) of the Act that is to be used in determining a hospital's reference resident level (the unweighted allopathic and osteopathic FTE resident count) (unless a hospital makes and CMS grants a timely request under section 1886(h)(7)(A)(ii)(II) of the Act). We proposed that if a rural hospital has less than 250 beds in its most recent cost reporting period ending on or before September 30, 2002, the hospital would not be subject to a possible reduction to its FTE resident cap under section 1886(h)(7)(A) of the Act. However, if a rural hospital has at least 250 beds in its most recent cost reporting period ending on or before September 30, 2002, we proposed that the rural hospital would be subject to a possible reduction to its FTE resident cap. (Proposed redesignated § 413.79(c)(3)(i).)

Comment: Several commenters inquired as to whether our proposed changes for wage areas, if finalized, would affect a teaching hospital's status as urban or rural for purposes of section 422. Specifically, the commenters asked how a hospital that is currently located in a rural area (that is, non-MSA), but under our proposals for wage areas, would be located in an MSA effective October 1, 2004, would be treated for purposes of determining if and by much its FTE resident cap would be reduced. The commenter also questioned whether it would be considered a rural hospital under the first and second level priority categories under the criteria for determining whether the hospital will receive increases in its FTE resident caps. Several commenters believed that any hospital that was considered rural during the most recent cost reporting period ending on or before September 30, 2002 should be considered rural for purposes of section 422 and if reporting less than 250 beds, any resident positions below its FTE resident cap should be exempt from redistribution.

Response: Under section 1886(h)(7) of the Act, there are two instances in which a hospital's rural or urban designation could affect determinations made under this section for that hospital. First, under section

1886(h)(7)(A)(i)(II) of the Act, rural hospitals with less than 250 acute care inpatient beds are exempted from the possible 75 percent reduction to their FTE resident caps. Second, section 1886(h)(7)(B)(iii)(I) of the Act, established "hospitals located in rural areas" as the first priority category for CMS to determine which hospitals will receive increases in their FTE resident caps. In both instances, we proposed that, for purposes of the amendments made by section 422, any hospital located in an area that is not in an MSA is a rural hospital, regardless of any reclassification under § 412.102 or § 412.103. However, we did not specify as of what date a hospital must be located in an area that is not an MSA in order to be a rural hospital. That is, a hospital may be located in an area that is not currently in an MSA, but will become an MSA effective October 1, 2004. (Alternatively, a hospital may be located in an area that is currently an MSA, but will become rural effective October 1, 2004.) We believe it is reasonable and consistent with the July 1, 2005 effective date for both reductions and increases in FTE resident caps under section 1886(h)(7) of the Act, to use the urban or rural designation that is in effect on July 1, 2005. Therefore, we are requiring that, for purposes of section 1886(h)(7) of the Act (that is, both for purposes of determining if a hospital is a rural hospital with less than 250 beds, and also whether a hospital qualifies to receive higher priority to receive an increase in its FTE resident caps), a hospital located in an area that is not in an MSA effective October 1, 2004, is a rural hospital. Any hospital that is located in an area that is not currently in an MSA, but will become an MSA effective October 1, 2004, will not be considered a rural hospital for the purpose of applying section 1886(h)(7) of the Act. Alternatively, a hospital located in an area that is currently an MSA, but will become rural effective October 1, 2004, will be considered a rural hospital for the purpose of applying section 1886(h)(7) of the Act.

In section IV.O.2.i. of the preamble to the May 18, 2004 proposed rule, we proposed six priority categories (derived from the priorities established by section 1886(h)(7)(B) of the Act) to determine the order in which hospitals would be eligible to receive increases in their FTE resident caps. The first three priority categories are reserved for rural hospitals (hospitals that are located outside of an MSA as of July 1, 2005). The fourth level priority category is reserved for hospitals located in a

"small" urban MSA (defined as an MSA with a population of less than 1,000,000). And the fifth and sixth level priority categories are reserved for hospitals located in "large" urban areas (defined by section 1886(d)(2)(D) of the Act as an MSA with a population of more than 1,000,000). For purposes of determining the order in which hospitals would be eligible to receive increases in their FTE resident caps under section 1886(h)(7)(B) of the Act, we are requiring that a hospital located in an MSA with a population of less than 1,000,000 effective October 1, 2004, is a "small" urban hospital and that a hospital located in an MSA with a population of more than 1,000,000 effective October 1, 2004 is a "large" urban hospital.

We note that there may be hospitals with less than 250 beds that are currently located outside of an MSA that will be redesignated as of October 1, 2004, to be located within an MSA. As such, these hospitals do not qualify for exemption from FTE resident cap reductions under section 1886(h)(7)(A)(i)(II) of the Act. As stated above, we did not specify in the proposed regulations the date on which a hospital must be in an area that is not an MSA in order to be a rural hospital. Hospitals located outside of an MSA with fewer than 250 beds may have believed that the hospital is exempt from section 1886(h)(7) of the Act and, therefore, failed to consider whether to file a timely request (by June 14, 2004) to use the cost report containing July 1, 2003 (to reflect an expansion of an existing program) or to request that its reference resident level be adjusted to include residents in certain newly approved programs. Therefore, we are allowing hospitals that are redesignated as of October 1, 2004 to be located within an MSA to make a timely request by August 23, 2004 to use the cost report containing July 1, 2003, as the reference cost report if the requirements of 1886(h)(7)(A)(ii)(II) of the Act (expansion of existing programs) are met. Furthermore, we are allowing hospitals that meet the requirements of section 1886(h)(7)(A)(ii)(III) of the Act (expansions under newly approved programs) to request by August 23, 2004 that their reference resident levels be adjusted to include residents in certain newly approved programs.

Comment: One commenter noted that the proposed rule stated that CMS would be addressing, in the IPPS FY 2005 final rule, issues related to determining a hospital's bed count, such as observation beds and unused beds, some of which may be clarifications of existing policy. The commenter asked

for clarification as to whether these policies concerning the bed count will be applied in determining whether a rural hospital with less than 250 beds.

Response: In the May 18, 2004 proposed rule, we proposed that, for purposes of determining whether a rural hospital has less than 250 beds, we would use data from the rural hospital's most recent cost reporting period ending on or before September 30, 2002. We proposed that if a rural hospital has less than 250 beds in its most recent cost reporting period ending on or before September 30, 2002, it would not be subject to a possible reduction to its FTE resident cap under section 1886(h)(7)(A) of the Act. We separately indicated that we plan to address comments concerning unoccupied beds, observation beds, and some other patient day issues that were proposed in the May 19, 2003 IPPS proposed rule in the IPPS final rule for FY 2005. As planned, in § 412.105(b) of this final rule, we have finalized a new policy concerning unoccupied beds, which has a prospective effective date of October 1, 2004. Therefore, the new policy concerning unoccupied beds would not impact the determination of a rural hospital's bed size based on its most recent cost report ending on or before September 30, 2002. We have also amended our policy in this final rule with respect to observation days for patients who are ultimately admitted as inpatients. This policy is a revision of existing policy, the effective date is prospective (October 1, 2004), and consequently, this policy would not impact the determination of a rural hospital's bed size based on its most recent cost report ending on or before September 30, 2002. The other policies that we have finalized concerning dual-eligible days and Medicare+Choice days do not apply to the determination of a hospital's bed size. However, we note that in the August 1, 2003 IPPS final rule, we clarified at 42 CFR 412.105(b)(3) that beds otherwise countable for IME purposes when used for outpatient observation services, skilled nursing swing-bed services, or ancillary labor/delivery services, are excluded from the allowable count of available bed days. Because this policy was a clarification of existing policy, it would apply to the determination of a hospital's bed size in its most recent cost reporting period ending on or before September 30, 2002.

Comment: Some commenters expressed "deep concern" over what they believed is an unintended consequence of section 422 in that rural hospitals with at least 250 beds face possible reductions to their current FTE

resident caps, when those caps were increased by previous legislation that was intended to encourage the growth of residency training in rural areas. The commenters were specifically referring to section 407(b) of Public Law 106-113 (the Balanced Budget Refinement Act (BBRA) of 1999), which provided for a 30 percent increase to rural hospitals' direct GME and IME FTE resident caps, effective April 1, 2000. The commenters explained that the extensive plans they had set in motion to expand their residency programs were nowhere near completion as of their reference cost reporting period under section 886(h)(7)(A). They stated that this "sudden reversal" of the 30 percent increase to their caps would prevent them from meeting their educational and patient care missions in rural communities, and asked that the final rule contain a provision excepting these larger rural hospitals from cap reductions under section 1886(h)(7)(A) of the Act.

Response: We understand that the commenters are in a somewhat unique situation, but we note that Congress specifically limited the exception from the application of section 1886(h)(7)(A) of the Act to rural hospitals with less than 250 beds. We do not believe we have the authority to expand the exception to rural hospitals with 250 beds or more from reductions under section 1886(h)(7)(A) of the Act. However, we believe that if these hospitals have been in the process of increasing the number of residents training in existing programs, they will likely qualify to request that their cost reporting period that includes July 1, 2003 be used as the reference cost reporting period. We believe that, between the effective date of section 407(b) of the BBRA and the cost report that includes July 1, 2003, these hospitals had several years to increase their resident counts. Therefore, a sizeable portion of this increase should be reflected on the cost report that includes July 1, 2003, thereby limiting the amount of slots lost under section 1886(h)(7)(A)(i) of the Act. In addition, because these hospitals are located in a rural area, they would be among those to receive first priority to obtain additional slots if they apply for increases to their FTE resident caps under section 1886(h)(7)(B) of the Act.

e. Determining the Estimated Number of FTE Resident Slots Available for Redistribution

Under section 1886(h)(7)(A) of the Act, we will determine the number of resident positions available for redistribution by estimating possible

reductions to hospitals' FTE resident caps. We believe that section 422 allows us to distinguish between the FTE counts that are used to determine the number of FTE resident slots that are available for redistribution (that is, the "resident pool"), and the actual number of FTE residents by which hospitals' FTE resident caps are ultimately reduced. In the May 18, 2004 proposed rule (69 FR 28293), we proposed to estimate the reduction to a hospital's FTE resident cap under section 1886(h)(7)(A) of the Act for purposes of determining the number of FTEs that a hospital might contribute to the resident pool. This interpretation was based on the language at section 1886(h)(7)(B)(i) of the Act, as added by section 422(a)(3), which states that the "aggregate number of increases in the otherwise applicable resident limits under this subparagraph may not exceed the Secretary's estimate of the aggregate reduction in such limits * * *" (emphasis added). We proposed to interpret this language to mean the aggregate number of FTE residents by which we increase the FTE resident caps of qualifying hospitals under section 1886(h)(7)(B) of the Act must not be more than the estimate of the aggregate number of FTE residents by which we would reduce the FTE resident caps of hospitals whose reference resident levels are less than their otherwise applicable FTE resident caps. However, we could subsequently perform an audit, as described further in section IV.O.2.f.(3) of this preamble, in order to make a final determination regarding any reductions to a hospital's FTE resident cap.

To ensure that we will begin making payments for most hospitals based on the revised FTE resident caps by July 1, 2005, in the May 18, 2004 proposed rule, we proposed to set a date by which we will have estimated a hospital's resident level and compared it to the hospital's otherwise applicable resident cap to estimate whether, and by how much, the hospital's FTE resident cap would be reduced. We did not propose to commit to make a final determination as to whether, and by how much, a particular hospital's FTE resident cap should be reduced as of this date, nor did we propose to commit to inform any hospital that it will receive an increase to its FTE resident cap by this date. Rather, we only proposed to use this date as an internal "deadline" to ensure that we will have sufficient time to distribute the resident pool and begin making payments for most hospitals based on the revised FTE resident caps by July 1, 2005. We proposed that this date be May 1, 2005, and that the date

would apply for all hospitals for purposes of determining an estimate of whether and by how much their FTE resident caps should be reduced.

Accordingly, in the event that the fiscal intermediaries have not completed an audit (explained further under section IV.O.2.f.(3) of this preamble) by May 1, 2005, we proposed that CMS may estimate the number of FTE residents by which a hospital's FTE resident cap should be reduced by May 1, 2005. For example, a fiscal intermediary may estimate by May 1, 2005, that Hospital A's FTE resident cap should be reduced by 10 FTEs. Thus, we would place 10 FTEs into the resident pool. It is possible that even after May 1, 2005, the fiscal intermediary may continue to audit Hospital A's relevant cost report(s) to determine if, in fact, 10 FTEs is the appropriate amount by which to reduce Hospital A's FTE resident cap, and could ultimately conclude that Hospital A's FTE resident cap should only be reduced by 8 FTEs. If the fiscal intermediary makes this final determination by May 1, 2005, we would change the number of FTE residents in the resident pool attributable to Hospital A from 10 FTEs to 8 FTEs. If the fiscal intermediary does not make this determination by May 1, 2005, based on the audit, we would only reduce Hospital A's FTE resident cap by 8 FTEs effective July 1, 2005, but the number of FTE residents in the resident pool attributable to Hospital A would remain at 10 FTEs (the estimated number as of May 1, 2005). Similarly, if the fiscal intermediary ultimately concluded that Hospital A's FTE resident cap should be reduced by 12 FTEs, but this final determination is not made by May 1, 2005, Hospital A's FTE resident cap would be reduced by 12 FTEs effective July 1, 2005, but the number of FTE residents in the resident pool attributable to Hospital A would remain at 10 FTEs.

As we stated above, because we believe that section 422 allows us to distinguish between the FTE counts that are used to determine the size of the resident pool, and the actual number of FTE residents by which hospitals' FTE resident caps are ultimately reduced, we proposed in the May 18, 2004 proposed rule, to use preliminary information in certain instances to estimate possible reductions to hospitals' FTE resident caps. As described further below, sections 1886(h)(7)(A)(ii) and (h)(7)(A)(iii) of the Act direct CMS to adjust the determination of a hospital's reference resident level in certain instances, due to an expansion of an existing program that is not reflected on the most recent settled cost report, or to

include the number of residents for which a new program was accredited, or for hospitals that are members of the same Medicare GME affiliated group as of July 1, 2003. We note that, in adjusting the determination of the reference resident level in these instances, the reference resident level established for purposes of determining possible reductions to a hospital's FTE resident cap under section 1886(h)(7)(A) of the Act may not be the actual or audited number of FTE residents that we would otherwise use for direct GME or IME payment purposes. For example, for expansions under newly approved programs (as explained in more detail in section IV.O.2.f.(3) of this preamble), we proposed to adjust the reference resident level to include the number of residents for which a new program was accredited at a hospital even though, at the time the fiscal intermediary is determining possible reductions to a hospital's FTE resident cap, the hospital may not be training the full complement of residents for which the program was accredited. Thus, the number of FTE residents (including those training in the newly accredited program) for purposes of IME and direct GME payment would be dependent upon the actual number of FTE residents the hospital is permitted to count in a particular cost reporting period, as determined in accordance with the regulations at § 412.105 for IME and § 413.86 for direct GME.

In addition, in the proposed rule we stated that we realize that there may be instances where a hospital's FTE resident cap or a hospital's FTE resident count for the reference cost reporting period might be under appeal. We believed that appeals related to these issues should be resolved through the normal course of business. In the event that an appeal that may affect determinations made under section 1886(h)(7)(A) of the Act is not resolved by May 1, 2005, we proposed that we would estimate the number of FTE residents by which a hospital's FTE resident cap should be reduced (or not reduced, as applicable) by May 1, 2005.

Comment: One commenter requested a waiver from the FTE resident cap reduction provisions of section 422 for a special circumstance. The commenter detailed a situation where a hospital, because of financial difficulties, had discontinued its residency program and had submitted a plan to the state in which the hospital is located to close the hospital. Through action of the state's Supreme Court, the hospital's petition for authorization to close the Hospital was denied. A committee appointed by the state Supreme Court

selected another hospital as a sponsor that lent financial support to the subject hospital. A formal merger between the two hospitals has been opposed by the state's Attorney General. The subject hospital's residency programs have not grown to the level maintained prior to the petition for closure and the hospital was training residents well below its FTE resident cap during the reference cost reporting period. As such, the hospital believes that its FTE resident caps will be reduced pursuant to section 422. The commenter requests that the hospital be exempt from FTE resident cap reductions and that this exemption extend to the Medicare GME affiliated group of which the hospital is a part to preserve the group's future ability to build their teaching programs.

Response: We sympathize with the commenter and believe that the particular circumstances experienced by this hospital are unusual and not specifically addressed by the Act or the proposed regulations. However, as we noted above, the statute provided for only a limited exemption from the provisions of section 1886(h)(7)(A)(i) of the Act for small rural hospitals. Therefore, we cannot grant the commenter's request. As we stated above, hospitals that believe they will receive a reduction to their FTE resident cap are not precluded under section 1886(h)(7)(B) of the Act from applying for an increase in their FTE resident cap.

Comment: Numerous commenters were concerned about how to determine possible cap reductions in instances where a hospital's FTE resident count for the reference cost reporting period is under appeal. One commenter was concerned that the number of FTE residents by which a hospital's FTE resident cap would be reduced would not reflect the final settlement of the cost report, which could unfairly harm hospitals whose FTE resident counts in the reference period were ultimately increased through the cost report appeal process. Another commenter emphasized that if appeals for payment purposes are made completely independently of the FTE resident count determinations for purposes of section 422, "it could potentially result in the rather bizarre situation of a hospital's resident cap being permanently lowered by an amount that is later found to be based on an erroneous resident count determination." The commenter continued that the result would "undermine the credibility of CMS, its fiscal intermediaries, and the process for making determinations under section 422, and therefore, CMS should ensure that it will not occur."

One commenter noted that CMS proposed to estimate the aggregate reduction in FTE resident caps under section 1886(h)(7)(A) of the Act based on available data as of May 1, 2005, which means that, for some hospitals, the hospital-specific actual reduction in the FTE resident cap can be based on further audit and appeal activity that may take place at any time after May 1, 2005. Thus, according to CMS' proposal, the number of FTEs in the resident pool attributable to a specific hospital might be higher than or lower than the actual number by which that hospital's FTE count will be reduced as of July 1, 2005. The commenter objected to this proposal and urged a more "budget neutral" approach that would promote finality for section 422. The commenter claimed that not only might this proposal lead to an improper increase or reduction in the estimated aggregate reduction in FTE resident caps, but it would also generate undue uncertainty about whether, and by how much, any given hospital's FTE cap will be reduced as of July 1, 2005. The commenter proposed that, to avoid this uncertainty and to promote finality, each hospital's FTE resident count should be permanently reduced by the same number of FTEs attributable to that hospital that are added to the pool for redistribution as of May 1, 2005. Under the commenter's proposal, fiscal intermediaries will need to conduct and attempt to complete audit activity by May 1 (or perhaps a later deadline if CMS so chooses). Whether those audits are complete or not, CMS would use the best available data as of the deadline so that the aggregate total of increases to the "redistribution pool" would equal the total of the permanent decreases to the hospitals' FTE resident caps effective July 1, 2005. Appeals and audits of the reference period that continue after May 1, 2005, would ultimately only impact that particular fiscal year's direct GME and IME reimbursement, but would have no impact on FTE resident cap adjustments under section 1886(h)(7)(A) of the Act. As such, the commenter agreed with CMS' statement in the proposed rule that the actual FTE resident count used for purposes of direct GME or IME payment in the reference period need not equal the FTE resident count used for purposes of determining possible reductions to a hospital's FTE resident cap under section 1886(h)(7)(A) of the Act. Finally, the commenter stated that since, under its proposal, all hospitals would know prior to the start of an impacted fiscal year precisely by how many FTEs their caps would be

reduced, this advance knowledge would aid hospitals in deciding whether and to what extent they would enter into Medicare GME affiliation agreements as of July 1, 2005.

Response: In the May 18, 2004 proposed rule (69 FR 28294), we stated that we realize there may be instances where a hospital's FTE resident cap or a hospital's FTE resident count for the reference cost reporting period might be under appeal. We further stated that we believe appeals related to these issues should be resolved through the normal course of business. In the event an appeal that may affect determinations made under section 1886(h)(7)(A) of the Act is not resolved by May 1, 2005, we proposed that we would estimate the number of FTE residents by which a hospital's FTE resident cap should be reduced (or not reduced, as applicable) by May 1, 2005.

Since the publication of the proposed rule, and after considering the detailed and thoughtful comments we received on the issue of cost reports that are under appeal, we believe that it is in the best interest of the Medicare program, CMS, the fiscal intermediaries, and the hospitals, to adopt an approach that allows for finality as early as possible during the process of implementing this provision. We believe that Congress gave some consideration to the challenges we would encounter in implementing a provision as complex as section 422 in such a short timeframe by providing the Secretary with the discretion to distinguish between the FTE counts that are used to estimate the number of FTE resident slots that are available for redistribution (that is, the "redistribution pool"), and the actual number of FTE residents by which hospitals' FTE resident caps are ultimately reduced. We therefore had proposed to interpret the language at section 1886(h)(7)(B)(i) of the Act to mean that the aggregate number of FTE residents by which we increase the FTE resident caps of qualifying hospitals under section 1886(h)(7)(B) of the Act must not be more than the estimated aggregate number of FTE residents by which we would reduce the FTE resident caps of hospitals whose reference resident levels are less than their otherwise applicable FTE resident caps.

We also believe the Congress expected and provided for administrative expediency under section 1886(h)(7)(A)(ii)(I) of the Act by stating that a possible reduction in a hospital's FTE resident cap would, generally, be based upon "the reference resident level for the most recent cost reporting period of the hospital ending on or before

September 30, 2002, for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary" (emphasis added). As stated in the May 18, 2004 proposed rule (69 FR 28295–28296), we proposed to interpret this language to mean that, if a hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002, has been settled, then, unless the hospital submits a timely request to use the cost reporting period that includes July 1, 2003, we would use the hospital's settled cost report without further audit to determine possible reductions to the FTE resident caps. Furthermore, the fact that the Congress took the unusual step of including the language at section 1886(h)(7)(D) of the Act which provides that, "There shall be no administrative or judicial review * * * with respect to determinations made under this paragraph," supports the position advocating for finality. If we were to delay determinations concerning hospital-specific FTE cap determinations until all affected cost reports are settled, audited, and appealed through the various channels normally available to providers, the language at section 1886(h)(7)(D) of the Act would be rendered meaningless. Therefore, despite its complexity and potential for profound and long-term GME payment ramifications, we believe that the Congress did not expect the implementation of this provision to linger indefinitely. Rather, by limiting appeal rights, and instituting an effective date of July 1, 2005 (which requires implementation in a relatively short timeframe), the Congress expected section 1886(h)(7) of the Act to be implemented with expediency and finality.

Consistent with Congressional intent and in response to comments, we believe it would be disruptive to CMS, the fiscal intermediaries, and the hospitals if we do not establish a framework that encourages determinations under section 1886(h)(7)(A)(i) of the Act to be made final by July 1, 2005. Therefore, we are not finalizing our proposed policy to wait for reference period cost reports that are under appeal to be resolved before making a final determination as to whether and by how much a hospital's FTE resident cap will be reduced. We do, however, perceive the need in certain instances to continue audit work for a limited time period past July 1, 2005 to promote the accuracy of FTE resident cap determinations. In this final rule, we are adopting a policy that will require the

fiscal intermediaries to use the latest available cost report or audit data at the time they make their determinations. That is, if a hospital's reference period cost report has been settled, then the fiscal intermediary will make a final determination as to whether and by how much a hospital's FTE resident cap would be reduced based on the FTE resident level in that settled cost report. If the hospital's reference period cost report is under appeal and a final decision has not been rendered at the time the fiscal intermediary makes the determination, then the fiscal intermediary would not wait until a decision is rendered, but instead, would use the reference resident level from the settled (per the Notice of Program Reimbursement (NPR)) cost report. If the settled reference period cost report had been appealed and the final decision is rendered in time for the fiscal intermediary to make the FTE resident cap determination, then the fiscal intermediary would use the FTE resident level that will be used in issuing the subsequent NPR as established through the appeal. However, if the reference period cost report has never been settled at the time the fiscal intermediary is making the determination as to whether and by how much a hospital's FTE resident cap should be reduced, then, whether the reference period cost report is the as-submitted most recent cost report ending on or before September 30, 2002, or the cost report that includes July 1, 2003, the reference resident level is subject to audit by the fiscal intermediary, and the final determination regarding any possible reduction to the hospital's FTE resident cap is not subject to appeal. Although we will make every effort to provide fiscal intermediaries with the resources and funding they need to complete as many audits as possible in time to notify each hospital by July 1, 2005 of their FTE cap determinations under section 1886(h)(7)(A) of the Act, there may be instances where the audits of the reference resident levels may not be completed by July 1, 2005. However, we anticipate that the fiscal intermediaries will be able to complete audits related to section 1886(h)(7)(A) of the Act by December 2005, which is six months into the July 1, 2005—June 30, 2006 academic year. All determinations made after July 1, 2005 and through December 2005 will be effective retroactively to July 1, 2005.

Comment: One commenter noted that some hospitals' 1996 FTE resident caps have yet to be finalized, or have been finalized only recently. The commenter

requested that CMS consider these situations when comparing caps to resident counts. The commenter gave an example in which some hospitals may have an FTE resident count in the reference period cost report that once matched their corresponding FTE resident cap, but that cap was later increased during the audit and appeal process. If the settled (post-audit and/or appeal) FTE resident cap is used in the cap and count comparison, the hospital's FTE resident cap would be reduced, "even though the hospital was at its cap as it knew it to be as of 2002." The commenter asserted that such a result would be "patently unfair" and should be addressed in the final rule.

Response: The commenter's point is well taken, but we note that the reverse situation could also occur in that a hospital's 1996 FTE resident cap may later be reduced as the result of an appeal. If the reduced settled FTE resident cap were to be used in the cap and count comparison under section 1886(h)(7)(A) of the Act, the reduction in the hospital's FTE resident cap would be lessened (or there could be no reduction at all), even though the hospital's FTE resident count was below its cap "as it knew it to be as of 2002." Accordingly, where the hospitals' FTE resident cap used in its reference cost report is revised on an appeal, some hospitals could benefit by using the original FTE resident cap while other hospitals would not. We do not believe it is appropriate to decide our policy based on the possible occurrence of a circumstance that could produce favorable results for some and unfavorable results for others. Therefore, as stated in response to the previous comment regarding situations where the FTE resident count in the reference cost reporting period is under appeal, in the interest of finality, we will instruct the fiscal intermediaries to use the latest determined 1996 FTE resident caps for direct GME and IME that are available as of the time the determination regarding any possible FTE resident cap reduction is being made. If, as of the time the fiscal intermediary makes the determination as to whether and by how much a hospital's FTE resident cap should be reduced, an appeal of the FTE resident cap for the reference cost reporting period has not been resolved (that is, a final decision has not been rendered), then the fiscal intermediary would use the FTE resident cap amount from the initially settled (per the NPR) reference period cost report. However, if, as of the time that the fiscal intermediary makes the determination as to whether and by

how much a hospital's FTE resident cap should be reduced, the FTE resident cap appeal has been resolved, we would use the FTE resident cap as established by the appeal.

We are, however, sympathetic to the commenter's point that there could be instances where, as the result of an appeal of the 1996 FTE resident cap that was resolved at the time the fiscal intermediary makes the determination, the hospital's FTE resident cap would be reduced, "even though the hospital was at its cap as it knew it to be as of 2002." Such a hospital may apply for an increase in its FTE resident cap under section 1886(h)(7)(B) of Act. In this final rule, under section IV.O.2.m. of this preamble, we are adding an Evaluation Criterion to address this situation where a hospital's FTE resident cap was reduced under section 1886(h)(7)(A)(i) of the Act because the resident level in its reference period cost report equaled or was above its FTE resident cap in effect at that time, but as a result of the resolution of an appeal concerning the FTE resident cap (for example, the 1996 FTE resident cap, as adjusted for new programs, if applicable), the FTE resident cap was later increased to an amount that is greater than the reference resident level.

Comment: Several commenters acknowledged CMS' need to estimate the aggregate reduction in FTE resident caps in order to "redistribute" positions to other hospitals by the July 1, 2005 implementation deadline, but expressed concern that if the finalized number of FTE resident cap reductions exceeds the number of redistributed cap slots, the result would be a permanent reduction in the national total number of resident positions eligible for Medicare program support. The commenters asserted that this was not the intent of Public Law 108-173. Rather, one commenter believed that, while the Congress was permitting the use of estimate in administering the redistribution, the Congress was not "sanctioning" aggregate additions or reductions to the number of FTE residents counted for purposes of Medicare direct GME and IME reimbursement. Another commenter noted that Public Law 108-173 requests that CMS submit a report to the Congress by July 1, 2005, that contains recommendations regarding whether to extend the application deadline for hospitals seeking to increase their resident limits. The commenter stated that, because of audit and appeal timeframes, CMS may not know the final aggregate number of FTE resident cap reductions by July 1, 2005, urged CMS to address this situation in its report, and recommended that the

application process be extended or reopened in the event that the final resident limit reductions exceed distributed slots.

Response: We acknowledge the commenters' concern that, to the extent the number of slots in the "resident pool" attributable to certain hospitals is based on estimates of the amount by which those hospitals' FTE residents caps will be reduced, and the finalized number of FTE resident cap reductions exceeds the number of redistributed cap slots, the result would be a permanent reduction in the total number of resident positions that would be counted for purposes of Medicare direct GME and IME payments. As explained in response to previous comments, we will make every effort to provide fiscal intermediaries with the resources and funding they need to complete as many audits as possible in time to notify each hospital by July 1, 2005, of their determinations under section 1886(h)(7)(A) of the Act. Therefore, we anticipate that by May 1, 2005, the number of hospitals for which we believe additional audit work is required (and, therefore, we "estimated" the amount by which their FTE resident caps would be reduced) will be relatively small. However, we acknowledge that, as a result of the possibility of some remaining audits (which we believe will be completed by the end of calendar year 2005), there is a slight possibility that the final number of FTE cap reductions could be more than the estimated size of the "resident pool" as of July 1, 2005. To address this concern, in drafting the report to Congress due by July 1, 2005, we will consider ways in which this potential situation may be addressed, and, if appropriate, would request that Congress extend the deadline for increases in resident limits.

Comment: One commenter agreed with CMS that, given the short timeframe for implementation of section 422 and the complexity involved in determining the number of positions available for redistribution, it is reasonable for CMS to exercise its discretion to make a "best estimate" of the aggregate number of FTE cap reductions under section 1886(h)(7)(A) of the Act by a particular date and proceed with the "redistribution" under section 1886(h)(7)(B) of the Act. However, the commenter was "extremely concerned" that CMS ensure that hospitals at risk of having their FTE resident cap reduced have ample opportunities to submit additional documentation to the fiscal intermediary so that the hospital's residents are not "undercounted". The

commenter noted that section 1886(h)(7)(D) of the Act specifies that "There shall be no administrative or judicial review under section 1869, 1878, or otherwise, with respect to determinations made under this paragraph." The commenter urged CMS to not interpret this statement to mean that a determination of the fiscal intermediary with regard to FTE resident cap reductions will be final, without any external appeal mechanism. Rather, the commenter suggested CMS should appoint an ombudsman who would be available to adjudicate hospital-specific issues as they arise.

Response: As stated in response to the previous comment, we believe the fact that Congress included the language at section 1886(h)(7)(D) of the Act stating that "There shall be no administrative or judicial review * * * with respect to determinations made under this paragraph," clearly means that the Congress did intend for the determination of the fiscal intermediary with regard to FTE resident cap reductions to be final, without any external appeal mechanism. Because of this statutory language, together with the requirement that all reductions and increases in FTE resident caps be made effective July 1, 2005, we do not believe it is appropriate to allow hospitals (or CMS) to appeal determinations concerning the FTE cap reductions (or the FTE cap increases, for that matter) under section 1886(h)(7) of the Act. In addition, as indicated previously, we believe that Congress intended this provision to be implemented fairly, but efficiently, avoiding the delays and uncertainty that would be produced by an appeals process. Furthermore, we note that, as with any audit and cost report settlement process, the fiscal intermediaries will provide the hospitals with an opportunity to review and respond to the audit adjustments before they are finalized.

Comment: One commenter said the proposed regulations are unclear as to whether the policy to ensure that the aggregate number by which FTE resident caps are increased through the redistribution provisions at section 1886(h)(7)(B) of the Act, does not exceed the estimated aggregate number by which FTE resident caps are reduced under section 1886(h)(7)(A) of the Act would be applied individually to each hospital that requests additional residency slots, or whether the policy would be applied to the national aggregate amounts. The commenter stated that if a hospital loses resident positions as part of the reductions under section 1886(h)(7)(A) of the Act, it could

be due to a number of factors that have "nothing to do with the ability of a program to recruit and retain residents" in other programs. The commenter requested that if CMS intended that the rule requiring that aggregate increases not exceed aggregate decreases be applied on a hospital-specific basis, it should be eliminated.

Response: The commenter is referring to our proposal relating to the language at section 1886(h)(7)(B)(i) of the Act, as added by section 422(a)(3) of the MMA, which states that the "aggregate number of increases in the otherwise applicable resident limits under this subparagraph may not exceed the Secretary's estimate of the aggregate reduction in such limits * * *" (emphasis added). As explained in response to previous comments, we proposed to interpret this language to mean that the aggregate number of FTE residents by which we increase the FTE resident caps of qualifying hospitals under section 1886(h)(7)(B) of the Act may not exceed the estimate of the aggregate number of FTE residents by which we would reduce the FTE resident caps of hospitals whose reference resident levels are less than their otherwise applicable FTE resident caps. As is evident from the use of the word "aggregate" and the plural form of "hospital," we intended that this principle be applied on a national aggregate basis, and not to each hospital individually. Rather, as long as the total number of FTE residents by which we increase the FTE resident caps of all hospitals nationally is not more than the estimated number of FTE residents by which we reduce the FTE resident caps of all hospitals nationally, we will have complied with the statute at section 1886(h)(7)(B)(i) of the Act.

f. Determining the Possible Reduction to a Hospital's FTE Resident Cap

(1) Reference Resident Level—General

In order to determine if a hospital's resident level is less than the hospital's otherwise applicable FTE resident cap, section 1886(h)(7)(A)(ii) of the Act, as added by section 422 of Pub. L. 108-173, directs the Secretary to use one of two reference cost reporting periods. Section 1886(h)(7)(A)(ii)(I) of the Act directs CMS to use a hospital's most recent cost reporting period ending on or before September 30, 2002, "for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary," as the reference period, unless we grant the hospital's timely request to use a later cost report under section 1886(h)(7)(A)(ii)(II) of the Act, as described under section IV.O.2.f.(2) of

this preamble. Generally, if the hospital's resident level for either direct GME or IME is less than the hospital's otherwise applicable resident cap for direct GME or IME, respectively, for the most recent cost reporting period ending on or before September 30, 2002, the hospital's FTE resident cap for direct GME or IME will be reduced by 75 percent of the difference between the resident level and the otherwise applicable FTE resident cap. On April 30, 2004, we issued a One-Time Notification (OTN) (Transmittal 77, CR 3247), "Instructions Related to 'Redistribution of Unused Resident Positions', Section 422 of the Medicare Modernization Act of 2003 (MMA), Public Law 108-173, for Purposes of Graduate Medical Education (GME) Payments" that prescribed certain requirements related to the implementation of section 422 and established a deadline by which a hospital must exercise its option to request that we use a later cost report as the reference cost report. If the hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002, is settled by April 30, 2004, the date on which the OTN was issued, we proposed in the May 18, 2004 proposed rule to use that cost report to determine if, and by how much, a hospital's FTE resident cap should be reduced. We noted that the "settled" cost report does not necessarily mean the initial cost report settlement. The fiscal intermediary may have previously settled the cost report, reopened it to audit it, and then settled the cost report again, issuing a revised Notice of Program Reimbursement (NPR). Thus, we would refer to the more recently issued NPR. When a hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002, has been settled by April 30, 2004, we proposed to use the most recently settled cost report as of April 30, 2004, to determine any reduction to the hospital's FTE resident cap under section 1886(h)(7)(A)(ii)(I) of the Act (unless we grant the hospital's timely request under section 1886(h)(7)(A)(ii)(II) of the Act to use a later cost report, as described in section IV.O.2.f.(2) of this preamble). If the hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002 has not yet been settled as of April 30, 2004, we proposed that the as-submitted cost report would be used to determine any reduction in the FTE resident cap, subject to audit by the fiscal intermediary. If the cost report was initially settled, but then reopened, and

the fiscal intermediary has not issued a revised NPR prior to April 30, 2004, the data from the initially settled cost report will be used to determine the possible reductions to the FTE resident caps. (Discussion and comments on this portion of the proposed rule are located at section IV.O.2.f.(3) of this preamble.)

(2) Expansion of an Existing Program

Section 1886(h)(7)(A)(ii)(II) of the Act, as added by section 422(a) of Public Law 108-173, provides that if a hospital's resident level increased due to an expansion of an existing program, and that expansion is not reflected on the hospital's most recent settled cost report, a hospital may make a timely request to CMS that, rather than using its most recent cost reporting period ending on or before September 30, 2002, to determine if its FTE resident cap should be reduced, CMS should use the cost report for the hospital's cost reporting period that includes July 1, 2003. For example, assume a hospital's most recent settled cost report is September 30, 2000 (that is, no NPRs were issued for subsequent year cost reports). The hospital increased its resident level due to an expansion of an existing program in its fiscal year ending September 30, 2001. The hospital may submit a timely request that CMS use its cost report that includes July 1, 2003 (which would be its cost report for the fiscal year ending September 30, 2003), to determine if and by how much the hospital's FTE resident cap should be reduced. (Proposed redesignated § 413.79(c)(3)(ii)(A)(2)). As explained on page 3 of the April 30, 2004 OTN, to be considered a timely and proper request, a hospital's request to use its cost reporting period that includes July 1, 2003, must be signed and dated by the hospital's chief financial officer (or equivalent) and submitted to its fiscal intermediary on or before June 4, 2004 (later revised to June 14, 2004). In its timely request, the hospital must include the following:

(1) The FTE resident caps for direct GME and IME and the number of unweighted allopathic and osteopathic FTE residents for direct GME and IME in its most recently settled cost report (that is, its cost report that is more recently settled as of April 30, 2004.

(2) The FTE resident caps for direct GME and IME and the unweighted allopathic and osteopathic FTE residents for direct GME and IME for each cost report after its most recently settled cost report, up to and including its cost reporting period that includes July 1, 2003. If the cost reporting period that includes July 1, 2003, has not

ended as of June 4, 2004, the hospital must report the estimated number of unweighted allopathic and osteopathic residents for that cost reporting period.

(3) If not already reported in accordance with steps 1 and 2 above, the FTE resident caps for direct GME and IME and the number of unweighted allopathic and osteopathic FTE residents for direct GME and IME in its most recent cost reporting period ending on or before September 30, 2002.

In addition, as we stated in the April 30, 2004 OTN, a hospital should refer to its most recently settled cost report as of the issuance of the OTN (that is, April 30, 2004) to determine whether the hospital believes it has expanded an existing program in a cost reporting period subsequent to the one for the most recently settled cost report.

In the May 18, 2004 proposed rule, we also proposed that, for purposes of this provision, an "expansion of an existing program" means that, except for expansions due to newly approved programs, as described below in section IV.O.2.f.(4) of this preamble, the hospital's total number of unweighted allopathic and osteopathic FTE residents training in existing programs in a cost reporting period up to and including the hospital's cost report that includes July 1, 2003, is greater than the resident level in the hospital's most recent settled cost report. (Proposed redesignated § 413.79(c)(3)(ii)(A)(3)). In other words, generally, we proposed that as long as a hospital trained more unweighted allopathic and osteopathic FTE residents in a cost reporting period after its most recent settled cost report in programs that were existing during the cost reporting period for the most recently settled cost report, it may submit a timely request that its cost report that includes July 1, 2003, be used for purposes of determining any FTE resident cap reduction under section 1886(h)(7)(A)(i) of the Act. We noted that if a hospital expanded an existing program after its most recent settled cost report, and then subsequently reduced its FTE resident count to the extent that it actually trained fewer unweighted allopathic and osteopathic FTE residents in its cost report that includes July 1, 2003, than in its most recent cost reporting period ending on or before September 30, 2002, the hospital would not benefit from, and would likely not make, a timely request that its cost report that includes July 1, 2003, be used for purposes of determining a possible reduction to its FTE resident cap.

Comment: One commenter stated that, even though the current deadline of June 14, 2004, for timely requests has

passed, because the process was included in the proposed rule and is subject to comment and possible revisions, CMS should reopen the timely request deadline for all hospitals. Another commenter was "extremely dismayed" that CMS stated that the timely requests are "binding" even if the reduction to the hospital's FTE resident cap would have been less had the hospital not submitted a timely request to use the cost report that includes July 1, 2003. The commenter declared that it is "absolutely not reasonable for CMS to make a [hospital's] request such as this 'binding' in full knowledge that inherent in making such a request, there must be at least a small element of estimation, and an incorrect estimate might eventually work to a hospital's disadvantage when the data and documentation issues are reviewed more thoroughly." The commenter recommended that if it is found that a hospital's reduction to its FTE resident cap would be less if the hospital had not made the timely request, the request should be "null and void," and the hospital should either be allowed to withdraw its request, or CMS should use the hospital's most recent cost report ending on or before September 30, 2002, as the reference cost report.

Response: We acknowledge the unique circumstances surrounding implementation of section 1886(h)(7) of the Act in that it requires hospitals to supply, and CMS and the fiscal intermediaries to review, a large amount of technically difficult information regarding FTE resident counts and caps in a relatively short timeframe, in order to assess and make modifications effective July 1, 2005. If we had more time to implement section 1886(h)(7) of the Act, we would have waited until after publication of this final rule to establish a deadline for all hospitals to submit timely requests due to expansions of existing programs not reflected on the most recent settled cost report, (or due to expansions under newly approved programs). We note that many of the reference cost reporting periods are subject to audit under section 1886(h)(7)(A)(ii) of the Act. Given our limited time and audit resources, we believe it would be inefficient for the fiscal intermediaries to audit the cost reporting period that includes July 1, 2003, for a hospital that submitted a timely request, and then, in the event that the hospital regrets having submitted that request, audit the cost report ending on or before September 30, 2002. Therefore, due to the extremely tight timeframe mandated

by the statute, and considering that GME audits can be lengthy and complicated processes, we believe that we needed to issue the OTN on April 30, 2004, establish June 4, (later changed to June 14) 2004, as the deadline for a hospital's "timely request" under section 1886(h)(7)(A)(ii) of the Act, and make submissions of timely requests "binding". We note that, to allow hospitals more time to evaluate their FTE resident data, we reissued this OTN (CR 3247, Transmittal 87) on May 26, 2004 with a revised "timely request" deadline of June 14, 2004. In those OTNs, we explained that, "In the Fiscal Year (FY) 2005 Hospital Inpatient Prospective Payment System (PPS) proposed rule, we will be proposing procedures for determining the number of "unused" residency positions, as well as an application process for hospitals that seek additional residency slots, and specific criteria that we will use in determining which hospitals will receive the additional residency positions. However, *since the procedures would not be finalized before publication of the FY 2005 Hospital Inpatient PPS final rule (by August 1, 2004), and the provisions of that final rule would not become effective until October 1, 2004 (at least 60 days after publication of the final rule), we are notifying you and your providers in this OTN of certain information that we will need in order to determine in a timely fashion the number of unused resident positions available for redistribution*" (emphasis added).

In issuing the OTNs, and in conjunction with the additional information provided in the proposed rule, we believe that we provided enough information for hospitals to determine whether their FTE residents caps would be subject to reduction, whether the hospital had an expansion of an existing program, and whether it would be advantageous for the hospital to submit a timely request to use the cost report that includes July 1, 2003 as the reference period. Furthermore, we believe that, as a general proposition, a hospital should know the validity of its FTE resident count, and be able to assess whether its FTE count is below its FTE resident cap. Therefore, the issuance of proposed and final regulations should have had little, if any, impact, on a hospital's decision to submit a timely request. However, we do accede that this may not be the case for hospitals located in areas for which the urban or rural status will change as of October 1, 2004, as described previously in section IV.O.d. of this

preamble. Accordingly, we are providing another limited opportunity after publication of this final rule only for hospitals located in areas whose rural status will change to urban as of October 1, 2004, as stated in section IV.O.d. of this preamble, to make a timely request under section 1886(h)(7)(A)(ii) of the Act.

Comment: One commenter noted that because the June 14, 2004 deadline for submitting a timely request was prior to the issuance of the final rule, the enforcement of that deadline could be problematic, even though CMS issued a One-Time Notification (CR 3247) instituting this deadline. The commenter recommended that CMS use the deadline of June 14, 2004, issued in the OTN as a guideline, rather than a firm deadline, with respect to allowing a hospital to use an alternative cost report.

Response: We disagree with the commenter's suggestion that the June 14, 2004 deadline for submission of a timely request should be used as a guideline, and not a firm deadline. We note that sections 1886(h)(7)(A)(ii)(II) and (III) of the Act specifically hinge a hospital's ability to use its cost report that includes July 1, 2003, or to adjust its reference resident level due to newly approved programs, on the submission of a timely request, and clearly gives the Secretary the discretion to establish what a timely request should be. As we explained in the OTN and in response to the previous comment, if the modifications under section 1886(h)(7) of the Act had not been made effective July 1, 2005, we could have waited until after publication (or perhaps even the effective date) of this final rule to establish a deadline for all hospitals to submit timely requests. However, because we have a limited amount of time in which to implement section 1886(h)(7) of the Act, and the provisions of this final rule will not be effective until October 1, 2004, we chose to exercise our discretion and subregulatory authority to issue the OTN and require that timely requests must be submitted by June 14, 2004. Accordingly, all requests submitted after June 14, 2004 (except for those for which a new deadline is established under this final rule) are not timely, and may not be used by the fiscal intermediaries to allow for use of the cost report that includes July 1, 2003, or to adjust the reference resident level to reflect newly approved programs.

Comment: One commenter was concerned that hospitals "must choose" between two reference cost reporting periods, regardless of whether those cost reports have been settled. The

commenter believed that there is too much uncertainty surrounding cost reports that are not settled, and requested that hospitals be given an opportunity to make or withdraw a timely request once both its most recent cost report ending on or before September 30, 2002, and its cost report that includes July 1, 2003 is settled.

Response: We are not accepting the commenter's request, because it is possible that a hospital's most recent cost report ending on or before September 30, 2002, and its cost report that includes July 1, 2003, will not be settled until well after the effective date of section 1886(h)(7) of the Act of July 1, 2005. Waiting until all reference cost reports are settled would prevent this provision from being implemented in a timely fashion, and would generally be disruptive to fiscal intermediaries and to hospitals.

Comment: One commenter noted that there may be hospitals that have increased their resident levels in the reference period due to new programs that do not qualify as a "newly approved program" under section 1886(h)(7)(ii)(III) of the Act because they were either accredited after January 1, 2002, or they were in operation during the providers' reference periods, or both. The commenter asked whether increases in resident counts due to these new programs can be considered expansions of existing programs, and, if so, whether the commenter could request that its cost report that includes July 1, 2003 be used to determine if and by how much its FTE resident cap would be reduced. The commenter believed that CMS should not deny such a hospital the ability to use the cost report that includes July 1, 2003, and CMS should not reduce the hospital's FTE resident caps based on a lower FTE resident count on the cost report ending on or before September 30, 2002 if its FTE resident level has subsequently increased due to the addition of the new program(s) not addressed under section 1886(h)(7)(A)(ii)(III) of the Act.

Response: Section 1886(h)(7)(A)(ii)(II) of the Act, as added by section 422(a) of Public Law 108-173, provides that if a hospital's resident level increased due to an expansion of an existing program, and that expansion is not reflected on the hospital's most recent settled cost report, a hospital may make a timely request to CMS that, rather than using its most recent cost reporting period ending on or before September 30, 2002, to determine if its FTE resident cap should be reduced, CMS should use the cost report for the hospital's cost reporting period that includes July 1, 2003. In the May 18, 2004 proposed rule

(69 FR 28295), we proposed that "expansion of an existing program" means that the hospital's total number of unweighted allopathic and osteopathic FTE residents in existing programs in a cost reporting period up to and including the hospital's cost report that includes July 1, 2003, is greater than the resident level in the hospital's most recent settled cost report. In other words, generally, as long as a hospital trained more unweighted allopathic and osteopathic FTE residents in a cost reporting period after its most recent settled cost report in programs that were existing during the cost reporting period for the most recently settled cost report, it may submit a timely request that its cost report that includes July 1, 2003, be used for purposes of determining any FTE resident cap reduction under section 1886(h)(7)(A)(i) of the Act. We believe this definition of an existing program is consistent with the language and intent of section 1886(h)(7)(A)(ii)(II) of the Act, which specifically addresses expansions of existing programs not reflected on the hospital's most recent settled cost report. Therefore, in order for a hospital to qualify to submit a timely request to use its cost report that includes July 1, 2003, the increase in its overall resident level must be due to an increase in the number of residents that were in residency programs in which the hospital was training residents in its most recent settled cost report. For the purposes of this provision, a hospital first must determine whether the total unweighted allopathic and osteopathic FTE count (not program-specific, but for all allopathic and osteopathic programs combined) in a cost reporting period subsequent to its most recent settled cost reporting period up to and including the cost report that includes July 1, 2003, is greater than the total unweighted allopathic and osteopathic FTE count in its most recent settled cost report. If there has been an increase in the total unweighted allopathic and osteopathic FTE resident count since the last settled cost report, the hospital must determine if that increase is due to expansion of a program(s) in which that hospital trained FTE residents in its most recent settled cost report, or whether the increase is due to a new or a different specialty program for which the hospital did not train FTE residents in its most recent settled cost report. For example, assume that a hospital's most recent settled cost report ending on or before September 30, 2002, is the cost reporting period ending December 31, 2000, and the hospital only trained 10 FTE internal medicine residents in that

period. The hospital began training 2 FTE residents in a pediatrics program in 2001, so that the hospital's total unweighted allopathic and osteopathic resident level on its FYE December 31, 2001 cost report increased by 2 FTEs to equal 12. Because the increase in the resident level is entirely attributable to the residents in the pediatrics program, a specialty program in which the hospital did not train FTE residents in its FYE December 31, 2000 cost report, this hospital would not qualify to use the cost report that includes July 1, 2003, as its reference period because the increase in the resident level is due to residents in a new program rather than an expansion of an existing program not reflected on the last settled cost report. On the other hand, if any of the additional residents counted in FYE December 31, 2001 (using the same example) would be internal medicine residents, a program in which the hospital did participate and train FTE residents in FYE December 31, 2000 (its last settled cost report), the hospital may qualify to make a timely request to use the cost reporting period that includes July 1, 2003 due to an expansion of an existing program that was not reflected on the last settled cost report of FYE December 31, 2000.

(3) Audits of the Reference Cost Reporting Periods

As mentioned under section IV.O.2.f.(1) of this preamble, to determine a possible reduction to a hospital's FTE resident cap, section 1886(h)(7)(A)(ii)(I) of the Act, as added by section 422(a) of Public Law 108-173, directs CMS to use a hospital's most recent cost reporting period ending on or before September 30, 2002, "for which a cost report has been *settled* (or, *if not, submitted (subject to audit)*, as determined by the Secretary" (emphasis added). In the May 18, 2004 proposed rule (69 FR 28295), we proposed to interpret this language to mean that, if a hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002, has been settled, then, unless the hospital submits a timely request to use the cost reporting period that includes July 1, 2003, we would use the hospital's settled cost report without further audit to determine possible reductions to the FTE resident caps. We also proposed to interpret this language to mean that if a hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002, has not been settled, the hospital's as-submitted cost report for the most recent cost reporting period ending on or before September 30, 2002, would be subject to audit by

the fiscal intermediary. In addition, as stated under section 1886(h)(7)(A)(ii)(III) of the Act, use of a hospital's cost report that includes July 1, 2003 is made "after audit and subject to the discretion of the Secretary." A hospital's cost report that includes July 1, 2003 may be at various stages of settlement, or may not even be submitted at the time this proposed rule is published. For example, if a hospital has a fiscal year end of June 30, its cost reporting period that includes July 1, 2003 would not end until June 30, 2004. This cost report is not required to be submitted until 5 months after the cost reporting period closes, which would be by December 1, 2004. In any case, the fiscal intermediary would need to make a determination as to whether a hospital has actually increased its resident level due to an expansion of an existing program that is not reflected on the most recent settled cost report. Further, the FTE resident counts that are included (or would be included) in the cost report that includes July 1, 2003, are subject to audit by the fiscal intermediary to ensure that an appropriate determination is made as to whether, and by how much, a hospital's FTE resident cap will be reduced. To facilitate these determinations, in the May 18, 2004 proposed rule, we proposed that the fiscal intermediaries may audit the FTE resident counts as necessary in the most recently settled cost reports and in the cost reports up to and including the cost report for the cost reporting period that includes July 1, 2003.

Fiscal intermediaries will perform desk or onsite audits related to section 422, using instructions that will be issued in a separate document. As we explained in the OTN, Transmittal No. 77, CR 3247, in the interest of time and the most efficient use of audit resources, we have required that if a hospital would like CMS to use its cost report that includes July 1, 2003, as its reference period due to an expansion of an existing program, the hospital must notify the fiscal intermediary in accordance with the instructions provided in the OTN by June 4, 2004 (later revised to June 14, 2004). If a hospital submits a timely request that its cost report that includes July 1, 2003, be used, we proposed that the fiscal intermediary would audit that cost report and previous cost reports as necessary to determine if the hospital increased its resident level due to an expansion of an existing program that is not reflected on the most recent settled cost report. If a hospital does not submit a timely request to the fiscal intermediary that its cost report that

includes July 1, 2003, be used, we proposed that the fiscal intermediary would use the cost report for the most recent cost reporting period ending on or before September 30, 2002, to determine if, and by how much, a hospital's FTE resident cap should be reduced, as specified under section 1886(h)(7)(A)(ii)(I) of the Act. If the cost report that is used to determine the possible reduction to a hospital's FTE resident count is for a period of less than or more than 12 months, we proposed that the fiscal intermediary would prorate the FTE resident caps and unweighted FTE residents to equal 12-month counts.

Comment: Some commenters urged CMS to keep in mind that Congress' intent is to redistribute only "unused" slots, and requested that a hospital's FTE resident cap should not be reduced on account of FTEs that were disallowed because the hospital did not fulfill paperwork or other requirements associated with receiving direct GME or IME payments. The commenters believed that the legislation dictates that the hospital's FTE resident cap not be reduced as a consequence of technical lapses because the slots are unquestionably being "used", despite the fact that for cost report payment purposes, a lower FTE count may be used. One commenter added that, in the case where there is a discrepancy between a hospital's submitted FTE resident count and the audited FTE resident count, and the audited count would result in a (more substantial) lowering of the hospital's FTE resident cap, then the determination should be made on the basis of the as-submitted FTE resident count.

Response: We are sympathetic to the commenter's point that it was not the intention of Congress to reduce a hospital's FTE resident cap solely because the hospital failed to comply with certain paperwork requirements necessary for receiving direct GME and IME payment with respect to FTE residents that a hospital actually trained. Nevertheless, we believe that Congress was aware that there could be certain anomalies in a hospital's FTE count in a given year, and therefore, provided for some flexibility in determining the reference resident levels by granting hospitals the option to use the cost report that includes July 1, 2003 due to expansions of existing programs that were not reflected on the most recent settled cost report under section 1886(h)(7)(A)(ii)(II) of the Act, or to adjust the reference resident level to include the number of residents in newly approved programs under section 1886(h)(7)(A)(ii)(III) of the Act, rather

than only using the most recent cost report that ended on or before September 30, 2002. We believe that Congress in fact intended that CMS use only allowable FTE resident counts in determining any applicable reductions to a hospital's FTE resident cap under this provision. Furthermore, in directing CMS to use "resident levels", or FTE data from the hospital's cost reporting period ending on or before September 30, 2002 or the cost reporting period that includes July 1, 2003, the statute directs that the cost reports to be used are "subject to audit".

Comment: One commenter stated that the proposed rule does not provide an indication of how or when audits under section 422 will be performed or what standards will be used to determine a hospital's unused resident slots. The commenter asked that CMS provide specific, detailed information about such audits and then review and respond to providers' comments prior to finalizing the audit protocols.

Response: We believe it is inappropriate to share the details of the audit procedures with providers and allow them the opportunity for comment. The Medicare audit program has always been confidential, to be shared only with the fiscal intermediaries, and will continue to be so. However, as with the audits conducted as part of any cost report settlement process, the fiscal intermediaries will request documentation needed to audit the FTE resident count and will provide hospitals with the opportunity to review and to respond to the proposed audit adjustments, prior to the finalization of the audit adjustments.

(4) Expansions Under Newly Approved Programs

Under section 1886(h)(7)(ii)(III) of the Act, as added by section 422(a)(3) of Public Law 108-173, a hospital may request that its reference resident level be adjusted to include residents in certain newly approved programs. Specifically, if a hospital's new program was accredited by the appropriate accrediting body (that is, the Accreditation Council on Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA)) before January 1, 2002, but was not in operation during the hospital's reference period, the hospital may submit a timely request that we adjust the reference resident level to include the number of residents for which a new program was accredited at a hospital(s). In the May 18, 2004 proposed rule (69 FR 28296), for a hospital that requests an adjustment due to a newly approved

program, we proposed to determine a hospital's reference period as we otherwise would. If a hospital received accreditation for a new medical residency training program before January 1, 2002, but the program was not in operation (that is, the hospital did not begin training residents in that program) during its reference period (which will be either the most recent cost reporting period ending on or before September 30, 2002, or the cost reporting period that includes July 1, 2003), the hospital may submit a timely request by June 4, 2004 (later revised to June 14, 2004), as explained in the OTN, that its resident level for its reference period be adjusted to reflect the number of accredited slots for which that new medical residency training program was approved. We note that section 1886(h)(7)(A)(ii)(III) of the Act does not require that CMS include the number of residents for which the new program is accredited in the hospital's reference cost reporting period for purposes of determining direct GME and IME payment in that reference cost reporting period. Rather, CMS is only required to include the number of residents for which a new program was accredited in the resident level for purposes of determining if, and by how much, a hospital's FTE resident cap should be reduced under section 1886(h)(7)(A) of the Act.

For example, assume a hospital that has a fiscal year end of June 30 received accreditation in October 2001 to train 10 residents in a new surgery program. The hospital does not have an expansion of an existing program not reflected on its most recent settled cost report, so its reference period is the most recent cost reporting period ending on or before September 30, 2002. The hospital first begins to train residents in the new surgery program on July 1, 2002. The new surgery residents are *not* reflected on the hospital's June 30, 2002 cost report, which is the hospital's most recent cost reporting period ending on or before September 30, 2002. Thus, the hospital may submit a timely request that we increase its resident level for the cost report ending June 30, 2002, by 10 FTE residents to reflect the residents approved for the new surgery program for purposes of determining if the hospital's reference resident level is below its otherwise applicable resident cap. However, we note that if the hospital's fiscal year end in this example was September 30, a program accredited in October 2001 and begun on July 1, 2002, would be in operation during the hospital's cost reporting period ending on September 30, 2002,

and the hospital could not receive an increase to its resident level for its cost reporting period ending September 30, 2002, to include the total number of accredited resident positions in the new surgery program. If the new program was accredited for a range of residents (for example, a hospital receives accreditation to train 6 to 8 residents in a new internal medicine program), we proposed that the hospital may request that its resident level for its most recent cost reporting period ending on or before September 30, 2002 be adjusted to reflect the maximum number of accredited positions (which, in this example, would be 8 internal medicine residents). We also proposed that at the time the hospital makes the timely request to have its resident level adjusted to include the number of accredited resident positions, the new program need not be training the full complement of residents for which the program was accredited. (Proposed redesignated § 413.79(c)(3)(A)(3)(ii)). In addition, if more than one hospital was approved as a training site for the residents in the newly accredited program (that is, more than one hospital sponsors the program or there are other participating institutions that serve as training sites for the residents in the program), we proposed that the adjustment to a requesting hospital's reference resident level would reflect the appropriate portions of the FTE residents in the new program that would be training at that hospital.

Similarly, if, in addition to having accreditation for a new program, a hospital has an expansion of an existing program that is not reflected on the most recent settled cost report, that hospital may submit a timely request that its resident level for the cost reporting period that includes July 1, 2003, be adjusted to include the number of resident positions for which a new program was accredited. We proposed that a hospital whose reference period is the one that includes July 1, 2003, may only request that its reference resident level be adjusted to include the accredited number of residents for a new program if, in accordance with section 1886(h)(7)(A)(ii)(III) of the Act, the new program was approved by the appropriate accrediting body before January 1, 2002, but was not in operation during the cost reporting period that includes July 1, 2003. This proposal was based on our interpretation of the statutory language, which states that "the Secretary shall adjust the reference resident level *specified under subclause (I) or (II)* to include the number of residents that

were approved * * * for a medical residency program * * * but which was not in operation *during the cost reporting period used under subclause (I) or (II)* * * *" (emphasis added). Because the statute provides for an adjustment to the reference resident level "specified under subclause I or II," as mentioned above, for hospitals that request an adjustment under section 1886(h)(7)(A)(ii)(III) of the Act, we proposed to identify the applicable reference period as we otherwise would under section 1886(h)(7)(A)(ii)(I) and (II) of the Act. That is, we proposed to use the hospital's most recent cost reporting period ending on or before September 30, 2002, as the reference cost reporting period, unless the hospital submits a timely request to use the cost reporting period that includes July 1, 2003, due to an expansion of an existing program that is not reflected on the cost recent settled cost report. We also noted that, as mentioned above, subclause (III) requires that the program be accredited before January 1, 2002, but not be in operation during the hospital's reference cost reporting period, or in this case, the period that includes July 1, 2003. This means that, in order for the hospital to receive an adjustment to its reference resident level under section 1886(h)(7)(A)(ii)(III) of the Act for the cost reporting period that includes July 1, 2003, the new program also cannot be in operation in the cost reporting period that includes July 1, 2003. Thus, while we believe it is possible for a hospital to qualify for this adjustment because the hospital started a new program that is not reflected on its most recent cost reporting period ending on or before September 30, 2002, we believe that few, if any, hospitals will qualify for this adjustment for a new program that was not in operation in the cost report that includes July 1, 2003, because it is unlikely that a program would receive its accreditation prior to January 1, 2002, and still not be in operation by July 1, 2003.

Comment: Several commenters believed that the proposed "new program" exception as outlined in the proposed rule and the recently issued One-Time Notification (Change Request 3247, Transmittal 87, issued on May 26, 2004) is too restrictive. Under the proposal, a hospital's resident count can only be increased if no residents from the newly approved program were training during the relevant cost reporting period. One commenter gave an example that if a new residency program "was accredited on January 1, 2001 and began training residents on July 1, 2001, and the hospital's relevant

cost reporting year for implementing section 422 was July 1, 2001 to June 30, 2002, that year would likely reflect only residents being trained in the first program year [of the new program.] If the hospital's FTE resident count is below its resident FTE cap for that year * * * it is at risk of having its cap reduced even though it has committed to training the residents in that program and was intending to use its 'cap space' for that program." The commenter asserted that such a result is contrary to the intent of Congress and that the proposed rule should be modified in its final version to allow new residency programs to grow to their full complement.

Response: Under section 1886(h)(7)(ii)(III) of the Act, as added by section 422(a)(3) of Public Law 108-173, a hospital may request that its reference resident level be adjusted to include residents in certain newly approved programs. Specifically, if a hospital's new program was accredited by the appropriate accrediting body (that is, the ACGME or the AOA) or approved by the American Board of Medical Specialties (ABMS) before January 1, 2002, but was *not in operation* during the hospital's reference period, the hospital may submit a timely request that we adjust the reference resident level to include the number of residents for which a new program was accredited at a hospital(s). While we sympathize with the commenters' points, we have interpreted "not in operation" to mean that the hospital was not training residents in that program during its reference cost reporting period. As such, a residency program that was accredited before January 1, 2002, and was training any residents during the hospital's reference cost reporting period would not be eligible to make a timely request that its resident level for its reference period be adjusted to reflect the number of accredited slots for which that new medical residency training program was approved.

We are, however, sympathetic to the commenters' point that hospitals with new residency programs that were in operation during the reference period may not be able to grow to their full complement of residents if their FTE resident cap is reduced if their reference FTE resident count is below their reference FTE resident cap. However, such a hospital may apply for additional FTE resident slots under section 1886(h)(7)(B) of the Act in an attempt to adjust its cap to allow for payment for the additional slots in the new program. In this final rule, as discussed under section IV.O.2.m. of this preamble, we are adding an evaluation criterion to

address the situation where a hospital's FTE resident cap was reduced under section 1886(h)(7)(A)(i) of the Act and the hospital had started a new residency program (accredited before January 1, 2002) that was in operation during the reference period but had not yet reached a full complement and the hospital has requested additional slots to allow the new program to train residents in FTE positions that were not included in the reference resident period. For the purposes of this criterion, we are defining a new program as a program that has been in operation (training residents) for three or fewer years in the reference period. In addition, the hospital must not qualify for adjustment to its reference FTE resident count under section 1886(h)(7)(ii)(III) of the Act and the hospital's FTE resident cap must have been reduced under section 1886(h)(7)(A)(i) of the Act.

Comment: One commenter described a situation where a hospital took over permanent sponsorship and training of residents in a program from another hospital that was experiencing financial difficulties. The hospital became the sponsor of and received accreditation for 16 residents in the program by November 2002, while continuing to train the remnant of residents that transferred from the other hospital. The hospital began training its own residents in the program on July 1, 2003, and planned to grow the program to its full complement of 16 residents by July 1, 2005. The commenter requested that, due to the circumstances surrounding the program which experienced a temporary drop in enrollment due to another hospital's financial difficulties, the hospital be permitted to adjust its reference resident level on its cost report that includes July 1, 2003 to reflect the full 16 accredited slots, rather than the 10 actual FTEs that were training in that cost reporting period.

Response: As with many situations brought to our attention by commenters, we are sympathetic to this commenter's concerns, but we note that the language at section 1886(h)(7)(ii)(III) of the Act precludes us from granting the commenter's request. Specifically, under section 1886(h)(7)(ii)(III) of the Act, a hospital may request that its reference resident level be adjusted to include residents in certain newly approved programs if the new program was accredited by the appropriate accrediting body before January 1, 2002, was not in operation during the hospital's reference period, and the hospital submits a timely request that we adjust the reference resident level to include the number of residents for which a new program was accredited at

the hospital. Therefore, the commenter's hospital would not qualify to have the resident level on its cost report that includes July 1, 2003 adjusted to reflect residents in its new program for two reasons: first, its program received accreditation after January 1, 2002, not before January 1, 2002 as the statute specifies; second, the program was in operation during the hospital's reference cost reporting period (that is, the cost report that includes July 1, 2003). In order for the hospital to receive an adjustment to its reference resident level under section 1886(h)(7)(A)(ii)(III) of the Act for the cost reporting period that includes July 1, 2003, the new program also cannot be in operation in the cost reporting period that includes July 1, 2003.

(5) Affiliations

Section 1886(h)(7)(A)(iii) of the Act, as added by section 422(a)(3) of Public Law 108-173, directs the Secretary to consider whether a hospital is a member of a Medicare GME affiliated group (as defined under § 413.86(b)) as of July 1, 2003, in determining whether a hospital's FTE resident cap should be reduced. As described above, some hospitals that have reduced their resident levels below their FTE resident caps may have affiliated with other hospitals that would otherwise exceed their FTE resident caps. Thus, while some hospitals were below their FTE resident caps prior to entering into a Medicare GME affiliation agreement, upon affiliating, their FTE resident caps were temporarily reduced because some or all of their excess FTE slots were temporarily added to the FTE caps of other hospitals as part of the affiliation agreement. Under the Medicare GME affiliation agreement, these otherwise "excess" FTE slots have been transferred for use by other hospitals, and, therefore, CMS would take into account the revised caps under the affiliation agreement for both the hospital that would otherwise be below its FTE resident cap and the revised caps of the other hospital(s) that are part of an affiliated group. In determining whether hospitals' FTE resident caps should be reduced under section 1886(h)(7)(A)(i) of the Act, section 1886(h)(7)(A)(iii) of the Act directs CMS to consider hospitals "which are members of the same affiliated group . . . as of July 1, 2003." In the May 18, 2004 proposed rule (69 FR 28297), we proposed that hospitals that are affiliated "as of July 1, 2003" means hospitals that have in effect a Medicare GME affiliation agreement, as defined in existing § 413.86(b), for the program year July 1, 2003 through June 30, 2004,

and have submitted a Medicare GME affiliation agreement by July 1, 2003 to their fiscal intermediaries with a copy to CMS. These hospitals may have already been affiliated prior to July 1, 2003, or may have affiliated for the first time on July 1, 2003. In either case, in determining possible reductions to a hospital's FTE resident cap, we proposed to use a hospital's cap as revised by the July 1, 2003 Medicare GME affiliation agreement. We believe this interpretation is consistent with the intent of section 1886(h)(7)(A)(iii) of the Act, as added by section 422(a)(3) of Public Law 108-173, in that a hospital's FTE resident cap should not be reduced if some or all of its excess resident slots have been transferred for use by hospitals with which it is affiliated (that is, the hospital is training at least as many FTE residents as are in its "affiliated" FTE resident cap).

Although hospitals in an affiliated group base the FTE cap adjustments on an aggregate FTE resident cap, we proposed that we would determine whether a hospital's FTE resident cap should be reduced on a hospital-specific basis. Section 1886(h)(7)(A)(iii) of the Act states that "the provisions of *clause (i)* shall be applied to hospitals which are members of the same affiliated group * * *" (emphasis added). Clause (i) of section 1886(h)(7)(A) of the Act, as described above, requires the reduction of hospitals' FTE resident caps under certain circumstances, based on the otherwise applicable FTE resident cap and the resident level in the applicable reference period, as described above (which would be either a hospital's most recent cost reporting period ending on or before September 30, 2002, or the cost reporting period that includes July 1, 2003). We proposed to interpret this reference to clause (i) to mean that the Secretary is to use a hospital's July 1, 2003 "affiliated" FTE resident cap as the otherwise applicable FTE resident cap when determining a possible reduction to the FTE resident cap. In other words, if a hospital is affiliated as of July 1, 2003, we proposed to superimpose the "affiliated" FTE resident cap onto the hospital's reference cost reporting period.

Specifically, as we stated under section IV.O.2.f.(1) of this preamble, consistent with section 1886(h)(7)(A)(ii)(I) of the Act, to determine possible reductions to a hospital's FTE resident cap, we proposed that we would use a hospital's most recent cost reporting period ending on or before September 30, 2002. If a hospital is part of a Medicare affiliated group for the program year beginning July 1, 2003, we are proposing to compare the hospital's July 1, 2003 "affiliated" FTE resident cap to its resident level on the most recent cost report ending on or before September 30, 2002. If the hospital's resident level from its most recent cost report ending on or before September 30, 2002, is below its July 1, 2003 "affiliated" FTE resident cap, we are proposing to permanently reduce the hospital's FTE resident cap, that is, the hospital's FTE resident cap without the temporary adjustment under the July 1, 2003 affiliation agreement, by 75 percent of the difference between the hospital's resident level and the July 1, 2003 "affiliated" FTE resident cap.

Alternatively, as stated above under section IV.O.2.f.(2) of this preamble, consistent with section 1886(h)(7)(A)(ii)(II) of the Act, a hospital may submit a timely request to CMS that its cost report that includes July 1, 2003, be used as the reference period to determine possible FTE resident cap reductions because of an expansion of an existing program that is not reflected on the hospital's most recent settled cost report. If a hospital is affiliated for the program year beginning July 1, 2003, and we grant the hospital's timely request to use the cost reporting period that includes July 1, 2003, because its expansion of an existing program(s) is not reflected on the most recent settled cost report, we proposed to compare the hospital's July 1, 2003 "affiliated" FTE resident cap to its resident level on the cost report that includes July 1, 2003. If the hospital's resident level from its cost report that includes July 1, 2003 is below its July 1, 2003 "affiliated" FTE resident cap, we proposed to permanently reduce the hospital's FTE resident cap, that is, the hospital's FTE

resident cap without the temporary adjustment under the July 1, 2003 affiliation agreement, by 75 percent of the difference between the hospital's resident level and the July 1, 2003 "affiliated" FTE resident cap.

For example, Hospital A's most recent cost report ending on or before September 30, 2002 is FYE December 31, 2001. Hospital A has a direct GME FTE resident cap (unadjusted for an affiliation) of 100, and an IME FTE resident cap (unadjusted for an affiliation) of 90. Hospital A did not have an expansion of an existing program that was not reflected on its most recent settled cost report, and therefore, its FYE December 31, 2001 cost report is being used as the reference period for purposes of determining a possible reduction to its FTE resident caps. Hospital A's unweighted direct GME count of allopathic and osteopathic FTE residents on its December 31, 2001 cost report is 60. Hospital A's IME count of allopathic and osteopathic FTE residents on its December 31, 2001 cost report is 55.

Hospital B, with a FYE of September 30, expanded an existing program, and that expansion is not reflected on its most recent settled cost report. Hospital B has submitted, and we have granted, a timely request that its cost report that includes July 1, 2003 (that is, its FYE September 30, 2003 cost report) be used for purposes of determining a possible reduction to its FTE resident caps. Hospital B has a direct GME FTE resident cap (unadjusted for an affiliation) of 100, and an IME FTE resident cap (unadjusted for an affiliation) of 95. Hospital B's direct GME unweighted count of allopathic and osteopathic FTE residents on its September 30, 2003 cost report is 120, and its IME count of allopathic and osteopathic FTE residents for the same period is 110.

On July 1, 2003, Hospital A and Hospital B entered into a Medicare GME affiliation agreement. Under the affiliation agreement, the hospitals' FTE resident caps are revised as follows:

Affiliation Year				
July 1, 2003 through June 30, 2004				
	Direct GME FTE Resident Cap	Direct GME Affiliated Cap	IME FTE Resident Cap	IME Affiliated Cap
Hospital A	100	60	90	55
Hospital B	100	140	95	130

To apply section 1886(h)(7)(A)(i) of the Act, Hospital A's affiliated FTE resident caps as of July 1, 2003, are compared to its direct GME and IME allopathic and osteopathic

FTE resident counts from its FYE December 31, 2001 cost report, and Hospital B's affiliated FTE resident caps as of July 1, 2003, are compared to its direct GME and IME

allopathic and osteopathic FTE resident counts from its FYE September 30, 2003 cost report, as follows:

	Affiliated Direct GME Cap	Unweighted Allopathic and Osteopathic FTE Count	Unweighted count below affiliated cap?	If yes, reduce <u>actual</u> FTE resident cap by 75 percent of difference between affiliated cap and unweighted count
Hospital A	60	60 (from FYE 12/31/01)	No	--
Hospital B	140	120 (from FYE 9/30/03)	Yes	$100 - [.75(140 - 120)] = 85$

	Affiliated IME Cap	Allopathic and Osteopathic FTE Count	Count below affiliated cap?	If yes, reduce <u>actual</u> FTE resident cap by 75 percent of difference between affiliated cap and count
Hospital A	55	55 (from FYE 12/31/01)	No	--
Hospital B	130	110 (from FYE 9/30/03)	Yes	$95 - [.75(130 - 110)] = 80$

Effective for portions of cost reporting periods beginning on or after July 1, 2005, Hospital A's FTE resident caps for direct GME and IME will remain at 100 and 90, respectively, while Hospital B's FTE resident caps for direct GME and IME will be reduced to 85 and 80, respectively.

We also noted that there are hospitals that may have been members of a Medicare GME affiliated group in program years that coincide with or overlap the reference cost reporting periods, but these hospitals were not affiliated as of July 1, 2003. As such, they are not subject to the May 18, 2004 proposed policy described above applicable to section 1886(h)(7)(A)(iii) of the Act, as added by section 422(a)(3). For these hospitals, we proposed to compare the resident level in the applicable reference period to the FTE resident cap as adjusted by the

affiliation agreement applicable to that reference period. If a hospital's resident level is below its otherwise applicable FTE resident cap for that reference period cost report, we proposed to permanently reduce the hospital's FTE resident cap, that is, the hospital's FTE resident cap without the temporary adjustment under the affiliation agreement for that period, by 75 percent of the difference between the hospital's resident level and the otherwise applicable FTE resident cap. (Proposed redesignated § 413.79(c)(3)(iv)(B)). For example, assume a hospital with a June 30 fiscal year end affiliated for one program year from July 1, 2001, through June 30, 2002. On its June 30, 2002 cost report (that is, its most recent cost report ending on or before September 30, 2002), its FTE resident cap is 20, its cap as revised by the affiliation agreement is 25, and its resident level is 21 FTEs.

Because this hospital's resident level of 21 is below its otherwise applicable FTE resident cap of 25, the hospital's FTE resident cap of 20 will be reduced as follows: $20 - [(.75)(25 - 21)] = 17$. We proposed to apply the same methodology described above in the event that the reference period is a hospital's cost report that includes July 1, 2003 (that is, for a hospital that had an expansion of a program that is not reflected on its most recent settled cost report and that made a timely request to use the period that includes July 1, 2003), if that hospital is not affiliated as of July 1, 2003, but its cost report that includes July 1, 2003 overlaps with a program year for which the hospital was affiliated. In other words, section 1886(h)(7)(A)(i) of the Act will be applied by comparing a hospital's reference resident level to the otherwise applicable FTE resident cap, as adjusted

for any affiliation agreement for the reference period.

Comment: Some commenters acknowledged the challenges that CMS faced in implementing section 422, particularly section 1886(h)(7)(A)(iii) of the Act related to hospitals that are members of a Medicare GME affiliated group “as of July 1, 2003,” and commended CMS for its work on proposals related to this provision. However, those commenters, along with many others, expressed concern about the proposed policy related to hospitals that were affiliated as of July 1, 2003, and asked that our final policy concerning possible FTE resident cap reductions for these hospitals be amended substantially.

Generally, the comments concerning Medicare GME affiliation agreements fell into the following four categories:

(1) Hospitals that are affiliated for the academic year beginning July 1, 2003 should have their applicable FTE resident cap for the period including July 1, 2003 compared to their applicable resident level for the period including July 1, 2003. The commenters expressed great concern regarding the proposed methodology whereby a hospital’s “affiliated” FTE resident cap for the period July 1, 2003 to June 30, 2004 would be compared to the hospital resident FTE counts corresponding to a different (in some cases, not even overlapping) period for purposes of section 422. Although the commenters recognized that, in proposing this methodology, CMS was attempting to reconcile and give meaning to seemingly inconsistent provisions within section 422, they strongly believed that teaching hospitals should be provided with, and that CMS has the authority to provide, the “most straightforward” option. They stated that it would not “make sense” to reduce the FTE resident cap of a hospital based on a comparison of its cap in an affiliation agreement that was from a period different than its reference cost reporting period. Therefore, most commenters generally recommended that each hospital’s specific July 1, 2003 “affiliated” FTE resident cap should be compared to its FTE resident count for the July 1, 2003 through June 30, 2004 academic year, while one commenter recommended that CMS allow each hospital to elect whether to have its specific July 1, 2003 “affiliated” FTE resident cap compared to its FTE resident count for the period July 1, 2003 to June 30, 2004, for purposes of determining if and by how much the hospital’s FTE resident caps would be reduced.

(2) *Hospitals that are affiliated for the academic year beginning July 1, 2003 should be permitted to compare their FTE resident caps from their modified, final submitted Medicare GME affiliation agreements for the academic year beginning July 1, 2003 and ending June 30, 2004 to their applicable resident level for the cost reporting period including July 1, 2003.* The commenters noted that the existing regulations allow hospitals to modify their affiliation agreements by June 30 of a particular academic year to reflect the realities of the time spent in various training rotations in the event that the planned number of FTEs trained at each hospital, as specified in the affiliation agreement submitted to the fiscal intermediary by July 1 of that year, differs from the actual training rotations that occurred during the year. The commenters stressed that, for purposes of the “redistribution of unused resident slots”, it is also important to allow affiliated hospitals to modify their arrangements to reflect the actual distribution of the member hospitals’ FTE residents and their aggregate FTE resident cap; and the use of final, possibly modified affiliated FTE caps could avert unintended adverse consequences.

(3) *Hospitals that are affiliated for the academic year beginning July 1, 2003 should be given the opportunity after the final rule is published to amend the affiliation agreement that was in place as of June 30, 2004.* The commenters asked that CMS grant hospitals that were affiliated for the academic year beginning July 1, 2003, the option to modify those affiliations after publication of the final rule to account for “unintended consequences,” since the deadline of June 30, 2004 for potential amendments to the July 1, 2003 agreements occurred during the comment period for the FY 2005 IPPS proposed rule, and there was still much uncertainty regarding how the agreements would be accounted for under section 422. The commenters stated that they should be granted this option because, when hospitals elected to join an affiliated group as of July 1, 2003, the hospitals “had no way of knowing that this election would have implications for potential reductions to their hospital-specific resident FTE caps.”

(4) *Hospitals that are affiliated for the academic year beginning July 1, 2003 and that are at or above the aggregate cap should be treated as a group and should not lose any resident positions under section 422.* Several commenters argued that the presence of the language at section 1886(h)(7)(A)(iii) of the Act

concerning hospitals that are “members of the same affiliated group * * * as of July 1, 2003” implies that Congress was giving special consideration to hospitals that had elected to join an affiliated group for Medicare purposes, and that the initial FTE resident cap and count comparison under section 1886(h)(7)(A)(i) of the Act should first be conducted at the affiliated group level. The commenters urged CMS to ensure that a determination that finds the aggregate count of the hospitals in the affiliation to be higher than the aggregate cap should “automatically and without question” exempt all hospitals within the group from any reduction in hospital-specific caps. Some commenters suggested that this interpretation is consistent with CMS’ current policy on affiliated groups for payment purposes when the group as a whole is under the aggregate cap. Some commenters also added that in the case where the groups aggregate FTE count is below the corresponding affiliated aggregate FTE cap, CMS should use a hospital-specific comparison to determine which hospitals in the group should have their FTE resident caps reduced. Another commenter recommended that CMS should aggregate the excess FTE resident slots for the entire affiliated group, and any reduction should be prorated among all hospitals in the affiliated group.

Response: We have given a considerable amount of thought to each comment received regarding our proposed policy on hospitals that are part of a Medicare GME affiliation group for the academic year beginning July 1, 2003. In addition, during the comment period for the proposed rule, we listened to many questions and concerns raised as a result of the issuance of the OTN, which included a deadline of June 14, 2004 for all hospitals, whether affiliated or not, to submit a timely request to the fiscal intermediary if a hospital wanted its cost report that includes July 1, 2003 to be used for purposes of determining possible reductions to its FTE resident caps. We acknowledge that the proposal concerning affiliated groups presented certain difficulties, particularly in light of the June 14, 2004 deadline. To mitigate those concerns, we issued a notice on June 15, 2004 on the CMS Web site [Notice on “Redistribution of Unused Resident Positions, <http://www.cms.hhs.gov/providers/hipps/resident.asp>],” which stated, “If, in response to comments, we finalize any policy with respect to application of section 1886(h)(7)(A) of the Act that differs from a policy described in the

OTNs and the proposed IPPS rule, we will provide another limited opportunity after publication of the final rule for affected hospitals to make or withdraw a timely request under section 1886(h)(7)(A)(ii) of the Act.”

Before stating our final policy, we would first like to explain our reasoning behind the proposal concerning affiliated groups relating to section 1886(h)(7)(A)(iii) of the Act. As is the case with any statutory language, the assumption must be that the Congress included this specific language at section 1886(h)(7)(A)(iii) of the Act to direct or grant the authority for the Secretary to take (or not take) certain action concerning affiliated groups that would not otherwise have been taken (or not taken) in the absence of that language. However, sections 1886(h)(7)(A)(i) and (C)(ii) of the Act already accounted for the application of aggregate caps in instances where hospitals might have been affiliated during their reference cost reporting periods by defining “otherwise applicable resident limit” to include adjustments to FTE caps resulting from a hospital’s participation in a Medicare GME affiliated group. As a result, we do not believe there is a “most straightforward” interpretation, as the commenter suggested, to the language at section 1886(h)(7)(A)(iii) of the Act concerning affiliations. We believed (and continue to believe) that this language was meant to “protect” hospitals that were affiliated “as of July 1, 2003” in some way. However, we realized that, whatever proposal we chose, some hospitals would benefit while other hospitals would not. We struggled (and have continued to struggle) to interpret the language in a meaningful manner. We ultimately proposed to interpret section 1886(h)(7)(A)(iii) of the Act to mean that, for hospitals that were affiliated “as of July 1, 2003,” we would superimpose the “affiliated” FTE resident caps “as of July 1, 2003” onto the hospitals’ reference cost reporting periods. Thus, we proposed that, if a hospital is part of a Medicare GME affiliated group for the program year beginning July 1, 2003, we would compare the hospital’s July 1, 2003 “affiliated” FTE resident cap to its resident level on the most recent cost report ending on or before September 30, 2002. Similarly, for a hospital that submitted a timely request to use the cost reporting period that includes July 1, 2003, as its reference cost report, we would compare the hospital’s July 1, 2003 “affiliated” FTE resident cap to its

resident level on the cost report that includes July 1, 2003.

Since publication of proposed rule, after reviewing all of the comments, we have revisited the proposal and have considered alternative interpretations of section 1886(h)(7)(A)(iii) of the Act. We believe we are adopting an interpretation of the statute that is both consistent with the statute and addresses the commenters’ concerns. First, we are convinced by the commenters’ argument that the presence of the language at section 1886(h)(7)(A)(iii) of the Act concerning hospitals that are “members of the same affiliated group * * * as of July 1, 2003” (emphasis added), means that the Secretary should treat those hospitals, and only those hospitals, that are affiliated for the academic year beginning July 1, 2003 as a group for purposes of determining possible FTE resident cap reductions. That is, for hospitals that are affiliated “as of July 1, 2003,” the comparison under section 1886(h)(7)(A)(i) of the Act between the FTE resident cap and count should first be conducted at the affiliated group level, and if the hospitals’ aggregate FTE resident counts are equal to or exceed the hospitals’ aggregate affiliated FTE resident caps for direct GME and IME respectively, then no reductions would be made to any of the individual hospitals’ FTE resident caps (that is, the hospitals’ FTE resident caps without the temporary adjustment under the July 1, 2003 affiliation agreement), even if, when considered on a hospital-specific basis, one or more of the member hospitals FTE caps would otherwise have been reduced under section 1886(h)(7)(A)(i) of the Act. As we will explain further below, we are also interpreting “as of July 1, 2003” to mean that the determination as to whether the aggregate affiliated FTE resident cap exceeds the aggregate FTE resident count is made using the sum of the hospital-specific FTE resident caps and the sum of the hospital-specific FTE resident counts from each affiliated group-member hospital’s cost report that includes July 1, 2003. We also believe that if hospitals that are “members of the same affiliated group * * * as of July 1, 2003” are to be treated as a group in instances where the FTE resident counts of the group as a whole equal or exceed the aggregate affiliated FTE resident cap, then it is also appropriate that these hospitals should be treated as a group in instances where the FTE resident counts of the group as a whole are below the aggregate affiliated FTE resident cap. Section 1886(h)(7)(A)(iii) of the Act states that “the provisions of

clause (i) shall be applied to hospitals which are members of the same affiliated group * * *” (emphasis added). Clause (i) of section 1886(h)(7)(A) of the Act, as described above, requires the reduction of hospitals’ FTE resident caps under certain circumstances, based on the otherwise applicable FTE resident cap and the resident level in the applicable reference period. In this final rule, we are interpreting the reference in section 1886(h)(7)(A)(iii) of the Act to clause (i) to mean that, where the aggregate FTE resident counts of the affiliated group as a whole are below the aggregate affiliated FTE resident cap, the Secretary is to use a hospital’s cost reporting period that includes July 1, 2003 as the reference period to determine possible reductions to the FTE resident caps. This would apply even when the hospital did not submit a timely request to use the cost report that includes July 1, 2003 (that is, regardless of whether there was an expansion of an existing program that was not reflected on an affiliated hospital’s most recent settled cost report). Using FTE information from each hospital’s cost report that includes July 1, 2003, we will determine the extent to which any hospitals in the affiliated group trained a number of FTE residents in excess of their individual “affiliated” FTE resident caps. Any hospital in the affiliated group that trained a number of FTE residents in excess of its individual “affiliated” FTE resident caps, would not have its FTE resident caps reduced. However, any hospital in the affiliated group that trained fewer FTE residents than its individual “affiliated” FTE resident caps would have its FTE resident caps reduced, and the aggregate reduction will be shared pro rata among the hospitals whose FTE counts were below their “affiliated” FTE caps during their cost report that includes July 1, 2003. Accordingly, we envision that the fiscal intermediaries will determine possible FTE resident cap reductions to hospitals that are affiliated for the academic year beginning July 1, 2003 in the following manner:

First, the fiscal intermediaries will identify those hospitals that are affiliated “as of July 1, 2003,” which as we proposed, means hospitals that have in effect a Medicare GME affiliation agreement, as defined in existing § 413.86(b), for the program year July 1, 2003 through June 30, 2004, and have submitted a Medicare GME affiliation agreement by July 1, 2003 to their fiscal intermediaries with a copy to CMS. Consistent with existing regulations

regarding affiliated groups (63 FR 26338 May 12, 1998), since a hospital could have an agreement with one hospital for a particular program and another hospital for a different program, the affiliated group for aggregate cap purposes includes the original two hospitals that have an agreement and every hospital that has an agreement with any of those hospitals. Then, for direct GME and IME respectively, the fiscal intermediaries will identify the "1996" FTE resident cap (adjusted for new programs, if applicable), and the unweighted allopathic and osteopathic FTE resident count from each hospital that is part of that affiliated group, from each hospital's cost report that includes July 1, 2003. (Note that since the 1996 cap and FTE count information from the cost report that includes July 1, 2003 is being used for purposes of section 422, the caps as amended on the July 1, 2003 affiliation agreement are irrelevant. The only purpose for the July 1, 2003 affiliation agreement is to identify those hospitals that are affiliated "as of July 1, 2003"). In many cases, the hospitals in the affiliated group will not all have the same fiscal year end. Therefore, for example, for a hospital with a FYE of June 30, the fiscal intermediary will identify the FTE resident cap (that is, the "1996" cap, as adjusted for new programs, if applicable) and the unweighted allopathic and osteopathic FTE resident count from the hospital's FYE June 30, 2004 cost report. For a hospital with a FYE of December 31, the fiscal intermediary will identify the FTE resident cap (that is, the "1996" cap, as adjusted for new programs, if applicable) and the unweighted allopathic and osteopathic FTE resident count from the hospital's FYE December 31, 2003 cost report. Next, the fiscal intermediary will add those FTE resident caps from those cost reports to determine the aggregate "affiliated" cap. The fiscal intermediary will also add the FTE resident counts for IME and direct GME respectively from those cost reports to determine the aggregate count. If the aggregate FTE resident counts are equal to or exceed the aggregate FTE resident caps, then no reductions would be made under section 1886(h)(7)(A)(i)(I) of the Act to the FTE resident caps of any of those hospitals in the affiliated group. Each hospital's "1996" FTE resident cap would not be reduced effective July 1, 2005, even if on a hospital-specific basis, a hospital had trained fewer

residents in its cost report that includes July 1, 2003 than its adjusted "affiliated" cap. As stated above for hospitals affiliated as of July 1, 2003, where the number of residents trained by those affiliated hospitals equals or exceeds their aggregated "1996" FTE resident caps, no reductions under section 1886(h)(7)(A)(i) of the Act would be required. However, where the aggregate FTE resident counts are below the aggregate FTE resident caps, a reduction to a hospital's FTE resident cap would be necessary. In these cases, *for each hospital*, the fiscal intermediary will determine the following FTE information from the *cost report that includes July 1, 2003*:

(1) The "1996" FTE resident cap (as adjusted by new programs, if applicable)—For IME from worksheet E, Part A of the Medicare cost report, the sum of lines 3.04 and 3.05. For direct GME from worksheet E-3, Part IV of the Medicare cost report, the sum of lines 3.01 and 3.02.

(2) The "affiliated" FTE resident cap—For IME, line 3.07. For direct GME, line 3.04.

(3) The total number of allopathic and osteopathic FTE residents—For IME, line 3.08. For direct GME, line 3.05.

(4) The difference between the aggregate "affiliated" FTE resident cap and the total FTE resident counts for all of the affiliated hospitals—For IME, Σ line 3.08 minus Σ (lines 3.04 + 3.05). For direct GME, Σ line 3.05 minus Σ (lines 3.01 + 3.02).

(5) For IME, for those hospitals whose FTE resident count from line 3.08 is greater than the "affiliated" FTE resident cap on line 3.07, indicate "zero." For direct GME, for those hospitals whose FTE resident count from line 3.05 is greater than the "affiliated" FTE resident cap on line 3.04, indicate "zero." For IME, for those hospitals whose FTE resident count from line 3.08 is less than the "affiliated" FTE resident cap on line 3.07, determine the difference between the hospital's "affiliated" FTE resident cap and the hospital's FTE resident count—line 3.08 minus line 3.07. For direct GME, for those hospitals whose FTE resident count from line 3.05 is less than the "affiliated" FTE resident cap on line 3.04, determine the difference between the hospital's "affiliated" FTE resident cap and the hospital's FTE resident count—line 3.05 minus line 3.04.

(6) For IME and direct GME separately, to determine the total amount by which the FTE resident counts are below the "affiliated" FTE resident caps, add the amounts determined under step 5 for each hospital that trained fewer residents than its "affiliated" FTE resident caps.

(7) For IME and direct GME separately, determine a pro rata cap reduction for each hospital by dividing the hospital-specific amount in step 5 by the total amount for all of those hospitals in step 6, and multiply by the amount in step 4. (that is, (step5/step6) \times step 4).

(8) For IME and direct GME separately, determine the actual cap reduction for each hospital by multiplying the pro rata cap reduction from step 8 by 0.75.

(9) For IME and direct GME separately, determine the reduced FTE resident cap for each hospital by subtracting the actual cap reduction from step 8 from the "1996" FTE resident cap from step 1. This is the hospital's FTE resident cap effective July 1, 2005.

The following is an example of how the reductions to the FTE resident caps will be determined where the FTE resident counts in the aggregate for hospitals that were affiliated as of July 1, 2003 are below the hospitals' FTE resident caps in the aggregate. (For ease of illustration, this example focuses on reductions to the IME caps only, but the methodology is the same for reductions to the direct GME caps):

Hospitals A, B, and C are affiliated for the academic year beginning July 1, 2003. Hospital C is also affiliated with Hospitals D and E for the academic year beginning July 1, 2003. Thus, the affiliated group for GME payment purposes, and for purposes of determining possible FTE cap reductions under 422 consists of Hospitals A, B, C, D, and E. Hospital A's and B's cost report that includes July 1, 2003 is their FYE June 30, 2004. Hospital C's and D's cost report that includes July 1, 2003 is their FYE December 31, 2003, and Hospital E's cost report that includes July 1, 2003 is its FYE September 30, 2003. Using steps 1 through 10 above, the reductions to the FTE resident caps of those hospitals in the affiliated group who trained residents below their "affiliated" FTE resident caps are determined in the table below.

Hospital	1996 FTE Caps (step 1)	"Affiliated" FTE Cap (step 2)	FTE Count (step 3)	Difference between FTE Count and "affiliated" Cap (step 5)	Pro rata reduction (step 7)	Actual Cap Reduction (step 8)	Final FTE Cap (step 9)
A	95	115	125	0	0	0	95
B	80	100	125	0	0	0	80
C	120	10	10	0	0	0	120
D	115	90	75	-15	-8	-6	109
E		125	65	-60	-32	-24	
Totals	440	440	400	-75	-40	-30	410
		step 4	-40	step 6			

Hospitals A, B, and C trained residents either equal to or in excess of their "affiliated" FTE resident caps (as determined under step 5), and therefore, no reduction is made to their "1996" FTE resident cap (step 9). However, Hospital D's FTE resident count of 75 was 15 less than its "affiliated" FTE resident cap of 90, and Hospital E's FTE resident count of 65 was 60 less than its "affiliated" FTE resident cap of 125 (as determined under step 5). Under this methodology, the fact that Hospitals A and B exceeded their respective "affiliated" FTE resident caps minimizes the reductions to Hospital D's and E's "1996" FTE resident caps through the calculation of a pro rata reduction under step 7. (Hospital C's "affiliated" FTE resident cap equaled its FTE resident count). Thus, under step 8, the actual cap reduction of 6 FTEs for Hospital D is determined by taking 75 percent of 8 (rather than 75 percent of 15), and the actual cap reduction of 24 FTEs for Hospital E is determined by taking 75 percent of 32 (rather than 75 percent of 60). As a result, under step 9, Hospital D's final FTE resident cap effective on July 1, 2005 is determined to be 109 FTEs, and Hospital E's final FTE resident cap effective on July 1, 2005 is determined to be 6 FTEs. We note that the total final FTE resident cap effective July 1, 2005 is 410 FTEs (the total under step 9), which, mathematically, is the same as subtracting 400 (the total FTEs trained in the group) from 440 (the aggregate "1996" FTE resident caps), multiplying by 75 percent, and subtracting the result from the original aggregate cap of 440 (that is, $[440 - (0.75(440 - 400))] = 410$).

We also note that the reductions to Hospital D's and E's "1996" FTE resident caps were minimized only because Hospitals A and B exceeded their "affiliated" FTE resident caps. If

all hospitals in the affiliated group had trained residents below their "affiliated" FTE resident caps based on their cost reports that include July 1, 2003, then a pro rata reduction would not benefit these hospitals. The "1996" FTE resident caps of all of the hospitals in the affiliated group would be reduced by 75 percent of the difference between each hospital's "affiliated" FTE resident cap and FTE resident count.

We believe this final policy concerning hospitals that are affiliated "as of July 1, 2003" addresses the commenters' concerns in that it protects hospitals from any loss of slots if the aggregate counts equal to or exceed the "affiliated" FTE resident caps, and could limit the loss of slots in instances where the aggregate counts are below the "affiliated" FTE resident caps. We have also addressed the commenters' concerns in that, in instances where the aggregate count is below the "affiliated" FTE resident caps, it accounts for the final, modified affiliation agreements, since it uses the affiliated cap as reported on the cost report, and it also allows for a comparison of contemporaneous caps and counts. However, the commenters also requested that we provide an opportunity for hospitals that were affiliated "as of July 1, 2003" to modify their affiliation agreements after publication of the final rule, if the final policy is significantly different from the proposed policy. We do not believe it is appropriate to allow hospitals to modify their affiliation agreements after publication of the final rule. The only reason we allow hospitals to modify their agreements by June 30 of an academic year is to make the FTE counts of each hospital in the affiliation reflect the realities of the cross-training that occurred within that academic year. Thus, the decision as to whether or not an affiliation agreement should be

modified should be based solely on whether the FTE counts first projected in the affiliation agreement on July 1 of a year differ from the actual FTEs that trained at each hospital during the year. We do not believe it is appropriate to allow a modification of the affiliation agreement by a hospital in order to minimize the applicable reductions under section 1886(h)(7)(A)(i) of the Act.

Comment: One commenter described a situation where a hospital that is located in an other than large urban area is part of an affiliated group as of July 1, 2003 with a rural hospital that has less than 250 beds. The commenter stated that while the rural hospital is exempt from reductions to its FTE resident caps, the urban hospital could be "penalized" because of the slots acquired under the affiliation agreement with the rural hospital, if the urban hospital did not fill all of those slots in its reference cost reporting period. The commenter believed that Congress did not intend to discourage urban hospitals from affiliating with rural hospitals, and asked that CMS carve out any FTEs associated with the rural hospital from the urban hospital's FTE resident cap for purposes of determining the number of unused residency slots at the urban hospital.

Response: With the exception of rural hospitals with less than 250 beds as specified at section 1886(h)(7)(A)(i)(II) of the Act, we cannot exempt other hospitals outright from possible reductions to their FTE resident caps. However, as we stated in response to the previous comment concerning hospitals that were part of an affiliated group as of July 1, 2003, if the hospitals' aggregate FTE resident counts equal or exceed the aggregate "affiliated" FTE resident caps, then no reductions would be made to any of the hospitals' specific "1996" FTE resident caps, even if on an

individual basis, a hospital in the group was training fewer residents than its "affiliated" FTE resident cap. But if the aggregate FTE resident counts are below the aggregate "affiliated" FTE resident caps, then (except for rural hospitals with less than 250 beds), a hospital in the affiliated group that trained less FTE residents than its individual "affiliated" FTE resident cap would have its "1996" FTE resident cap reduced. Accordingly, the urban hospital described by the commenter would be subject to possible FTE resident cap reductions only if, for the hospital(s) with which it was affiliated as of July 1, 2003, the aggregate FTE resident counts were below the aggregate "affiliated" FTE resident caps and the urban hospital was also training fewer residents than its "affiliated" cap. However, since the rural hospital's FTE resident caps are protected from reductions under section 1886(h)(7)(A)(i)(II) of the Act, the urban hospital could continue to affiliate with the rural hospital on and after July 1, 2005, and, to the extent that the rural hospital has FTE slots available to "lend" to the urban hospital, the urban hospital could receive a temporary increase to its FTE resident caps via the affiliation agreement with the rural hospital. Therefore, although this urban hospital may lose slots under section 1886(h)(7)(A)(i) of the Act, it may be able to receive additional slots temporarily by affiliating with the rural hospital. In addition, the urban hospital may apply for a permanent increase to its FTE resident cap of up to 25 additional FTEs under section 1886(h)(7)(B) of the Act.

Comment: One commenter noted that under the proposed regulations at FR 69 28297 May 18, 2004 a hospital's reference resident level would be compared to the hospital's reference FTE resident cap as adjusted by Medicare GME affiliation agreements if the affiliation agreement is in effect as of July 1, 2003 or for program years that coincide with or overlap the reference cost reporting period. The commenter asked for clarification regarding a hospital that otherwise has an FTE resident cap of zero, but during its reference period, the hospital received a temporary increase to its FTE resident cap by participating in a Medicare GME affiliated group. The commenter stated that in its reference period, its resident level was below its FTE cap as adjusted by the affiliation agreement and asked if, as a result, CMS would reduce its FTE resident cap below zero.

Response: As we stated in the proposed rule FR 69 28299 May 18, 2004, hospitals that are participating in a Medicare GME affiliation agreement as

of July 1, 2003 or for program years that coincide with or overlap the reference cost reporting period are not subject to the proposed policy applicable to section 1886(h)(7)(iii) of the Act, as added by section 422(a)(3). For such hospitals, we will compare the resident level in the applicable reference period to the FTE resident cap as adjusted by the affiliation agreement applicable to that reference period. If a hospital's resident level is below its otherwise applicable FTE resident cap for that reference period cost report, we are proposing to permanently reduce the hospital's FTE resident cap, that is, the hospital's FTE resident cap without the temporary adjustment under the affiliation agreement for that period, by 75 percent of the difference between the hospital's resident level and the otherwise applicable FTE resident cap. However, a resident FTE cap would not be reduced below zero. That is, if the hospital's cap without adjustment under the affiliation agreement is zero, the hospital would not receive a reduction in their FTE resident cap if their reference resident count is below the reference affiliated resident FTE cap.

g. Criteria for Determining Hospitals That Will Receive Increases in Their FTE Resident Caps

Generally, under section 1886(h)(7) of the Act, as added by section 422(a)(3) of Public Law 108-173, CMS is to reduce by 75 percent the "unused" resident slots from hospitals that were below their FTE resident caps in a specific reference period, and "redistribute" the FTE slots for use by other hospitals. Under section 1886(h)(7)(B) of the Act, as added by section 422 of Public Law 108-173, the Secretary is authorized to increase the otherwise applicable FTE resident cap for each qualifying hospital that submits a timely application by a number that the Secretary may approve, for portions of cost reporting periods occurring on or after July 1, 2005. In implementing section 1886(h)(7)(B) of the Act, we note the difficulty in deciding which teaching hospitals are more "deserving" than others to receive the redistributed unused resident slots. Therefore, in the May 18, 2004 proposed rule (69 FR 28299), we proposed a decision making process that we believe was an objective process. In addition, we noted that section 422 does not provide detailed guidance to the Secretary for deciding which hospitals should receive the unused resident slots, but rather gives the Secretary discretion in making the choice of which hospitals should qualify.

Section 1886(h)(7)(B) of the Act, as added by section 422, does establish

certain parameters in the statutory language for hospitals to qualify to receive increases in their FTE resident caps. First, section 1886(h)(7)(B)(i) of the Act states that the aggregate number of increases in the otherwise applicable resident limits (caps) may not exceed the estimate of the aggregate reduction in the resident limits determined under section 1886(h)(7)(A) of the Act (as specified in section IV.O.2.e. of this preamble). Section 1886(h)(7)(B)(iv) of the Act states that in no case will any hospital receive an FTE cap increase of more than 25 FTE additional residency slots as a result of the redistribution. (Proposed redesignated § 413.79(c)(4)). In addition, section 1886(h)(7)(B)(ii) of the Act specifies that in determining which hospitals will receive the increases in their FTE resident caps, the Secretary is required to take into account the demonstrated likelihood that the hospital would be able to fill the position(s) within the first three cost reporting periods beginning on or after July 1, 2005.

In setting up an application process for hospitals to apply for the unused resident slots discussed in section IV.O.2.h. of this preamble, we had proposed to implement this "demonstrated likelihood" requirement as an eligibility criterion that a hospital must meet in order for CMS to further consider the hospital's application for an increase in its FTE resident cap. Thus, we had proposed that, in order to be eligible for consideration for an increase under section 1886(h)(7)(B) of the Act, a hospital must first demonstrate the likelihood that it will be able to fill the slots within the first three cost reporting periods beginning on or after July 1, 2005, by meeting at least one of the following four criteria and by providing documentation that it meets that criterion in its application for an increase in its FTE resident cap:

Demonstrated Likelihood Criterion 1. The applying hospital intends to use the additional FTEs to establish a new residency program(s) on or after July 1, 2005 (that is, a newly approved program that begins training residents on or after July 1, 2005).

The hospital must meet the requirements in provisions (1) and (2) below:

(1) In order to demonstrate that the hospital is, in fact, establishing a new residency program, the hospital must—

- Submit an application for approval of a new residency program to the ACGME or the AOA by December 1, 2004, and include a copy of that application with the application to CMS for an increase in its FTE resident cap; or

- Submit an application for approval of a new residency program to the ACGME or the AOA by December 1, 2004, and, if establishing an allopathic program, include a copy of the hospital's institutional review document or program information form concerning the new program with the application for the unused FTE resident slots; or

- Submit an application for approval of a new residency program to the ACGME or the AOA by December 1, 2004, and include written correspondence from the ACGME or AOA acknowledging receipt of the application for the new program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit).

(2) To demonstrate that the hospital will be likely to fill the slots requested, the hospital must comply with one of the following:

- If the hospital has other previously established programs, submit documentation that each of the hospital's existing residency programs had a resident fill rate of at least 95 percent in each of program years 2001 through 2003; or

- If the hospital has other previously established residency programs, submit copies of the cover page of the hospital's employment contracts with the residents who are or will be participating in the new residency program (resident specific information may be redacted); or

- If the hospital is establishing a new residency program in a particular specialty, submit documentation indicating that the specialty has a resident fill rate nationally, across all hospitals, of at least 95 percent.

Demonstrated Likelihood Criterion 2. The applying hospital intends to use the additional FTEs to expand an existing residency training program (that is, to increase the number of FTE resident slots in the program) on or after July 1, 2005, and before July 1, 2008.

The hospital must comply with the requirements in provisions (1) and (2) below:

(1) To demonstrate that the hospital intends to expand an existing program, the hospital must comply with one of the following:

- Document that the appropriate accrediting body (the ACGME or the AOA) has approved the hospital's expansion of the number of FTE residents in the program; or

- Document that the National Residency Match Program or the American Osteopathic Association Residency Match Program has accepted or will be accepting the hospital's

participation in the match for the existing program that will include additional resident slots in that residency training program; or

- If expanding an allopathic program, submit a copy of the hospital's institutional review document or program information form for the expansion of the existing residency training program.

(2) To demonstrate that the hospital will be likely to fill the slots of the expanded residency program, the hospital must comply with one of the following:

- Submit copies of the cover page of the hospital's employment contracts with the residents who are or will be participating in the expanded program (resident specific information may be redacted) and copies of the cover page of the hospital's employment contracts with the residents participating in the program prior to the expansion of the program.

- If the hospital has other previously established residency programs, submit documentation that each of the residency programs had a resident fill rate of at least 95 percent in each of program years 2001 through 2003.

- If the hospital is expanding an existing program in a particular specialty, submit documentation that the specialty has a resident fill rate nationally, across all hospitals, of at least 95 percent.

- If the hospital is expanding a program in order to train residents that need a program because another hospital in the State has closed a similar program, and the applying hospital received a temporary adjustment to its FTE cap(s) (under the requirements of § 413.86(g)(9)), submit documentation of this action.

Demonstrated Likelihood Criterion 3. The hospital is applying for an increase in its FTE resident cap because the hospital is already training residents in an existing residency training program(s) in excess of its direct GME FTE cap or IME FTE cap, or both.

The hospital must submit, with its application, each of the following:

- Copies of the most recent as-submitted Medicare cost reports documenting on Worksheet E, Part A and Worksheet E3, Part IV the resident counts and FTE resident caps for both direct GME and IME for the relevant cost reporting periods.

- Copies of the 2004 residency match information concerning the number of residents the hospital intends to have in its existing programs.

- Copies of the most recent accreditation letters on all of the hospital's training programs in which

the hospital trains and counts FTE residents for direct GME and IME.

Demonstrated Likelihood Criterion 4. The hospital is applying for the unused FTE resident slots because the hospital is at risk of losing accreditation of a residency training program if the hospital does not increase the number of FTE residents in the program on or after July 1, 2005.

The hospital must submit, with its application for an increase in its FTE resident cap, documentation from the appropriate accrediting body of the hospital's risk of lost accreditation as a result of an insufficient number of residents in the program.

In the May 18, 2004 proposed rule, we proposed that each hospital must meet at least one of the above criteria in order to demonstrate the likelihood that it will be able to fill the additional slots associated with any increase in the hospital's FTE resident cap within the first three cost reporting periods beginning on or after July 1, 2005. In other words, each hospital that wishes to apply for an increase in its FTE resident cap must, as a preliminary matter, meet the eligibility requirement of demonstrating the likelihood that it will fill the additional positions, in order for CMS to further consider the hospital's application for an increase in its FTE resident cap.

General Comment on the Process for Applying for the Increase to the FTE Caps Under Section 422

Comment: Several commenters complimented CMS on the proposed process for applying for the section 422 increase to the FTE caps. One commenter stated: "[the commenter] appreciates that CMS had a very difficult task in determining which teaching hospitals that wish to increase their FTE resident caps are 'deserving' of such an increase. The combination of very specific statutory language (for example, the hospital priority ordering) on the one hand and the discretion granted to the agency on the other hand, along with the short timeframe for implementation, clearly created significant challenges, and [the commenter] applauds the thought and effort that went into developing the criteria, and CMS's attempt to develop an 'objective process.'"

On the other hand, several commenters believed the proposed administrative process for hospitals to receive cap increases under section 422 was complex and burdensome. One commenter believed that CMS should withdraw the proposals on the increases under section 422 to "reconsider its position on this issue." Another

commenter stated that the proposed process is “so complicated and burdensome that most hospital systems will not participate in the process. Only large university affiliated residency programs have personnel to pursue this process of reallocation of [the estimated] pool of resident numbers.” In addition, another commenter believed the proposed process for applying for the increase under section 422 is “exceedingly complex and convoluted.” This commenter urged CMS to “take pains to minimize the complexity of the redistribution process so as to ensure that all eligible hospitals are able to quickly assess the opportunities.”

Response: We appreciate the consideration from the commenters on the difficult nature of implementing section 1886(h)(7)(B) of the Act. We also recognize the complexity in the application process. We believe the “complexity” is largely a function of CMS’s need to meet the statutory requirements for prioritizing the requests and for assuring that the requesting hospital has demonstrated the likelihood of filling the requested slots within 3 years. We hope that the complexity does not deter hospitals from availing themselves of the opportunity to apply for an increase to their FTE resident caps under section 422 of the MMA.

Comments on the Proposed Demonstrated Likelihood Criteria

Comment: We received a variety of comments from the public on the proposed Demonstrated Likelihood requirements, as described in the May 18, 2004 proposed rule. Some of the commenters were supportive of the proposals. One commenter stated: “[w]e believe it serves no worthy programmatic or policy purpose for CMS to grant increases in resident FTE caps absent clear and convincing evidence that a hospital making the application is an institution with a proven track record of training residents in an environment in which physicians-in-training wish to be educated.” Another commenter “wholeheartedly” complimented CMS for proposing, as a prerequisite to a hospital’s consideration to receive an FTE resident cap increase under section 422, “that each hospital meet at least one of the four criteria” proposed.

On the other end of the spectrum, many commenters requested that there be flexibility in the requirements for hospitals to “demonstrate the likelihood”. For instance, several commenters suggested that it is unnecessary and burdensome for hospitals to submit accreditation letters

in the Demonstrated Likelihood Criteria 1 through 4. One commenter suggested that hospitals that seek increases under section 422 be permitted to submit to CMS a “narrative explaining their need and use of the additional slots,” as an option available to demonstrate likelihood. This commenter also suggested that other types of documentation should be acceptable to CMS for a hospital to demonstrate the likelihood. The commenter suggested “minutes from internal management, graduate medical education, or board meetings, internal correspondence to the designated institutional office (DIO), or other forms of documentation that demonstrate the institution is seriously discussing initiating new programs.”

Response: We understand that the demonstrated likelihood criteria may be difficult to meet for some hospitals that wish to apply for an increase to their FTE resident caps. By proposing multiple options within each Demonstrated Likelihood Criterion, we hoped to provide flexibility to hospitals, to allow several options for hospitals to meet this preliminary eligibility criterion to be considered to receive an increase in its FTE resident cap, but to do so in as an objective and documentable way as possible. For this reason, as a first level test, to allow a hospital to demonstrate that it would be very likely to use any increase in its FTE resident cap for a program that is, or will likely soon be approved, we proposed to rely on accreditation letters from the appropriate approving bodies for the residency programs at the applicant hospitals. We regret that some commenters believe this would be burdensome. However, the commenters’ alternative proposal to allow a hospital to submit a “narrative explaining their need and use of additional slots” is, by its nature, subjective and not easily verifiable, which is exactly what CMS sought to avoid in developing the application process. To address the other suggestions from the commenter regarding the reliance on “minutes from internal management * * *” and other types of documentation to support the Demonstrated Likelihood Criterion, we considered each of the suggestions. It appears to us that each of the alternative types of documentation proposed by the commenters would not objectively demonstrate that the hospitals are seriously planning to start a new program or expand an existing program. Thus, we do not agree that these other types of documentation would demonstrate the likelihood that the hospital would fill any additional FTE slots if its application to receive an

increase in its FTE resident cap was approved. We believe that our demonstrated likelihood criteria, as finalized in this rule and explained further below, provide an appropriate balance between the flexibility desired by hospitals seeking to meet this eligibility criterion and the objectivity required for CMS to be assured that the criterion is meaningful and measurable.

Comment: We received one comment on the option under proposed Demonstrated Likelihood Criterion 1, for hospitals to demonstrate they can fill the slots of a new program that is established on or after July 1, 2005, that states:

“• Application for approval of the new residency program has been submitted to the ACGME or the AOA by December 1, 2004. (Copy attached.)”

The commenter states that, although the requirement for such documentation “may be reasonable,” the commenter believes the timeframe established by CMS “is simply not feasible.” The commenter believes the December 1, 2004 date “would require a hospital to apply to ACGME or AOA prior to knowing whether it will be granted the additional slots.” The commenter requests that CMS reevaluate the timeframe associated with this option.

Response: We understand the commenter’s concern about the uncertainty of an applicant hospital as to whether it would receive an increase in its FTE resident caps when it applies by December 1, 2004 for accreditation for a new program(s). However, we deliberately set up this criterion so that CMS is able to determine, at the time we evaluate hospital applications for increases in FTE resident caps, which hospitals are able to demonstrate the likelihood of filling the slots of the new program. Applications for new programs that will be submitted to the ACGME or the AOA after December 1, 2004 (which is the deadline for most hospital applications for increases in FTE resident caps) are not at all helpful to CMS for determining which hospitals can demonstrate the likelihood, since CMS will need to make FTE cap increase determinations under section 422 effective July 1, 2005. For this reason, we have decided to maintain the originally proposed date requirements associated with this option under this Demonstrated Likelihood Criterion 1.

Comment: We received many comments on Demonstrated Likelihood Criteria 1 and 2, concerning the ability of the hospital to demonstrate that it will be likely to fill the requested slots. Specifically, these commenters were concerned with the option under each criterion that “if the hospital is

[expanding an existing/establishing a new] residency program in a particular specialty, [the hospital must] submit documentation indicating that the specialty has a resident fill rate nationally, across all hospitals, of at least 95 percent.”

One commenter, representing a particular specialty in medicine, disliked the option of a national fill rate of 95 percent in the specialty, stating that the commenter preferred the option in the Demonstrated Likelihood Criteria 1 and 2 to use a hospital-specific fill rate to demonstrate that the hospital will likely fill the number of slots requested: “if the hospital has other previously established programs, submit documentation that each of the hospital’s existing residency programs had a resident fill rate of at least 95 percent in each of program years 2001 through 2003.”

Another commenter requested that if the national fill rate option is retained by CMS, that the threshold percentage of 95 percent should be reduced.

Several commenters asked CMS to define “fill rate,” as used in the Demonstrated Likelihood Criteria. They noted that the term fill rate is often confused with the “match fill rate,” and that not all resident positions are filled through a match process. However, these commenters felt that use of a clearly defined national fill rate is an appropriate measure. One commenter stated that, by “fill rate,” the commenter believed we were referring to resident match data. Several commenters requested that we also include in our definition that “national fill rate” refers to the fill rate as of July 1st of each year.

One commenter was opposed to the use of the national fill rate as an indication that a program is likely to fill new FTE resident slots awarded pursuant to section 1886(h)(7)(B) of the Act, because it believed this measure would be misleading. The commenter noted that hospitals may choose to conduct a training program with fewer residents than allowed by their approved accredited slots and that “the fact that all of the accredited resident slots are not utilized may have little bearing on the ability of the institution to attract residents to its residency programs.”

Response: Section 1886(h)(7)(B)(ii) of the Act specifies that in determining which hospitals will receive the increases in their FTE resident caps, we are required to take into account the demonstrated likelihood that the hospital would fill the position(s) within the first three cost reporting periods beginning on or after July 1, 2005. In order to make this

determination, we proposed four objective criteria, at least one of which must be met, in order to demonstrate a likelihood of filling the positions within the first three cost reporting periods beginning on or after July 1, 2005. Two of the criteria are for hospitals that intend to use the additional FTE resident cap slots to establish a new residency program(s) on or after July 1, 2005, or to expand an existing residency program on or after July 1, 2005. It is especially difficult to develop criteria that are administratively feasible, objective, and verifiable in order to demonstrate the likelihood that a hospital’s future plans will be implemented. In an effort to design criteria that would objectively demonstrate that hospitals would fill additional residency positions associated with a new or expanded program(s), we proposed several criteria, one of which is that the specialty for which the hospital intends either to start a new program or to expand an existing program has a resident fill rate nationally, across all hospitals that offer the program, of at least 95 percent. We believe new or expanded programs in a specialty that is 95 percent full nationally, across all hospitals, would be a reasonable basis for determining that a hospital has demonstrated the likelihood that it will fill new positions in that specialty.

However, we agree with the commenters that the “national fill rate” should be defined with more accuracy. Furthermore, in light of the comments we received regarding “fill rate” and “residency match,” we agree that it is necessary to more explicitly distinguish between “residency match” and “resident fill rate” for the purpose of determining that there is a demonstrated likelihood a hospital will fill the slots if granted an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act.

For purposes of the application for the increase to the FTE caps under section 422, we are defining “national fill rate” for each academic year, as the number of residents training in a program nationally as compared to the number of accredited slots in that program as of June 30 of that year. This information is available from the ACGME and the AOA. Furthermore, we are requiring that, for the purposes of an application for an increase to a hospital’s FTE resident cap under section 1886(h)(7)(B) of the Act, a hospital must use the “fill rate” for the most recent academic year for which data is available.

We agree with the commenter that hospitals may train fewer residents than the number of available accredited slots

in their approved programs due to reasons other than an inability to fill those slots. Accordingly, we agree that the proposed 95 percent threshold national fill rate for demonstrating the likelihood of filling FTE resident slots in a new or expanded program may not take into account some of the reasons (other than an inability to fill the positions) that a program may be training fewer residents than it is accredited to train. Therefore, as suggested by the commenter, we are lowering the fill rate “threshold” to 85 percent. We believe that this lower rate will reasonably identify those programs that are likely to fill FTE resident positions in newly approved or expanded programs (while providing some latitude to account for other factors, beside ability to fill accredited slots, that affect the national fill rate), and to fully utilize an increase in FTE resident cap slots that may be available under section 1886(h)(7)(B) of the Act. By establishing a threshold of 85 percent, we believe, based on the most current data available from both the ACGME and AOA, that we will have identified approximately 30 percent of the currently approved programs, as meeting this criterion. Accordingly, we believe the revised threshold will better identify those programs as having a demonstrated likelihood of actually filling the new or expanded programs.

Furthermore, based upon our additional research in response to public comments, we believe that a national fill rate is not necessarily the only indicator of the ability of hospitals to fill residency positions in its MSA or State. There may be characteristics particular to a region, such as population density, variety of practice settings, or access to technology or procedures that may allow a specified area to have a fill rate in a specific program that exceeds the program’s national fill rate. Therefore, we are expanding the ways that a hospital may satisfy the “fill rate” criterion. In this final rule, we are specifying that a hospital may demonstrate the likelihood of filling FTE resident positions associated with a possible increase in its FTE resident cap under section 422 by documenting that any of the following applies to the new program or to an expansion of an existing program:

- The specialty program has a resident fill rate nationally, across all hospitals, of at least 85 percent.
- The specialty program has a resident fill rate within the state in which the hospital is located of at least 85 percent.
- If the hospital is located within an MSA, the specialty program has a

resident fill rate within the MSA of at least 85 percent.

We are amending the proposed CMS Evaluation Form part A1(2) and part A2(2) to include the following language: "The specialty program has a resident fill rate either nationally, or within the state or the MSA in which the hospital is located, of at least 85 percent." For the purposes of demonstrating the likelihood of filling FTE resident positions for purposes of section 1886(h)(7)(B)(ii) of the Act, "fill rate" means, for the most recent academic year for which data is available, the number of residents training in a program compared to the number of accredited slots in that program as of June 30 of that year.

As we stated in the proposed rule, we believe that, of all the medical specialties, geriatrics is the one specialty that is devoted primarily to the care of Medicare beneficiaries. In addition, we note that encouraging residency training in geriatrics in the context of Medicare payments for direct GME and IME is consistent with Congressional intent as expressed, among other places, in section 712 of Public Law 108-173. As such, we are giving special consideration to geriatric programs to meet the "fill rate" criterion for demonstrating the likelihood of filling FTE resident slots under section 422. Geriatrics is not a separately approved training program; rather, it is a subspecialty of another specialty program. For example, there is a geriatrics subspecialty of family practice. In this final rule, for the purposes of meeting the 85 percent fill rate criterion, we will allow hospitals that are starting a new geriatrics program or expanding an existing geriatric program to use the fill rate associated with the overall specialty program (rather than the fill rate for the geriatric subspecialty) to meet this demonstrated likelihood criterion.

The proposed Demonstrated Likelihood Criterion 3 (as finalized in this rule) allows hospitals that are already training a number of FTE residents in an existing residency training program(s) in excess of its direct GME FTE cap or IME FTE cap, or both, to meet the demonstrated likelihood requirement. In order to document that it meets this criterion a hospital must submit copies of the 2004 "residency match" information concerning the number of residents the hospital has in an existing program. For purposes of the application of this demonstrated likelihood criterion, we are defining "residency match" as a national process administered by the National Residency Matching Program

(NRMP), the San Francisco Matching Program, the American Osteopathic Association Residency Match Program, or the Urology Matching Program, by which applicants to approved medical residency programs are paired with programs on the basis of preferences expressed by both the applicants and the program directors.

The proposed Demonstrated Likelihood Criterion 1 and Demonstrated Likelihood Criterion 2 (also finalized in this rule) also allow a hospital to demonstrate the likelihood of filling the requested slots by demonstrating that the hospital's existing residency programs had a "resident fill rate" of at least 95 percent in each of program years 2001 through 2003. For the purpose of fulfilling these demonstrated likelihood criteria, we are defining "resident fill rate" to mean, for the most recent academic year for which data is available, the number of residents training in each program at a hospital as compared to the number of accredited slots in each program at that hospital as of June 30 of that year. Furthermore, for the reasons stated above, we are lowering the threshold percentage from 95 percent to 85 percent.

Comment: One commenter questioned the need for the option under Demonstrated Likelihood Criteria 1 and 2 of a hospital providing the resident fill rate for its other residency programs. The commenter believes that a hospital's ability to fill the slots of a new program, for example, "bears no relationship" to the fill rate of the hospital's other program(s).

Response: We disagree with the commenter's contention that the fill rates in the hospital's existing residency programs "bear no relationship" to the hospital's ability to fill slots in other programs. We continue to believe that the hospital's fill rate in all of its programs is a meaningful indicator to "demonstrate the likelihood" that a hospital will fill slots in a new program or an expansion of an existing program for purposes of section 422 of Public Law 108-173. We believe the hospital's location, faculty, patient base, and reputation all have a direct bearing on the overall ability of a hospital to fill either its new or its existing residency positions and that this criterion provides an objective method of demonstrating the likelihood that the hospital will fill residency positions for purposes of section 422. As such, we continue to believe that it is appropriate to include the fill rates of existing programs as one of the methods by which a hospital may demonstrate the likelihood of filling FTE residency

positions for purposes of section 422. Of course, where a hospital's fill rates fall below the acceptable threshold, the hospital may still demonstrate a likelihood of filling the requested slots based on the fill rate, either nationally, within the MSA, or within the State that the hospital is located, for that program.

Comment: We received one comment on the option under the proposed Demonstrated Likelihood Criterion 2 that states that the hospital may demonstrate the likelihood of filling FTE resident slots by demonstrating that:

- Hospital has employment contracts with the residents who are or will be participating in the expanded program (resident specific information may be redacted) and employment contracts with the residents participating in the program prior to the expansion of the program. (Copy of the cover page of both documents attached.)

Similar documentation requirements were proposed under Demonstrated Likelihood Criterion 1 for new programs.

The commenter believed that it is "onerous and unnecessary" for CMS to require hospitals to submit resident employment contracts. The commenter also believed that hospitals would be unable to provide contract information by December 1, 2004 (the application deadline for most hospitals to request the increase to the FTE caps under section 422) since residents who will be training in a program that starts July 1, 2005 will not be identified until Spring 2005.

Response: We agree with the commenter that residency match results from the National Residency Match Program (NRMP) for the academic year beginning July 1, 2005 will not be available until March 2005. Similarly, residency match results from the American Osteopathic Association (AOA) for the academic year beginning July 1, 2005 will not be available until February 2005. Since employment contracts are not signed until after this date, we agree that hospitals will be unable to provide copies of the cover page of residents' employment contracts as a method of demonstrating the likelihood that the hospital will fill residency positions for purposes of an increase in its FTE resident caps by the December 1, 2004 application deadline. Therefore, we are removing this option from the final rule. Under the final rule, hospitals will be required to demonstrate the likelihood of filling the requested slots by either of the two other methods—

- If the hospital has other previously established programs, submit

documentation that each of the hospital's existing residency programs had a resident fill rate of at least 85 percent in each of program years 2001 through 2003; or

- If the hospital is establishing or expanding a program in a particular specialty, submit documentation indicating that the specialty has a resident fill rate either nationally, or within the state, or MSA in which the hospital is located, of at least 85 percent.

Comment: One commenter had concerns with the option under Demonstrated Likelihood Criterion 2 that states:

“• The National Residency Match Program or the American Osteopathic Association Residency Match Program has accepted or will be accepting the hospital's participation in the match for the existing program that will include additional resident slots in that residency training program. (Documentation attached.)”

The commenter stated that if “CMS will recognize only program expansions that take effect on or after July 1, 2005, for hospitals that utilize the NRMP, their resident match information is not required until early 2005—after the December 2005 application deadline.” The commenter also questioned how a hospital under this option would demonstrate that the matching program “will be accepting” the hospital's match participation with the expanded resident slots.

Response: Under the proposed Demonstrated Likelihood Criterion 2, a hospital may demonstrate that it intends to expand an existing program by documenting that either the National Residency Match Program or the AOA Residency Match Program have accepted or will be accepting the hospital's participation in the match for the existing program that will include additional resident slots in that residency training program. We agree with the commenter that resident match information for the academic year beginning July 1, 2005 is not due to the NRMP until February 2005. As such, hospitals will not be able to document that the NRMP has accepted or will be accepting the hospital's participation in the match for the existing program that will include additional resident slots by the December 1, 2004 application deadline. Therefore, we are removing this option for hospitals to demonstrate that they intend to expand an existing program from the final rule for NRMP programs. Programs utilizing the NRMP will be required to demonstrate the intent to expand an existing program by either of the two other methods:

- Document that the appropriate accrediting body (the ACGME or the AOA) has approved the hospital's expansion of the number of FTE residents in the program.

- If expanding an allopathic program, submit a copy of the hospital's institutional review document or program information form for the expansion of the existing residency program.

We note that the listing of programs participating in the AOA Match Program will be available on the National Matching Services website as of November 1, 2004. Therefore, programs utilizing the AOA Match Program may, in addition to the two options listed above, demonstrate the intent to expand an existing program by documenting that the AOA has accepted the hospital's participation in the match program by the December 1, 2004 application deadline. Therefore, this method of demonstrating the hospital's intent to expand an existing program will be adopted as final for programs participating in the AOA Match Program.

Comment: One commenter expressed concern about Demonstrated Likelihood Criterion 1 and the option to include information regarding the application for the approval of the new program. The commenter mentioned that, in many cases, there are letters of intent that are sent to the accrediting body a year or two prior to submission of the application for accreditation. This commenter states that “since in many instances, the institution cannot increase its slots, or begin a new program, without the Medicare reimbursement, many programs would be in the situation of needing a full-blown application to the accrediting body, before they know if they will be awarded new positions by a raising of their cap. It makes sense to allow this earlier letter of intent, to allow those institutions the ability to start a new program, if they receive the increase in paid positions under this program.”

Response: We believe that a letter of intent does not meet the standard of “demonstrated likelihood of the hospital filling the positions.” It would only seem to portend hopeful intention on the part of the hospital, rather than a commitment. Therefore, we are not adopting the commenter's suggestion of a letter of intent as source of documentation.

Comment: One commenter was concerned about the accreditation options under Demonstrated Likelihood Criteria 1 and 2. For example, the option under Demonstrated Likelihood Criterion 2, states—

- The appropriate accrediting body (the ACGME or the AOA) has approved the hospital's expansion of the number of FTE residents in the program. (Documentation attached.)”

One commenter believed that this option should recognize and accommodate hospitals that are planning to expand a residency program(s), but have already received ACGME accreditation.

Response: We understand that in many instances, hospitals receive accreditation from the approving body before training residents in the expanded program (which can be a period of a year or more after receiving the accreditation). We believe that our proposed language above already accommodates the idea of hospitals receiving accreditation for the expanded number of FTE slots.

Comment: We received two comments on the option to document, for proposed Demonstrated Likelihood Criteria 1 and 2, that the appropriate accrediting body has approved the hospital's new program or expansion of the number of FTE residents in the program. One commenter notes that an application for residency program expansion “is a complex, extensive document that cannot be prepared in the roughly six-month time frame from this notice of proposed rule making to the December 1st deadline. A request for expansion often triggers an ‘early’ site visit by the specialty Residency Review Committee (RRC) and site visitor schedules are booked six to 12 months in advance.” Another commenter notes that the proposed date by which a hospital would be required to document the approval of the accrediting body would mean that the hospital would have to file an application with the ACGME/AOA “before knowing whether it will receive the additional slots necessary to fund [the] new or expanded program. We urge CMS to reconsider this timeframe to allow hospitals to receive slots contingent on receiving [AOA/ACGME] approval.”

Response: CMS understands that the applications for approval of new/expanded programs for the ACGME and the AOA are extensive documents that demonstrate a commitment on behalf of the hospitals to establish/expand a program. For this reason, we believed applications for approval are good sources of documentation to demonstrate the likelihood for purposes of the section 422 increase. We recognize that applying for program approval is a lengthy process that takes a significant period of time before approval is given by the ACGME/AOA. The commenter is correct in believing

that it would be unlikely that hospitals would have enough time to apply for program approval from the ACGME/ AOA (either for expansion or new program accreditation) within the timeframe set up by CMS for applying for the section 422 caps. However we have chosen December 1, 2004 as the date on which to show the approval, (since, as explained earlier, we intend to begin the allocation of the section 422 cap process in December)—and need to know at that time whether hospitals can demonstrate the likelihood of filling the slots. Under this criterion, we believe we will enable hospitals that were already contemplating new/expanded program approval from the ACGME/ AOA to be considered to receive an increase in their FTE resident caps under section 422. Under another criterion, we have addressed the situation where a hospital was already training residents above its 1996 FTE caps, before CMS proposed and finalized the application process implementing section 422. We do not believe a hospital that is merely contemplating the future possibility that it will train a number of residents in excess of its FTE resident caps can demonstrate the likelihood that it will fill additional positions within the timeframe for our decision process under section 1886(h)(7)(B) of the Act.

Therefore, we are not making additional changes to this option under Demonstrated Likelihood Criteria 1 or 2.

Comment: We received one general comment that the “single best piece of evidence” for a hospital to “demonstrate the likelihood” of filling the slots under section 422 is the fact that a hospital is already training a number of residents in excess of its FTE caps.

Response: We agree with the commenter that hospitals are able to fulfill the demonstrated likelihood requirement by documenting to CMS that they are training a number of FTE residents that exceeds their FTE cap(s) in the manner described in this final rule.

Comment: One commenter asked for flexibility in the choices under the proposed Demonstrated Likelihood Criteria 1 and 2. Specifically, the commenter pointed out that sections A1(1) and (2) and A2(1) and (2) of both criteria offer options in order to fulfill the demonstrated likelihood requirement; and that CMS proposed that the hospital be able to meet “one of the following” choices under each requirement. The commenter suggested that CMS add language that directs the hospital applicant to “check all that apply” at the beginning of A1(1) and (2) and A2(1) and (2) of the criteria.

Response: We understand that a particular hospital applicant may be able to meet more than one of the choices under A1(1) and (2) and A2(1) and (2).

For instance, it is possible that, in order to meet A1(1), a hospital may have written correspondence from the ACGME or AOA acknowledging receipt of the application for a new residency program, but may also have the actual application for the approval of the new program. We would not ask hospitals to provide any more documentation than is necessary under each of the options under A1(1) that is chosen by the applicant hospital; however, to provide hospitals with additional flexibility, if an applicant hospital would like to choose more than one of the options under A1(1) and (2) and A2(1) and (2), we are adding language at the beginning of each of A1(1) and (2) and A2(1) and (2) of Demonstrated Likelihood Criteria 1 and 2 that says “Check at least one of the following, if applicable”.

Comment: One commenter stated that there are a few residency programs in a particular specialty that received accreditation from the ACGME in 2003, for which the hospitals sponsoring these programs are training their first class of PG-1 residents in July 2004. The commenter urged CMS to revise the proposed Demonstrated Likelihood Criterion 1 that relates to establishing a new residency program on or after July 1, 2005. Specifically, the commenter stated that the new programs described were accredited after January 1, 2002, “* * * and can more appropriately demonstrate ability to fill to the full complement of residents in the next three cost reporting years, except that those years will be 2004–2007, rather than 2005–2008.”

Response: Section 1886(h)(7)(B)(ii) of the Act, as modified by section 422 of Public Law 108–173, specifies that: “[i]n determining for which hospitals the increase in the otherwise applicable resident limit is provided * * * the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2005.” (Emphasis added.) We provided several methods for hospitals to be able to demonstrate to CMS under the proposed Demonstrated Likelihood Criterion 1 that they can fill the slots by showing to CMS that they are establishing a new residency program on or after July 1, 2005. We believe hospitals that establish new residency programs before July 1, 2005, could possibly meet Demonstrated Likelihood Criterion 2, relating to a hospital that is expanding an existing

residency program on or after July 1, 2005. From the perspective of applying for the cap increase under section 422, the new program that starts training residents in 2004 is an “existing residency program” if established before July 1, 2005, and it is “expanding” if that program is increasing in the number of FTE residents in the first three cost reporting periods beginning on or after July 1, 2005.

Comment: We received one comment asking whether a hospital that applies for an increase in its FTE resident cap under section 422 and establishes a newly accredited program that starts in 2006 would be eligible to receive “the full complement of accredited positions, or only the first and second year (for example, 12 of 18 accredited slots) under these [proposed] regulations.” Similarly, another commenter described the situation of a hospital that establishes a new residency program that, because of the length of the accreditation process and a relatively long match period, will be unable to accept its first class of PGY-1 residents until July 1, 2006. The commenter urged CMS to clarify whether a new program like this will be able to receive a full complement of residents for the three years beginning July 1, 2006.

Response: Assuming the applicant hospital can demonstrate the likelihood that it will fill the slots relating to a possible increase in its FTE resident caps under section 422, as provided in the criteria on the CMS Evaluation Form, and finalized in this final rule, the applicant hospital may request on its application an increase of up to 25 FTE residents for direct GME and IME. However, if the applicant hospital does not demonstrate the likelihood that it will fill any FTE slots as claimed for programs described by the hospital on the CMS Evaluation Form(s) at any point within the hospital’s first three cost reporting periods beginning on or after July 1, 2005, the hospital will not be eligible to apply for the increase to the FTE caps under section 422. We do not believe our proposed Demonstrate Likelihood Criterion 1 reflects this point and, accordingly, are making the following changes with this final rule:

“A1: *Demonstrated Likelihood Criterion 1.* The hospital intends to use the additional FTEs to establish a new residency program (listed above) on or after July 1, 2005 (that is, a newly approved program that begins training residents at any point within the hospital’s first three cost reporting periods beginning on or after July 1, 2005).”

Comment: One commenter stated that a hospital may meet the demonstrated

likelihood requirement by documenting that it is establishing a new program or expanding an existing program, on or after July 1, 2005. The commenter asked whether the hospital is then limited to submitting a CMS Evaluation Form only for that program: The commenter suggested that if the answer is yes and CMS ultimately grants additional slots to the hospital based on the needs for that program, it seems unclear whether CMS would take the view that the additional cap slots could only be used for the program listed in the application.

Response: As we have stated in this final rule, each application by a hospital must be program specific. That is, the hospital must complete a separate CMS Evaluation Form for each program and demonstrate the likelihood of filling the slots in each program. However, increases in hospital's FTE resident caps under section 422 for direct GME and IME, once granted to a hospital, are no longer program specific. Rather, the caps are applied to any residents the hospital trains in excess of its otherwise applicable FTE cap(s) (Which could include the hospital's 1996 caps, subject to permanent adjustments for new programs or reductions under section 1886(h)(7)(A) of the Act).

Comment: One commenter believed that the proposed rule omitted the documentation requirement in the Demonstrated Likelihood Criteria for new programs and expansions of existing programs for "what should be key"; that is, that the applicant hospital requesting the additional slots for the new/expansion program would have already exceeded its 1996 FTE caps in previous years.

Response: While we believe a majority of those hospitals applying for the increase to the FTE caps for new programs and expansions of existing programs will already be training a number of residents that exceeds their FTE caps, we do not believe this circumstance is a necessary condition for all of the hospitals that apply. For example, a hospital whose FTE resident cap is reduced under section 1886(h)(7)(A) of the Act may have been planning to establish a new program in July 2006 that would have put the hospital's FTE resident count above its 1996 FTE cap at that time. Therefore, we see no reason to require that, at the time of the hospital's application, the hospital necessarily either exceed or be at its FTE cap, in order to meet the demonstrated likelihood requirement. Thus, we are not adopting the commenter's proposal to require hospitals to be training a number of residents that is at or over their FTE

caps in order to meet the Demonstrated Likelihood Criteria 1 or 2.

We note that we will be aware if an applicant hospital is training residents in excess of its FTE caps, even if the hospital checks off Demonstrated Likelihood Criteria 1 or 2 because, as part of the hospital's application for the section 422 increase to the caps, we proposed that the hospital must provide both the FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report (69 FR 28301). We are finalizing this application requirement with this final rule. (We have included a summary of the application requirements at the end of this section of this preamble).

Comment: One commenter indicated that there is a lack of clarity with proposed Demonstrated Likelihood Criterion 1 by stating that the precise documentation requirements differ between what is discussed in the preamble and what is proposed on the CMS Evaluation Form. The commenter believed that the submission of a new program application should not be required under second option under (1).

Response: It may have appeared to the commenter that the documentation requirements in the preamble language and the proposed CMS Evaluation Form for Demonstrated Likelihood Criterion 1 were different, because the preamble language states that the hospital must, in conjunction with every available option, submit a copy of the application for approval for the residency program "to the ACGME or the AOA by December 1, 2004", whereas the proposed CMS Evaluation Form asks for a copy of the new program application for only one of the options. We would like to clarify that the documentation required for (1) under A1 is limited to what is requested on the CMS Evaluation Form, as finalized in this final rule. We are not requiring a copy of the new program application as part of the documentation associated with the second option under (1). In the second option, we are only requiring a copy of the institutional review document or program information form concerning the new program that hospitals include as part of their applications for approval.

Comment: Several commenters suggested that CMS include options under the demonstrated likelihood criteria that take into account programs that seek certification from the American Board of Medical Specialties ("ABMS"). For example, under Demonstrated Likelihood Criterion 1, under the first requirement, the hospital

is given choices for documenting its application for new program accreditation from the ACGME or the AOA. The commenters asked what hospitals should do to demonstrate likelihood if the programs for which the hospitals are requesting cap increases for under section 422 are certified by the ABMS.

Response: We agree with the commenter that there are certain residency programs that are certified by the ABMS and that do not require certification by the ACGME or AOA. Our regulations currently recognize these programs as approved programs for purposes of direct GME and IME payments. Therefore, we believe it is appropriate to include the ABMS as a certifying organization for the purposes of Demonstrated Likelihood Criterion 1 and Demonstrated Likelihood Criterion 2. We are adding the following language to the CMS Evaluation Form at A1(1):

- "Application for approval of the new residency program has been submitted to the ACGME, AOA, or the ABMS by December 1, 2004. (Copy Attached.)"
- "The hospital has received written correspondence from the ACGME, AOA, or ABMS acknowledging receipt of the new program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit). (Copy Attached.)"

We are also adding the following language to the CMS Evaluation Form at A2(1): "The appropriate accrediting body (the ACGME, AOA, or ABMS) has approved the hospital's expansion of the number of FTE residents in the program. (Documentation attached.)"

Comment: We received several comments suggesting that the requirements under proposed Demonstrated Likelihood Criterion 3 are burdensome. Proposed Demonstrated Likelihood Criterion 3 states—

- A3: *Demonstrated Likelihood Criterion 3.* Hospital is applying for an increase in its FTE resident cap because the hospital is already training residents in an existing residency training program(s) in excess of its direct GME FTE cap or IME FTE cap, or both. (Copies of each of the following attached.)
 - Copies of the most recent as-submitted Medicare cost reports documenting on Worksheet E, Part A and Worksheet E3, Part IV the resident counts and FTE resident caps for both direct GME and IME for the relevant cost reporting periods.
 - Copies of the 2004 residency match information concerning the number of

residents the hospital intends to have in its existing programs.

- Copies of the most recent accreditation letters on all of the hospital's training programs in which the hospital trains and counts FTE residents for direct GME and IME."

The commenters questioned why all of the documentation requirements are necessary to demonstrate that the hospital is already exceeding its FTE cap at the time the hospital is applying for an increase in its FTE resident caps. Specifically, one commenter suggested that the most obvious way for CMS to get the information on whether the hospital is counting residents above its FTE caps is the Medicare cost report. However, the commenter believed that "[i]n many instances an FTE request [to count a number of residents that is] greater than the cap is not entered into the cost report due to the fact that it is futile to do so as the reimbursement will not change. However, Intern and Resident Information Survey (IRIS) data, contract cover pages, resident schedules, etc. can all be used to demonstrate that the actual resident FTE that could be counted for IME and DME purposes is greater than the cap allows. This commenter proposed that CMS allow hospitals to use these alternative sources of information." This commenter believed that the second option, to use 2004 residency match information, only shows an intent to fill slots, not that the slots have actually been filled. The commenter believed that it would be more accurate to look at the hospital's 2004 fill rate, which is available after July 1, 2004. Finally, this commenter had concerns with the third option under this criterion—to look at accreditation letters on all the hospital's programs. The commenter believed that the Residency Review Committee (RRC) for family practice does not accredit a program with a specific number, and encouraged CMS to change this requirement because it "does not fit the configuration of family practice residency accreditation."

Response: We agree with the comment that "the most obvious way" for CMS to determine whether a hospital is training FTE residents in excess of its FTE cap is to look at Medicare cost report information. Regarding the comment that some hospitals do not show on the cost report that they are over their FTE caps because the excess FTE residents would have no effect on Medicare direct GME and IME payments, We do not agree that hospitals should not be reporting all the FTE residents that the hospital is training. According to the regulations under § 413.86(f) (as redesignated as

§ 413.78), hospitals must report the actual total number of FTE residents. The total number of residents the hospital trained (even if it is in excess of the cap(s)) is actually used in determining direct GME and IME payments. For example, if the number of FTE residents exceeds the hospital's FTE cap for direct GME, if the hospital has two different per resident amounts (PRAs) for primary care and non-primary care, we prorate the reduction in the allowable number of FTE residents to bring the number of primary care and non-primary care FTEs to the hospital's FTE cap. In addition, we note that representatives of hospitals must attest on the Medicare cost report to the truth and accuracy of the information reported. Thus, it is required that hospitals include the total number of FTE residents in their cost reports, even if the hospital, is not allowed to count the residents for purposes of Medicare direct GME and IME payments as a result of application of the FTE resident cap(s).

To respond to the comment concerning the use of IRIS data, we believe that IRIS data is most useful from the perspective of looking back at the past and assuring that hospitals are not submitting duplicate FTE counts; we do not believe IRIS data would be helpful to determine whether hospitals can "demonstrate the likelihood of filling the positions" in the future. The documentation requirement regarding resident employment contracts is addressed in another comment and response above.

We agree with the commenter that the second documentation requirement, regarding 2004 residency match information for all the programs at the hospital, only shows an intent to fill slots and not that slots have actually been filled. In proposing to require 2004 match information, we sought this information even though it is more relevant to a hospital's "intent to fill" programs because we believed the information would portend that the hospital would continue to be over its FTE cap on or after July 1, 2005, as the statute requires in the demonstrated likelihood requirement. However, we agree with the commenter, and have decided to offer another option under Demonstrated Likelihood Criterion 3 to allow hospitals to provide fill rate information of all programs at the hospital in 2004, in addition to offering 2004 match information.

Finally, regarding the documentation requirement for the copies of the recent accreditation letters for all of the hospital's programs, we disagree with the commenter's suggestion that we

intended to match the listed number of resident positions in the accreditation letters with the number of slots claimed on the Medicare cost report. Our purpose in proposing to require accreditation documentation for all programs is so that we could ensure that all the hospital's programs continue to be accredited, that is, to verify the legitimacy of the applicant hospital's programs, not to "match" the number on the accreditation letters to the FTE counts on the cost report Worksheets E, Part A and Worksheet E3, Part IV. In addition, we understand that although the ACGME does not specifically approve a limited number of slots for family practice programs, the number of available slots in each program is determined by the program itself and that data is then reported to the ACGME. Therefore, we are not accepting the commenter's request to excuse hospitals from providing accreditation documentation for family practice programs.

Comment: A number of commenters focused on proposed Demonstrated Likelihood Criterion 4, which states—
"Demonstrated Likelihood Criterion 4. The hospital is applying for the unused FTE resident slots because the hospital is at risk of losing accreditation of a residency training program if the hospital does not increase the number of FTE residents in the program on or after July 1, 2005. (Documentation attached from the appropriate accrediting body of the hospital's risk of lost accreditation as a result of an insufficient number of residents in the program.)"

Several commenters asked CMS to provide further explanation as to why CMS believed these circumstances merit the addition of this proposed Demonstrated Likelihood Criterion, particularly where the hospital is not training a number of FTE residents in excess of its 1996 FTE cap(s). One commenter asked why hospitals under this criterion do not demonstrate to CMS that the additional cap slots under section 422 are necessary because, increasing the resident slots would otherwise cause the hospitals to exceed their FTE caps. This commenter also believed that, under this criterion, hospitals should demonstrate fill rates as part of the documentation requirements.

Another commenter believed that this criterion does not fit with the requirement that the hospital demonstrate the likelihood that it will fill FTE resident slots "[i]n fact, it says just the opposite—that the program has not been able to fill its slots, and is under a threat of academic consequences. In such cases, we believe

it is perhaps better for the program to close, than to waste new slots on a program that has little chance of filling.”

Response: When we proposed Demonstrated Likelihood Criterion 4, we were under the impression that there were some hospitals that were training a number of residents below their FTE caps, and were at risk of losing their accreditation if they did not fill their residency program with more slots. However, based upon the public comments we received questioning why the criterion is necessary, and given that we did not receive any comments in support of the criterion, we agree that we should delete Demonstrated Likelihood Criterion 4 from the CMS Evaluation Form in this final rule.

h. Application Process for the Increases in Hospitals' FTE Resident Caps

As stated above, in the May 18, 2004 proposed rule, we proposed an objective decision-making process for determining how hospitals will be prioritized when identifying the hospitals that will receive increases in their FTE resident caps. In order for hospitals to be considered for increases in their FTE resident caps, section 1886(h)(7)(B)(i) of the Act, as added by section 422(a)(3) of Public Law 108-173 requires that each “qualifying hospital” submit a “timely application.” We proposed that each hospital must submit the following information on its application for an increase in its FTE resident cap:

- The name and Medicare provider number of the hospital.
- The total number of requested FTE resident slots (for all residency programs at the hospital) for direct GME or IME, or both (up to 25 FTEs).
- A completed copy of the CMS Evaluation Form (as described below) for each residency program for which the applicant hospital intends to use the requested increase in the number of FTE residents and source documentation to support the assertions made by the hospital on the Evaluation Form. (For example, if the hospital checks off on the Evaluation Form that the hospital is located in a geographic Health Professions Shortage Area (HPSA), the hospital would include documentation to support that assertion.) A copy of the blank proposed CMS Evaluation Form appears at the end of this section of the preamble.
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report.

- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following information in the hospital's application for an increase in its FTE resident cap:

“I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents.”

We further proposed that any hospital that wishes to receive an increase in its FTE resident cap(s) must submit a copy of its completed application (as described above) to the CMS Central Office and to the CMS Regional Office for the region in which the applicant hospital is located, and that the application must be received on or before December 1, 2004. (The mailing addresses for the CMS offices are indicated at the end of this section of the preamble.) We note that some hospitals' FTE counts will be subject to audit for purposes of section 1886(h)(7)(A) of the Act, and those audits may not be completed by December 1, 2004. Because the results of such an audit may be a factor in a hospital's decision whether to request an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act, we proposed to allow a later date for those hospitals to apply for increases in their FTE resident caps. Therefore, if a hospital's resident level is audited for purposes of section 1886(h)(7)(A) of the Act, and that hospital also wishes to apply for an increase in its FTE resident cap(s) available through section 1886(h)(7)(B) of the Act, we proposed that this hospital must submit a completed application to CMS and that the application must be received on or before March 1, 2005. We proposed that all completed applications that are timely received according to the above deadlines will be evaluated by us according to the criteria described under section IV.O.2.i. of this preamble for

determining the priority distribution of FTE resident slots. Hospitals that satisfy at least one of the “demonstrated likelihood” criteria will be further evaluated by the evaluation criteria described below. We proposed that those hospitals that are chosen to receive an increase in their FTE resident caps would be notified by CMS by July 1, 2005.

Comment: Several commenters expressed concerns regarding CMS's overall approach to evaluating the application for the increase to hospitals' FTE caps under section 422. They disagreed with the proposed requirement that, as part of a hospital's application for the increase to the 1996 FTE caps, that is, for the section 422 cap, the hospital must submit a completed copy of the CMS Evaluation Form for each residency program for which the applicant hospital demonstrates a need for the requested increase in the number of FTE residents. One of the commenters stated that “we have fundamental and serious concerns with * * * an evaluation form that focuses on residency programs, rather than hospital applicants * * * we think CMS' proposed process could lead, at a minimum, to a de facto situation of program-specific caps, which is contrary to the spirit and intent of the BBA.” The commenters were concerned with the possibility that CMS may take the view that the section 422 cap could only be used for the residency programs listed in the hospital's application for the increase. The commenters were also concerned that the evaluation criteria list program-specific criteria on the CMS Evaluation Form (such as a point for using the unused resident slots for establishing a new geriatrics program or for expanding an existing geriatrics program; or for a point for a new program that did not qualify for an adjustment because of the deadlines associated with the BBA). One commenter stated that CMS “should not favor one specialty over another but should view all specialty programs equally and leave decisions regarding the use of additional residency positions to the hospital.” The commenters preferred CMS to focus on the evaluation of the application for the section 422 cap on the hospitals and not on the hospital's residency programs.

Response: We understand the commenters' concerns about the possibility that we have proposed a program-specific section 422 cap. We did not propose and we are not finalizing in this final rule a program-specific section 422 cap. That is, once a hospital receives an increase in its otherwise applicable FTE resident cap

effective July 1, 2005, the portion of the cap relating to an increase under section 422 is applied to FTEs in any program that the hospital is training in excess of its 1996 FTE cap (which is subject to any permanent adjustments for new programs and any reductions under section 1886(h)(7)(A) of the Act), regardless of the hospital's program-specific basis for being granted the section 422 cap increase.

We note, however, that hospitals must sign an attestation as part of the hospital's application for the overall increase to the cap under section 422 to certify that the information claimed in the application is true at the time of the application. Thus, if a hospital claims on one of its CMS Evaluation Forms that the hospital is applying for the increase because it plans to use the FTEs because it is training residents from a program or a hospital that closed, and the applicant hospital no longer qualifies for a temporary adjustment to its cap, then at least at the time of the application, the hospital intends to use at least that part of its section 422 cap for this stated purposes (that is documented in the hospital's application). The section 422 caps, as well as the adjusted 1996 FTE caps, are applied to FTE residents counted by the hospital in all programs in the aggregate, not on a program-specific basis.

In response to the comments concerning our proposal to require a separate CMS Evaluation Form for each residency program for which the applicant hospital requests an increase in the number of FTE residents, we proposed such a requirement so that, as stated above and also in the proposed rule, we would be able to determine a hospital's "demonstrated likelihood" and to discern within which level priority category (first through sixth) the applicant hospital's application should be placed based on the residency specialty program for which the FTE cap increase is being requested. As we have stated, a hospital may apply for an increase in its FTE caps for more than one residency program at the hospital. It is possible that applications for the programs would fall within different level priority categories. For example, a hospital may apply for an increase in its cap(s) for one program that is the "only specialty training program in the State" (which would place the hospital's application in the fifth level priority category on the CMS Evaluation Form) and for another program that is not the only program in the State (which, assuming the hospital is located in a large urban area, would place the hospital on that Evaluation Form in the sixth level priority category). Therefore,

we proposed that hospitals complete an Evaluation Form for each residency program for which it is requesting an increase in its FTE resident cap. For these reasons, we are finalizing our proposed policy. We believe it would be difficult for us to establish "demonstrated likelihood" and to determine which hospital requests should have priority over others to receive the section 422 cap without asking hospitals to submit a CMS Evaluation Form for each program they are requesting as part of their application for the section 422 cap.

Finally, to respond to the comments concerning program-specific criteria on the CMS Evaluation Form, we proposed such criteria in an attempt to not only encourage certain public health and community goals, but also to correct certain anomalies relating to the FTE resident cap that may have been unintended consequences resulting from the BBA-mandated FTE caps. We believe our proposed program-specific criteria are important because we would, at least at the outset of awarding the section 422 cap increases, like to encourage certain behaviors in graduate medical education.

To demonstrate the point that the section 422 caps are hospital-specific and not program-specific, we give the following example to represent a scenario that we would view as an appropriate use of the section 422 caps:

Example: Hospital-specific section 422 caps. Hospital D, an urban hospital located in an other than large urban area that is training residents at its direct GME and IME 1996 FTE caps, applies to CMS for the section 422 caps because the hospital intends to expand its existing geriatrics residency program from 5 FTEs to 10 FTEs beginning July 1, 2005, and therefore checks off C2 on the CMS Evaluation Form and also demonstrates a likelihood of filling the slots of the program. CMS awards Hospital D 5 FTE residents for its direct GME and IME section 422 caps to be used by Hospital D beginning on or after July 1, 2005. In the middle of the 2008 program year, Hospital D realizes that it only had been able to increase its geriatrics residency program for two additional geriatrics residents. Hospital D would accordingly prefer to use 3 FTEs for direct GME and IME out of its section 422 cap for another unrelated program, because it would like to expand the number of FTE residents for that program. Thus, beginning July 1, 2009, Hospital D may count 2 FTE residents for geriatrics and 3 additional FTEs for another program in its section 422 caps.

Comment: One commenter asked whether "each residency program within a single hospital" must submit a separate CMS Evaluation Form.

Response: First, *hospitals*, not individual residency programs at hospitals, apply for the section 422

caps. As we have indicated earlier, the section 422 caps are not program-specific; rather, they are hospital-specific. Second, as discussed above and also in the proposed rule, we are requiring that each hospital submit as part of its application a separate CMS Evaluation Form for each residency program for which the applicant hospital intends to justify an increase in the number of FTE residents slots.

Comment: One commenter asked whether each hospital under a Medicare GME affiliation agreement should submit a CMS Evaluation Form for "the same specialty program."

Response: We are assuming the commenter is referring to a hospital that is applying for the section 422 cap increase and such a hospital will also participate in a Medicare GME affiliation agreement as of July 1, 2005, such that it is rotating residents in a particular program from the hospital to another hospital in the affiliation. We are clarifying in this final rule that—(1) hospitals that participate in a Medicare GME affiliation agreement under § 413.79(f) on or after July 1, 2005, may apply for the increase to their caps under section 422; and (2) hospitals that receive section 422 cap increases from CMS and participate in a Medicare GME affiliation agreement under § 413.79(f) on or after July 1, 2005 may only affiliate for the purpose of adjusting their 1996 FTE caps (adjusted for new programs and any reductions under section 1886(h)(7)(A) of the Act) for direct GME and IME. The additional slots that a hospital receives under section 422 may not be aggregated and applied to the FTE resident caps of any other hospitals. Adjustments under section 422 are limited to no more than 25 FTEs for any hospital that applies. We believe that if we were to allow affiliations using the section 422 cap increases, hospitals could circumvent the 25 FTE limit on the section 422 cap increases. We also believe this prohibition on affiliations relating to the section 422 cap increases is needed to facilitate tracking for the different direct GME and IME payment rates associated with FTE residents that are counted as a result of the section 422 cap increases. It would be very difficult for both providers and fiscal intermediaries to identify these "422" FTE residents in an affiliation agreement with two or more hospitals (some affiliations have multiple hospital participants). Therefore, we believe it is appropriate to prohibit hospitals that receive section 422 cap increases from including those FTE increases in the aggregate FTE cap in an affiliated group, effective July 1, 2005. However, hospitals that receive

section 422 cap increases may affiliate with other hospitals using the remainder of their FTE resident caps, that is, the 1996 cap as adjusted for new programs and reductions under section 1998(h)(A) of the Act. The following is an example of an affiliation between two hospitals (one of the affiliated hospitals has a section 422 cap for direct GME and IME):

Example: Affiliation agreement with section 422 caps. Hospital A has a 1996 FTE resident cap of 100 for both direct GME and IME and, effective July 1, 2005, a section 422 cap of 15 for both direct GME and IME. Hospital B has a 1996 FTE resident cap of 60 for both direct GME and IME and no section 422 cap. For the academic year ending June 30, 2006, the two hospitals enter into a Medicare GME affiliation agreement. Their combined 1996 direct GME and IME cap is 160 FTE residents (100 Hospital A + 60 Hospital B). The hospitals are prohibited from forming a Medicare GME affiliation agreement using the 15 FTE in Hospital A's section 422 cap. They may reallocate the 1996 FTE resident caps under the affiliation so that Hospital A's direct GME and IME 1996 cap is 90 and Hospital B's direct GME and IME 1996 cap is 70. Both Hospital A and Hospital B have a FYE of June 30. In addition to its 1996 cap of 90, Hospital A would have a section 422 cap(s) of 15 FTEs.

Hospital A: During FY 2006, Hospital A trains 100 FTE residents. Of the 100 FTE residents, Hospital A is able to count up to 90 FTEs in its 1996 cap as adjusted by the Medicare GME affiliation agreement described above and 10 residents as part of its section 422 cap.

- For direct GME, the 90 residents counted as part of the 1996 FTE cap are paid at the hospital's actual per resident amounts (primary care PRA and/or nonprimary care PRA) inflated to the current cost reporting period.

- For direct GME, the 10 FTE residents (100 total FTE—90 FTE counted in the 1996 cap) that Hospital A counts above its 1996 FTE cap, as adjusted by the affiliation agreement, are counted as part of the section 422 cap. These 10 FTE residents are paid at the locality-adjusted national average PRA under § 413.77(d)(2)(ii), inflated to the current cost reporting period.

- In order to calculate the IME adjustment factor for the 90 FTE residents counted as part of the 1996 FTE cap, Hospital A uses 1.37 (per section 502(a) of Public Law 108–173) as the IME adjustment factor formula multiplier.

- In order to calculate the IME adjustment factor for the 10 FTE residents counted as part of the section 422 cap, Hospital A uses .66 (per section 422(b)(1)(C) of Pub. L. 108–173) as the IME adjustment formula multiplier.

- The remaining 5 FTE available under Hospital A's section 422 cap are unused during the FYE June 30, 2006.

Hospital B: During FY 2006, Hospital B trains 75 FTE residents. Of these 75 residents, only 70 residents are counted as a result of Hospital B's 1996 FTE cap as adjusted by the Medicare GME affiliation agreement.

- For direct GME, the 70 FTE residents counted as part of the 1996 FTE cap are paid at the hospital's actual per resident amounts (primary care PRA or nonprimary care PRA) inflated to the current cost reporting period.

- In order to calculate the IME adjustment factor for the 70 FTE residents counted as part of the 1996 FTE cap, Hospital B uses 1.37 (per section 502(a) of Pub. L. 108–173) as the IME adjustment factor formula multiplier.

Hospital B cannot receive Hospital A's unused section 422 cap slots through the affiliation agreement. Therefore, 5 FTE residents training at Hospital B cannot be counted for purposes of direct GME and IME payment.

Comment: One commenter asked for clarification on which hospitals are eligible to submit an application for the section 422 caps by March 1, 2005, rather than December 1, 2004.

Response: We stated at the proposed rule the following information for the timeframe for submission of the section 422 cap increase applications:

"We further propose that any hospital that wishes to receive an increase in its FTE resident cap(s) must submit a copy of its completed application * * * to the CMS Central Office and to the CMS Regional Office for the region in which the applicant hospital is located, and that the application must be received on or before December 1, 2004 * * * We note that some hospitals' FTE counts will be subject to audit for purposes of section 1886(h)(7)(B) of the Act, and those audits may not be completed by December 1, 2004. Because the results of such an audit may be a factor in a hospital's decision whether to request an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act, we propose to allow a later date for those hospitals to apply for increases in their FTE resident caps. Therefore, if a hospital's resident level is audited for purposes of section 1886(h)(7)(A) of the Act, and that hospital also wishes to apply for an increase in its FTE resident cap(s) available through section 1886(h)(7)(B) of the Act, we propose that such a hospital must submit a completed application to CMS and that the application must be received on or before March 1, 2005." We hope this information is helpful and are finalizing the December 1, 2004 and March 1, 2005 deadline applications for the different hospitals in this final rule.

i. CMS Evaluation of Applications for Increases in FTE Resident Caps

As noted in section IV.O.2.h. of this preamble, in the May 18, 2004 proposed rule, we proposed to require hospitals to submit, with their applications for increases in their FTE resident caps, a completed copy of the CMS Evaluation Form. As we have stated, we proposed to make the process of evaluating the applications as objective as possible. Therefore, we proposed to use a CMS Evaluation Form that the hospital must complete and submit as part of its application. The CMS Evaluation Form will ask the hospital to check off which of the "demonstrated likelihood" criteria (described above in section IV.O.2.g. of this preamble) the hospital meets. We also proposed to require the hospital to provide the documentation that supports the "demonstrated likelihood" criteria it has checked off on the Evaluation Form.

Assuming that hospitals interested in applying for the increase in their FTE caps meet the eligibility criterion of "demonstrated likelihood," we proposed that applicant hospitals indicate on the CMS Evaluation Form the category(ies) for which it believes it will qualify. We will use this indication to prioritize the applications. This prioritization is derived from section 1886(h)(7)(B) of the Act, as added by section 422 of Public Law 108–173. That section established the following priority order to determine the hospitals that will receive increases in their FTE caps:

- *First, to hospitals that are "located in rural areas, as defined in section 1886(d)(2)(D)(ii) of the Act" (section 1886(h)(7)(B)(iii)(I) of the Act).* Section 1886(d)(2)(D)(ii) of the Act defines a rural area as any area outside a Metropolitan Statistical Area (MSA). Under the existing implementing regulations at § 413.62(f)(ii), an "urban area" means (1) a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA); or (2) the following New England counties: Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island. Under existing § 413.62(f)(iii), a "rural area" means any area outside an urban area. However, we note that under section III. of this preamble, which discusses changes in wage areas for FY 2005, we proposed to no longer recognize NECMAs as a distinct category of wage areas. Thus, for purposes of the amendments made

by section 422, we proposed that any hospital located in an area that is not in a MSA is a rural hospital, regardless of any reclassification under § 412.102 or § 412.103. We note that this definition of “rural” is consistent with our policy under section III. of this preamble concerning designation of wage index areas.

- *Second, to hospitals that are located in urban areas that are not large urban areas, as defined for purposes of section 1886(d) of the Act (section 1886(h)(7)(B)(iii)(II) of the Act).* Section 1886(d)(2)(D) of the Act defines “large urban area” as an “urban area which the Secretary determines * * * has a population of more than 1,000,000.” Existing implementing regulations at § 412.63(c)(6) state generally that the term “large urban area” means an MSA with a population of more than 1,000,000. Again, we note that we proposed changes to the definition of “urban area” to reflect the new geographic areas designated by the Office of Management and Budget under section III. of this preamble. Therefore, if the eligible hospital applying for an increase in its FTE resident cap is an urban hospital that is located in the proposed redefined MSA area with a population of less than 1,000,000, CMS will give such a hospital second priority (after all rural hospitals in the first priority category under the statute) in deciding which hospitals should receive an increase in their FTE resident caps.

- *Third, hospitals that currently operate, or will operate, a residency training program in a specialty for which there are not other residency training programs in the State (section 1886(h)(7)(B)(iii)(III) of the Act).* We proposed to interpret “a specialty for which there are not other residency training programs in the State” to mean the only specialty in either allopathy or osteopathy in a particular State. For example, if in State X, Hospital A would like to use the additional FTE residents in order to establish a new osteopathic emergency medicine program (which would be the first osteopathic emergency medicine program in State X), and Hospital B has already established an allopathic emergency medicine program in State X, Hospital A’s application for an increase in its FTE resident cap(s) would be put in the third priority category because Hospital A would be establishing a new osteopathic emergency medicine program, a specialty for which there are not other osteopathic emergency medicine programs in the State. We believe that a more “expansive” interpretation of “a specialty for which there are not other residency programs”

allows more hospitals to fit into this third priority category. In addition, it is our understanding that allopathic and osteopathic programs are, at least, nominally different disciplines in medicine. As a result, we believe that this more “expansive” interpretation for “a specialty for which there are not other residency programs” is the more appropriate interpretation.

As we described above, we proposed that applicant hospitals indicate on the CMS Evaluation Form the category(ies) for which it believes it will qualify; we will use this indication to prioritize the applications. Each of the categories (described below) is derived from the priorities established by section 1886(h)(7)(B) of the Act, as added by section 422 of Public Law 108–173. We proposed to use the following categories to determine the order in which hospitals would be eligible to receive increases in their FTE resident caps:

First Level Priority Category: The hospital is a rural hospital and has the only specialty training program in the State.

Second Level Priority Category: The hospital is a rural hospital only.

Third Level Priority Category: The hospital is an urban hospital that is located in a “not large urban area” and has the only specialty program in the State.

Fourth Level Priority Category: The hospital is an urban hospital that is located in a “not large urban area.”

Fifth Level Priority Category: The hospital has the only specialty training program in the State.

Sixth Level Priority Category: The hospital meets none of the statutory priority criteria.

We believe the first and third level categories are appropriate for our evaluation purposes (which is explained further below) because some hospitals that apply for the additional resident slots may fit into more than one of the three statutory priority categories listed in section 1886(h)(7)(B) of the Act. In addition, we proposed to give consideration first to those hospitals that meet more than one of the statutory priority categories over those hospitals that meet only one of the statutory priorities (see second, fourth, and fifth level priority categories.) We also proposed a sixth level priority category to identify those section 1886(d) of the Act hospitals that apply for additional resident slots, but do not fit into any of the priority categories listed in section 1886(h)(7)(B) of the Act (that is, hospitals in large urban areas).

As specified by the statute, we proposed to put each hospital’s application for an increase in its FTE

resident cap (based on how the hospital describes itself on the CMS Evaluation Form) into one of the “level priority categories” for evaluation purposes, giving first and second priority to the rural hospitals, as defined above. In addition, we note that we proposed that hospital applicants provide residency specialty program information as part of the application for the increase to the cap(s), as well as a CMS Evaluation Form for each residency program for which the applicant hospital intends to use the increased FTE resident slots. Our intention in proposing these requirements was for CMS to be able to discern within which level priority category the applicant hospital’s application should be placed based on the residency specialty program for which the FTE cap increase is being requested. In other words, it is possible that a hospital will apply for an increase in its FTE caps for more than one residency program at the hospital. It is possible that applications for the programs would fall within different level priority categories, for example, if a hospital in a large urban area is applying for an increase in its cap(s) for one program that is the “only specialty training program in the State” would place the hospital’s application in the fifth level priority category on the CMS Evaluation Form. For another program that is NOT the only program in the State, for a hospital in a large urban area, would place the hospital on that Evaluation Form in the sixth level priority category. Therefore, we proposed that hospitals complete an Evaluation Form for each residency program for which it is requesting an increase in its FTE resident cap.

Comment: Several commenters supported our proposals on the level priority categories, as stated in the proposed rule. One commenter stated that it was “extremely appreciative that CMS included a sixth category, for hospitals that do not meet any of the statutorily defined priority criteria (for example, hospitals located in large urban areas), within the priority ordering.”

Response: We appreciate the commenters’ support of the our proposals concerning the level priority categories.

Comment: We received several comments that addressed our interpretation of the third statutory priority at section 1886(h)(7)(B)(iii)(III) of the Act, which granted priority for a “residency program for which there are not other residency training programs in the State.” Several commenters were very supportive of our proposed interpretation of this language to mean

“the only specialty in either allopathy or osteopathy in a particular State.” One commenter stated: “[w]e strongly support this approach, and we believe it appropriately reflects the fact that osteopathic and allopathic disciplines offer residents- and patients-different approaches to health care.”

Another commenter, while supportive of our proposed implementation of section 1886(h)(7)(B)(iii)(III) of the Act, requested that we include interpretation that addresses a family medicine specialty which trains residents to care for “special populations-the underserved who require care to be delivered by physicians who have had special language and cultural training because the population served required it.”

Finally, another commenter asked us to clarify whether a hospital would be “the only program in the state” under section 1886(h)(7)(B)(iii)(III) of the Act, if the only other residency program in the state for a particular specialty is at a Federal or military hospital.

Response: We are pleased that the commenters are supportive of our proposed interpretation of “the only specialty in either allopathy or osteopathy in a particular State.” We are finalizing this interpretation with this final rule.

In response to the second comment, we believe we have limited discretion in interpreting the statutory priorities to accommodate the situation of a family practice program in which residents treat underserved populations, unless a family practice program in a particular state is the only family medicine program in that state. However, we hope we have accommodated hospitals that strive to serve “special populations” by proposing many of the Evaluation Criteria on the CMS Evaluation Form (see, for example, Evaluation Criteria Three or Seven).

Finally, in response to the third comment, we understand that residency programs at Veteran’s Affairs, Department of Defense, or other Federal hospitals are accredited program by either the ACGME or the AOA. Just because many of these military and Federal hospitals do not receive Medicare direct GME and IME payments for the training of interns and residents, does not mean that the residency programs at these hospitals do not exist for purposes of section 1886(h)(7)(B)(iii)(III) of the Act.

Therefore, we are clarifying here that if the residency program is accredited, even if that program is training residents at a Federal facility or military hospital, that program specialty exists for

purposes of interpreting section 1886(h)(7)(B)(iii)(III) of the Act.

Comment: We received several comments objecting to the priority for the increase to the cap under section 422 to rural hospitals. One commenter believed that the proposed first and second level priority categories to rural hospitals “will undermine the expansion plans of many urban teaching hospitals, especially those that share the same corporate structure and are part of a multi-hospital system.” The commenter requested that CMS remove the rural hospitals as the first and second level priorities for the increase to the caps under section 422.

Response: We believe we have limited statutory discretion in determining which hospitals should receive the increase to their caps under section 422. Our proposed level priority categories are derived from section 1886(h)(7)(B) of the Act, as added by section 422 of Public Law 108–173. That section established a priority order to determine the hospitals that will receive increases in their FTE caps. Section 1886(h)(7)(B)(iii)(I) of the Act gives first priority to hospitals that are “located in rural areas”. We understand there may be situations where urban hospitals, due to circumstance, stand to lose FTE slots because of section 1886(h)(7)(A) of the Act, and the increase to the caps under section 1886(h)(7)(B) of the Act gives first priority to rural hospitals. However, the statute that mandated the priorities determines this situation.

Comment: We received one comment requesting that CMS give priority under the section 422 cap increase to hospitals in small urban areas that are Level 1 Trauma Centers.

Response: While we do not believe we have discretion in interpreting the priority categories, we believe that hospitals that are Level 1 Trauma Centers provide good emergency services to the public. Along these lines, we have agreed to add a new Evaluation Criterion 14 with this final rule (see below) that addresses residency training for new or expanding residency programs in emergency medicine.

Comment: We received one comment on the priority categories generally that requested that CMS refine its methodology so that hospitals that “already exceed their FTE caps are given first priority within their Priority category.”

Response: As we have stated, the Congress has set the priorities as to which hospitals should receive the increase to their FTE caps first, without stating specifically that the hospitals applying for the cap increase must be at

or above its FTE caps to qualify for the increase. However, as we believe, like most commenters, that most hospitals that apply for the section 422 caps will be above their 1996 FTE caps, we have agreed to add new Evaluation Criterion 12 to address the situation of hospitals exceeding their FTE caps (see discussion of Evaluation Criteria below).

CMS Evaluation of Application for Increases in FTE Resident Caps

We note that section 1886(h)(7)(B)(iii) of the Act states that “increases of residency limits within the same priority category * * * shall be determined by the Secretary.” Therefore, we proposed to use the following criteria for evaluating the applications for increases in hospitals’ FTE resident caps within each of the six level priority categories described above:

Evaluation Criterion One. The hospital that is requesting the increase in its FTE resident cap(s) has a Medicare inpatient utilization over 60 percent, as reflected in at least two of the hospital’s last three most recent audited cost reporting periods for which there is a settled cost report. We have selected 60 percent utilization because it will identify hospitals where Medicare beneficiaries will benefit the most from the presence of a residency program, and it is consistent with the utilization percentage required for Medicare-dependent, small rural hospitals (MDHs) as specified in § 412.108. In addition, it identifies a type of hospital that warrants atypical treatment by the Medicare program because it is so reliant on Medicare funding.

Evaluation Criterion Two. The hospital will use the additional slots to establish a new geriatrics residency program, or to add residents to an existing geriatrics program. We believe that, of all the medical specialties, geriatrics is the one specialty that is devoted primarily to the care of Medicare beneficiaries. In addition, we note that encouraging residency training in geriatrics is consistent with Congressional intent as expressed, among other places, in section 712 of Public Law 108–173.

Evaluation Criterion Three. The hospital does not qualify for an adjustment to its FTE caps under existing § 413.86(g)(12) (proposed to be redesignated as § 413.79(k) in the proposed rule) for a rural track residency program, but is applying for an increase in its FTE resident cap(s) under section 1886(h)(7)(B) of the Act because it rotates (or in the case of a new program, will rotate) residents for at least 25 percent of the duration of the

residency program to any combination of the following: a rural area, as defined in section 1886(d)(2)(D)(ii) of the Act and § 412.62(f)(1)(iii) of the regulations; a rural health clinic (RHC), as defined in section 1861(aa)(1) of the Act and § 491.2 of the regulations; or a Federally Qualified Health Center (FQHC), as defined in section 1861(aa)(3) of the Act and § 405.2401(b) of the regulations. We believe that the Congress intended that the Secretary use section 422 to encourage resident training in rural areas, and we believe this criterion furthers this intention. We proposed to include residency training in FQHCs in this criterion because we understand that some FQHCs are located in rural areas. In addition, we indicated our encouragement of residency training at FQHCs because we believe that, similar to rural providers and RHCs, FQHCs provide services for medically underserved areas or populations, or both.

Evaluation Criterion Four. In portions of cost reporting periods prior to July 1, 2005, the hospital qualified for a temporary adjustment to its FTE cap under existing § 413.86(g)(9) (proposed to be redesignated as § 413.79(h) in the proposed rule) because it was training displaced residents from either a closed program or a closed hospital, and, even after the temporary adjustment, the hospital continues to train residents in the specialty(ies) of the displaced residents and is training residents in excess of the hospital's direct GME FTE cap or IME FTE cap, or both, for that reason. We believe this criterion is appropriate because it will help to sustain the level of residency training in the community.

Evaluation Criterion Five. The hospital is above its FTE caps because it was awaiting accreditation of a new program from the ACGME or the AOA during the base period for its FTE cap(s), but was not eligible to receive a new program adjustment as stated under existing § 413.86(g)(6)(ii) (proposed to be redesignated as § 413.79(e)(2) in the proposed rule). Under existing § 413.86(g)(6)(ii) and § 413.86(g)(13) (proposed to be redesignated as § 413.79(l) in the proposed rule), a hospital that had allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996 could receive an adjustment to its unweighted FTE cap for a new medical residency training program that either received its initial accreditation or began training residents on or after January 1, 1995 and on or before August 5, 1997. If a hospital failed to meet those deadlines, it was not eligible to have its cap(s) adjusted to

include residents in a new program. Under the proposed criterion, a hospital would apply for additional FTE residents if the hospital had submitted its application for a new program to the accrediting body before August 5, 1997, and received its accreditation after August 5, 1997 but before August 5, 1998. This would allow some hospitals to receive increases in their FTE resident caps in cases in which, in good faith, the hospital had submitted an application for accreditation for a new program prior to the date of enactment of FTE resident caps under the BBA, but because of the timing of the implementation of the FTE resident cap(s), had not yet received direct GME and IME payment for residents in the newly accredited program during the base period for the hospital's FTE resident cap(s).

Evaluation Criterion Six. The hospital is training residents in excess of its FTE resident caps because, despite qualifying for an FTE cap adjustment for a new program under § 413.86(g)(6)(i) or (g)(6)(ii) (proposed to be redesignated as § 413.79(e)(1) and (e)(2) in the proposed rule), it was unable to "grow" its program to the full complement of residents for which the program was accredited before the hospital's FTE resident cap was permanently set beginning with the fourth program year of the new program. Similar to evaluation criterion five above, this criterion would allow some hospitals that had, in good faith, started up a new residency program as required in the regulations but could not completely fill the new program within the allowed regulatory period, to receive increases in their FTE resident caps. For instance, this could have occurred because the program was a program of long duration (such as a 5-year general surgery program), and the hospital did not have the opportunity to "grow" the program to its full complement of residents because the regulations at §§ 413.86(g)(6)(i) or (g)(6)(ii) allow a program to grow for only 3 years before the hospital's FTE resident cap is permanently adjusted for the new program.

Evaluation Criterion Seven. The hospital is located in any one (or a combination) of the following: a geographic HPSA, as defined in 42 CFR 5.2; a population HPSA, (also defined at 42 CFR 5.2); or a Medicare physician scarcity county, as defined under section 413 of Public Law 108-173. We proposed to use this 3-part criterion in order to capture, as objectively as possible, medically underserved areas or patient populations (many of which are Medicare beneficiaries), or both. We

understand that if a particular community has been designated a HPSA (either a geographic or population HPSA), the designation information is available to hospitals from the Health Resources and Services Administration (HRSA) HPSA database at the Web site: <http://belize.hrsa.gov/newhpsa/newhpsa.cfm>. In addition, hospitals will be able to determine whether they are located in a Medicare physician scarcity county (consistent with section 413 of Pub. L. 108-173) on the CMS Internet Web site at www.cms.hhs.gov or upon publication of the annual final rule setting forth the Medicare physician fee schedule (which is generally published by November 1 of each year). We note that if Medicare does not publish the final rule setting forth the Medicare physician fee schedule in time for the application deadline for increases in FTE resident caps (December 1, 2004, or March 1, 2005, depending on the hospital), we proposed that we will not use the Medicare physician scarcity county designations (as defined under section 413 of Pub. L. 108-173) for purposes of this criterion.

Evaluation Criterion Eight. The hospital is in a rural area (as defined under section 1886(d)(2)(D)(ii) of the Act) and is a training site for a rural track residency program (as specified under § 413.86(g)(12) (proposed to be redesignated as § 413.79(k) in the proposed rule)), but is unable to count all of the FTE residents training at the rural hospital in the rural track because the rural hospital's FTE cap is lower than the hospital's unweighted count of allopathic or osteopathic FTE residents beginning with portions of cost reporting periods on or after July 1, 2005.

Evaluation Criterion Nine. The hospital is affiliated with a historically Black medical college. According to the language in the Conference Report for Public Law 108-173 (pages 204-205), the Conference agreement on section 422 generally restated the three statutory priority categories described above (rural, "small" urban, and only specialty program in the State) in terms of giving guidance to the Secretary for deciding which hospitals should receive the redistributed FTE resident slots. However, there was one additional cited criterion that the Conference indicated the Secretary should use in evaluating the hospital applications. Specifically, the Conference agreement states that the Secretary should consider whether the hospital is a "historically large medical college" (emphasis added). Upon consideration of this particular terminology, which, on its face, seems to contradict the three statutory priority

categories (that is, rural, "small" urban, and only specialty program in the State), we proposed to view the reference to "historically large medical colleges" as a scrivener's error, and to read this language to refer to "historically Black medical colleges." This proposed interpretation accomplishes two goals: first, we believe this interpretation serves the greater policy goal of encouraging residency training for the benefit of medically underserved populations. Second, we believe that this interpretation reflects the Conferees' intent in the language in the Conference Report. In addition, we proposed to identify "historically Black medical colleges" as Howard University College of Medicine, Morehouse School of Medicine, Meharry Medical College, and Charles R. Drew University of Medicine and Science. These four medical schools are identified as "historically Black medical colleges" by the American Medical Association (see <http://www.ama-assn.org/ama/pub/category/7952.html>). We proposed that the hospital will meet this criterion if it intends to use an increase in its FTE resident cap(s) under section 1886(h)(7)(B) of the Act to count residents in residency programs sponsored by any of the historically Black medical college listed above.

Evaluation Criterion Ten. The hospital is training residents in residency program(s) sponsored by a medical school(s) that is designated as a Center of Excellence for Underserved Minorities (COE) under section 736 of the Public Health Service Act in FY 2003. We understand that the COE program was established to be a catalyst for institutionalizing a commitment to underserved students and faculty, and to serve as a national resource and educational center for diversity and minority health issues. Therefore, we believe that it is appropriate to encourage hospitals to train residents in residency programs sponsored by medical schools that are designated as COEs. A hospital can verify whether it is training residents in programs sponsored by a medical school that is a COE. Medical schools that are COEs in FY 2003 are listed at the following Web site: <http://bhpr.hrsa.gov/diversity/coe/grantees2003.htm>. We note that, in FY 2003, there were 28 medical schools that were designated to be COEs.

In the May 18, 2004 proposed rule, we proposed to use the above set of criteria to evaluate the applications by hospitals for increases in their FTE resident caps that fall within each of the six level priority categories. We proposed to place each application in the appropriate priority level category based

on a review of the information the hospitals check off on the proposed CMS Evaluation Form for each allopathic and osteopathic specialty program requested by the applicant hospital, and the corresponding requested FTE cap increase (see the proposed form below). We proposed to place all of these evaluation criteria on the Evaluation Form and to ask the hospital to check off which criteria on the form apply for each specialty program for which an FTE cap increase is requested. Based on the assertions checked off on the form, we would score each CMS Evaluation Form (one point per criterion checked off). The higher scoring CMS Evaluation Form(s) for each applicant hospital within each level priority category would be awarded the FTE resident cap increases first. As we described above, we proposed to award the cap increases in the order of the six specified level priority categories because, as a general rule, we believe hospitals that meet more than one of the statutory priorities should be awarded the increases in their FTE resident caps first before other hospitals. We also believe that hospitals that meet a higher statutory priority category should receive first consideration by us over hospitals that meet lower statutory priorities. That is the reason, for instance, we proposed the first level (rural hospital + only specialty program in the State) and second level (rural only) priority categories to give all rural hospitals first consideration by us before any small urban hospital, as required by the statute.

Thus, first level priority category hospitals that score highest on the evaluation criteria on the CMS Evaluation Form for a particular specialty program would receive the increases in their FTE resident caps first. For example, if Hospital D is a rural hospital and is establishing the first osteopathic internal medicine residency program in State Y, thereby falling within the first level priority category, and Hospital D checks off on the CMS Evaluation Form that it has a Medicare utilization of 60 percent, is located in a geographic HPSA, and is affiliated with a historically Black medical college, Hospital D would receive a score of 3 points on the completed CMS Evaluation Form. We proposed that we would first award FTE cap increases to hospitals whose CMS Evaluation Forms for a particular program receive 10 points based on the number of evaluation criteria checked off by the hospital for the program (if there are any) and then to those with

successively fewer points within the level priority category. Hospital D would receive the increase in its FTE resident cap(s) requested on its application after all the hospitals in the first level priority category whose applications receive 10 through 4 points are awarded their requests first.

We proposed that we would award the increases in FTE resident caps to all those hospitals that are in the first level priority category (rural hospitals + only specialty program in the State) before evaluating those hospitals in the second level priority category (rural hospital), and would award the FTE resident slots to all those hospitals in the second level priority category before evaluating those hospitals in the third level priority category ("small" urban hospital + only specialty in the State), and so on. Once we reach an aggregate number of FTE resident cap increases from the aggregate estimated pool of FTE resident positions under section 1886(h)(7)(A) of the Act, but are unable, based on the number of remaining slots, to meet all of the requests at the next level priority category at the next score level, we proposed to prorate any remaining estimated FTE resident slots among all the applicant hospitals within that level priority category and with the same score on the hospital's application.

For example, assume all applicant hospitals in the first through fourth level priority categories receive the requested increases in their FTE resident caps by us, and we evaluate hospital applications next and accompanying CMS Evaluation Forms in the fifth level priority category (only specialty program in the State). At the point that we have awarded cap increases for all the fifth level priority category hospitals that scored 5 or above on their CMS Evaluation Forms for each residency program, we find that there is only a sufficient number of resident slots remaining in the estimated pool to grant half of the requests for slots from hospitals that scored 4 points. We proposed that we would prorate all of the remaining FTEs among the 4-point CMS Evaluation Forms and accompanying applications in the fifth level priority category. Thus, if we could have awarded a total of 200 FTE slots for direct GME and 185 FTE slots for IME to only the first 50 percent of the 4-point CMS Evaluation Forms in the fifth level priority category at the point that the estimated pool of FTE slots is spent, we proposed to prorate all of the 200 FTE slots for direct GME and 185 FTE slots for IME among all of the 4-point CMS Evaluation Forms and accompanying applications in that fifth priority category, no matter what level

of FTE resident cap increase was requested on the individual hospital's application.

We recognize the complexity of the proposed evaluation process for the award of increases in hospital's FTE resident caps under section 1886(h)(7)(B) of the Act. Therefore, we have included the following examples depicting the proposed procedures:

Example 1. Hospital M in State Z is an urban hospital located in an MSA that has a population of less than 1 million. Hospital M can demonstrate the likelihood that it will fill the requested five FTEs resident slots for direct GME and IME for a geriatric program because it is currently training a number of FTE residents that exceeds both of its FTE caps, and has attached to its application for an increase in its FTE resident caps a copy of Hospital M's past three Medicare cost reports (as filed or audited, whichever is most recent and available), which documents on Worksheet E, Part A and Worksheet E3, Part IV that, according to the resident counts and the FTE resident caps, Hospital M is training residents in excess of its caps. Hospital M has taken on geriatric residents from a teaching hospital in the community that closed, and is also located in a Medicare physician scarcity county.

We would evaluate Hospital M's application accordingly. It will be determined a fourth level priority category ("small" urban hospital); and will receive a score of 4 (expanding geriatrics program, Medicare physician scarcity area, residents from a closed hospital, training residents in excess of its 1996 FTE caps).

Example 2. Hospital K is a large academic medical center located in an MSA with a population of greater than 1,000,000 and is in a population HPSA. Hospital K regularly trains residents in programs sponsored by Meharry Medical College, and wishes to add more residents from Meharry, and therefore, has requested accreditation from the ACGME to expand the number of Meharry residents training in both allopathic surgery and osteopathic pediatrics programs. Hospital K is above both its direct GME and IME FTE caps.

Hospital K's CMS Evaluation Forms for allopathic surgery and osteopathic pediatrics would be submitted separately by the hospital and we would evaluate it (separately) accordingly. Both requests would put the hospital in the sixth level priority category (large urban hospital); it can demonstrate the likelihood of filling the slots (because Hospital K can document both that the hospital is above its caps and that it has requested ACGME accreditation to expand the programs); and will receive a score of 3 (population HPSA, historically Black medical college, training residents in excess of its FTE caps).

Example 3. Hospital E is a rural hospital located in a Medicare physician scarcity area and a geographic HPSA. It is a rural training site for an already established rural track residency program that has only been a training site since 2002. Therefore, Hospital E has an FTE resident cap of zero FTEs for direct GME and IME.

Hospital E's CMS Evaluation Form for the rural track family practice program and accompanying application would be evaluated by us accordingly. Second level priority category (rural hospital); it can demonstrate the likelihood of filling slots (because Hospital E can document that it is both over its cap of zero FTEs, and that it is a training site for an accredited rural track residency program; and will receive a score of 3 (a training site for a rural track, and a Medicare physician scarcity area, and a geographic HPSA, and training residents in excess of its FTE caps).

Example 4. Hospital W is a rural hospital that has FTE caps of 15 FTEs for both direct GME and IME. Hospital W requests a total FTE cap adjustment of 25 FTEs for both direct GME and IME; 5 FTEs are to expand an existing geriatric fellowship; and 20 FTEs are to establish the first osteopathic emergency medicine program in State K, in which Hospital W is located. Hospital W can document that it is at its FTE caps with existing residency programs. We would make the following assessment for Hospital W's Evaluation Form for the geriatric fellowship: Hospital W falls into the second level priority category for being a rural hospital; it can demonstrate the likelihood that it will fill the 5 FTE slots of the geriatric program by documenting that it has requested additional slots in the accreditation of the geriatrics program. Hospital W would receive a score of 1 on its CMS Evaluation Form for the geriatrics program. We would make the following assessment for Hospital W's CMS Evaluation Form for the new osteopathic emergency medicine program: Hospital W would meet the first level priority category for this Evaluation Form because, not only is it a rural hospital, but it is also requesting 20 FTEs for the only osteopathic emergency medicine program in the State; it can demonstrate the likelihood that it will fill the 20 osteopathic emergency medicine FTEs by documenting the accreditation request and also that it is over its FTE caps. Hospital W would receive a score of zero, because it did not meet any of the evaluation criteria on the CMS Evaluation Form. Although this request receives a score of zero, it will be granted its request as level one priority request before any other level priority category.

Comment: We received many comments in general support for our proposed evaluation criteria on the CMS Evaluation Form. One commenter stated: "[w]e applaud CMS in attempting to meet not just the letter of the law, but the spirit, in crafting its priority list to include priorities such as rural and underserved areas, minority institutions, etc." Another commenter stated that "[a]lthough the evaluation process as a whole is lengthy and confusing, we note that several of the individual criteria respond to longstanding problems with the way resident caps were determined under the BBA * * * We applaud CMS' decision to address these problems now through the resident redistribution process." The commenter listed the

proposed Evaluation Criteria Four, Five, and Six as serving this purpose.

Response: We appreciate the commenters' support of our proposals in this section.

Comment: Many commenters supported our proposed Evaluation Criterion Two, which states that the "hospital needs the additional slots to establish a new geriatrics residency program, or adding residents to an existing geriatrics program." Many of these commenters were pleased with CMS' acknowledgment in the proposed rule that "geriatrics is the one specialty that is devoted primarily to the care of Medicare beneficiaries" and strongly urged CMS to include this geriatrics language for Evaluation Criterion Two in this final rule. One commenter, in support of CMS finalizing the proposed Evaluation Criterion Two concerning geriatric programs, stated: "[a]s evidenced in a recent study published in Health Affairs (Apr 7, 2004), in states with higher concentrations of [general practitioners], Medicare spends less money per beneficiary and gets better quality. And the opposite is true for states with higher specialist concentrations."

Response: We appreciate the commenters' support of our proposal to include a point in the Evaluation Criteria for residency training in geriatrics residency programs. We are accordingly finalizing this proposed criterion in this final rule.

Comment: Two commenters requested that CMS add a new criterion to the evaluation criteria to evaluate the hospital applications for the increase in hospitals' FTE caps that would give hospitals a point in their applications if the hospital will use the additional slots to establish a new family practice program, or add residents to an existing family practice program.

Response: We agree to add a new evaluation criterion on the CMS Evaluation Form in this final rule that addresses primary care residency training, because we believe there is a statutory basis in the Medicare program for encouraging primary care residency training. The statute at section 1886(h) of the Act cites primary care programs for special treatment. For example, with both primary care and non-primary care programs, the statute has permanently assigned a higher direct GME PRA for the hospital's primary care residency programs. As specified at section 1886(h)(5)(H) of the Act, "primary care resident" means "a resident enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine,

or osteopathic general practice.” We are incorporating this definition at § 413.75(b). Therefore, in this final rule, we are including a new Evaluation Criterion 11 to read as follows:

“C11: Evaluation Criterion 11. The hospital needs the additional slots to establish a new primary care residency program, or to expand an existing primary care residency program, as primary care is defined under § 413.75(b).”

Comment: We received several comments asking CMS “to favor rural and other underserved training sites” in determining priority for the increase under section 422.

Response: By proposing such criteria as Evaluation Criteria Three or Seven, we believe we have addressed awarding hospitals that train residents in rural and underserved areas. We are finalizing the proposed criteria on these issues, as well as adding new Evaluation Criteria that may also address these issues.

Comment: We received several comments concerning our proposed Evaluation Criterion Four, which states—

“In portions of cost reporting periods prior to July 1, 2005, the hospital qualified for a temporary adjustment to its FTE cap under existing § 413.86(g)(9) (proposed to be redesignated as § 413.79(h) in the proposed rule) because it was training displaced residents from either a closed program or a closed hospital, and, even after the temporary adjustment, the hospital continues to train residents in the specialty(ies) of the displaced residents and is training residents in excess of the hospital’s direct GME FTE cap or IME FTE cap, or both, for that reason.”

One commenter noted that hospital closure “is not the only chaotic factor with which existing teaching hospitals in a given area must cope * * * changes in a community’s demography and needs, the hospital’s facilities and resources, and the resident training programs of other hospitals * * *” are other factors that hospitals consider when deciding use of resident slots. Therefore, the commenter requested that CMS consider a “key priority” for the redistribution of unused positions under section 422 should be “to keep the slots within the original MSA, or for resident slots lost by facilities not in an MSA, within the original state.” Similarly, other commenters requested that CMS modify the proposed Evaluation Criterion 4 to address hospitals that are training residents from one or more hospitals in its community “who have downsized their residency program(s) but did not close these programs.” One

commenter believed that this “downsizing” could occur because the Residency Review Committee (RRC) required the downsizing.

Another commenter requested that CMS consider modifying this evaluation criterion to account for a hospital that “qualified for a temporary adjustment because it was training displaced residents from either a closed program or a closed hospital regardless of whether the [hospital] continued to train residents in that specialty.” The commenter believed that CMS should “award” hospitals that served a “distinct public good,” regardless of whether they continued to train residents in the same specialty.

One commenter recommended that CMS change the criterion to a requirement of documentation of acceptance of the resident(s) from the closed hospital/closed program plus proof of “closure notice.”

Finally, another commenter encouraged CMS to “keep closed hospital resident slots in the community by distributing those slots to the facility that completed the training of those residents, with permanent count increases.”

Response: We recognize that there are many considerations that hospitals must take into account when determining the need for more resident slots, including the need for more training within a community, hospital (or program). However, in including Evaluation Criterion Four, we did not intend to attempt to maintain resident levels on a state or MSA basis. Rather, we were only addressing concerns that have been brought to our attention by hospitals that have, in the past, provided for training residents from either closed hospitals or closed programs. We also do not agree with the commenter that we should address the need of hospitals that take on the training of residents from hospitals where programs are “downsized.”

To address the second commenter’s suggestion on modifying the criterion to award hospitals that received the temporary adjustment to the cap for training residents from programs or hospitals that closed, regardless of whether the hospitals continue to train residents in the same specialty, we proposed Evaluation Criterion Four because we believed it would address an issue left unresolved by the temporary adjustment for closed hospitals or programs. We understand from speaking to many hospitals that took on the training of displaced residents, that they continued to have cap problems long after they had received the temporary cap adjustment

under § 413.79(h), since these hospitals continued to train other residents in those slots even after the original displaced residents completed their training. Because we understand that the specialty program at the hospital that allowed the displaced residents to complete their training continues to fulfill a need in the community of the hospital for training in that program, we believe our Evaluation Criterion Four should be finalized as proposed, thereby rewarding those hospitals that serve this community in this fashion.

To address the comment requesting that, instead of the hospital documenting that the hospital had qualified for a temporary adjustment to its cap and was still training residents in the same specialty, that CMS should look to whether the hospital documented “acceptance of the resident” and “proof of closure,” as we stated above, by proposing Evaluation Criterion Four, we attempted to address the specific situation of a hospital continuing to have cap problems as a result of training more residents in that program long after it had received the temporary cap adjustment under § 413.79(h). We understand that there are multiple situations of hospitals training residents from a closed hospital/program; however, we believe the documentation requirements in the proposed criterion more closely reflects the situation we intended to address. Therefore, we are not adopting the commenters changes in this final rule.

Finally, to address the commenter’s concern with our awarding hospitals permanent cap adjustments that take on residents from closed hospitals, we hoped to do so by proposing the Evaluation Criterion Four. While there is no guarantee that hospitals that meet Evaluation Criterion Four necessarily receive the section 422 caps (that is, the permanent cap adjustments sought by the commenter), we attempted to acknowledge the important role and “public good” such hospitals serve by finalizing Evaluation Criterion Four.

Comment: Many commenters believed that, generally, only hospitals that are counting FTE residents that exceed their 1996 FTE caps for direction GME and/or IME would be interested in applying for the section 422 caps. One commenter stated: “[a] primary purpose (if not the primary purpose) of section 422 [in Pub. L. 108–173] is to provide ‘cap relief’ to hospitals that have resident counts that exceed their caps.” Therefore, the commenters believed that CMS should reflect the situation of a hospital exceeding its 1996 FTE cap in the evaluation criteria on the CMS Evaluation Form.

In addition, two commenters believed that CMS should assign special weighting factors or extra points (rather than just one point per evaluation criterion as stated in the proposed rule) to such a criterion on the final CMS Evaluation Form. Similarly, another commenter believed that CMS should adjust the Evaluation Criteria to include 0–2 points based on the percentage by which the applicant hospital's projected FTE count is in excess of 1996 FTE caps.

Response: Although we believe we may have already addressed the concern of hospitals exceeding their 1996 FTE caps in some of the evaluation criteria on the CMS Evaluation Form, we agree with the commenters that a primary purpose of the Congress of writing section 422 is to address situations of "cap relief" for hospitals that have exceeded their caps. Therefore, we are adding another criterion to the final evaluation criteria on the CMS Evaluation Form that states—

"C12: Evaluation Criterion 12. The hospital is above its direct GME and/or IME FTE cap on the count of residents, as stated in the Medicare cost report on the worksheets E, part A or the worksheets E3, part IV, in the hospital's most recently as submitted Medicare Cost Report."

Because we are also finalizing the other Evaluation Criteria on the proposed CMS Evaluation Form that address hospitals that exceeded their caps, we are not awarding extra weighting factors or extra point(s) to the new "exceed FTE cap" Evaluation Criterion, as the commenters suggested. We already believe that we are awarding two points for those hospitals that meet any of the proposed Evaluation Criteria (that are finalized with this final rule) plus the new "exceed FTE cap" criterion. For the same reason, we will not be "prorating" points based on how much an applicant hospital is projecting it will exceed its 1996 FTE caps. Therefore, we will only be awarding one point if a hospital meets the "exceed FTE cap" evaluation criterion on the CMS Evaluation Form.

Comment: We received several comments asking CMS to include recognition in the evaluation criteria on the CMS Evaluation Form of emergency medicine residency programs. Two commenters stated that "[e]mergency physicians are required to see a large number of patients to gain experience and clinical expertise across a large range of injuries and illnesses they will need to diagnose and treat." Along a similar vein, these commenters believe that CMS should recognize programs that include "bio-terrorism and disaster

preparedness training and coordination with State EMS organizations and the Department of Homeland Security."

Response: Because the Congress has specifically addressed the importance of emergency physicians and bio-terrorism preparedness (see, for example, the Conference Report accompanying H.R. 267, page 803, Report 108–401), we agree to add a point in the Evaluation Criterion on the CMS Evaluation Form in this final rule to address emergency medicine programs that include bio-terrorism training as part of their programs. New Evaluation Criterion 14 states—

"C14: Evaluation Criterion 14. The Hospital is above its cap and needs the additional slots to establish a new emergency medicine residency program or expand an existing emergency medicine residency program. The emergency medicine residency program includes training in bio-terrorism preparedness."

Comment: We received several comments on the proposed Evaluation Criterion One that gives a point to a hospital that "is requesting the increase in its FTE resident cap(s) [and] has a Medicare inpatient utilization over 60 percent, as reflected in at least two of the hospital's last three most recent audited cost reporting periods for which there is a settled cost report."

Two commenters stated that, because of the time lag associated with settling Medicare cost reports, CMS should accept submitted Medicare cost reports for the proposed Medicare utilization Evaluation Criterion. The commenters also believed that "CMS * * * should consider modifying this criterion to include Medicare share based only on Medicare inpatients as a share of Medicare and privately insured patients. Many teaching hospitals treat a significant number of Medicaid and uninsured patients and they should not be disadvantaged."

We received several comments suggesting that instead of relying on the Medicare inpatient percentage, CMS should consider hospitals that are eligible for Medicare Disproportionate Share Hospitals (DSH) payments. Another commenter stated that CMS should consider any hospital that has a Medicare DSH percentage greater than 25%, "since that is an indicator that the hospital is serving a disproportionate share of low income patients."

Another commenter requested that we modify the Evaluation Criterion so that a hospital would qualify if it had a Medicare inpatient utilization of 50 percent or greater. Finally, another commenter suggested that we modify this Evaluation Criterion so that a

hospital would qualify if its inpatient utilization for Medicare, Medicaid and uninsured patients is over 60 percent.

Response: As we stated in the proposed rule at 69 FR 28302, we proposed Evaluation Criterion One because we believe 60 percent would "identify hospitals where Medicare beneficiaries will benefit the most from the presence of a residency program, and it is consistent with the utilization percentage required for Medicare-dependent, small rural hospitals (MDHs) as specified in § 412.108. In addition, it identifies a type of hospital that warrants atypical treatment by the Medicare program because it is so reliant on Medicare funding." We modeled the proposed Evaluation Criterion One off of the Medicare policy concerning MDHs, which at § 412.108, specifies, among other things, that the hospital must capture the Medicare utilization "on at least two of the hospital's last three most recent audited cost reporting periods for which there is the Secretary has a settled cost report." We continue to believe that the 60 percent threshold is appropriate for purposes of establishing priorities under section 422, and based on the hospital's post recently settled cost reports. Therefore, we are not adopting the commenters' proposal to accept submitted Medicare cost reports or to lower the threshold of Medicare inpatient utilization to 50 percent or greater to meet this Evaluation Criterion.

In addition, we are not adopting the commenters' proposal to include inpatient Medicare utilization based as a share of Medicare and privately insured patients, or as a share of Medicare, Medicaid and uninsured patients, for purposes of the Evaluation Criterion One. It has been a longstanding policy for Medicare Part A payments, including in Medicare graduate medical education patients, that Medicare inpatient utilization is calculated based upon a hospital's Medicare inpatient days divided by total hospital inpatient days. The "total hospital inpatient days" has always included any patients admitted in a hospital—that would include uninsured patients, privately insured patients and others. We do not believe it is appropriate to interpret "total hospital inpatient days" to include only Medicare patients and privately insured patients; doing so, would allow hospitals to have higher "Medicare inpatient utilization" for purposes of meeting this evaluation criterion than they would ordinarily for purposes of any other Medicare payments.

In response to the suggestions that we should look at hospital eligibility for Medicare DSH or look at whether the hospital has a Medicare DSH percentage of 25 percent instead of looking at the 60 percent of Medicare inpatient utilization for the applicant hospital, we do not believe these indicators show a commitment to Medicare populations. Rather, these indicators measure Medicaid and SSI beneficiaries treated at the hospital as a proxy for uncompensated care. Accordingly, we continue to believe that Medicare utilization is the way for hospitals to demonstrate their commitment to Medicare populations and not by measuring Medicare DSH.

Comment: One commenter questioned whether CMS proposed accompanying documentation requirements with the proposed Evaluation Criteria on the CMS Evaluation Form. The commenter stated: "It seems that the attestation is all that is required for those hospitals that indicate on the application form that they meet one or more of the criteria * * * this proposal seems somewhat at odds with the proposed documentation requirements associated with the demonstrated likelihood criteria * * *"

Response: We disagree with the comments since we did propose documentation requirements accompanying the proposed evaluation criteria on the CMS Evaluation Form. Among the requirements we proposed at 69 FR 28300–28301 that hospitals must meet to apply for the section 422 increase to the FTE caps is that the hospital must include: "[a] completed copy of the CMS Evaluation Form * * * for each residency program for which the applicant hospital intends to use the requested increase in the number of FTE residents and source documentation to support the assertions made by the hospital on the Evaluation Form. (For example, if the hospital checks off on the Evaluation Form that the hospital is located in a geographic Health Professions Shortage Area (HPSA), the hospital would include documentation to support that assertion.) (Emphasis added.) We are finalizing this proposed requirement, as stated in part here, in this final rule.

Comment: We received one comment asking CMS to clarify that a hospital which is within a level priority category and meets a Demonstrated Likelihood Criterion will be entitled to obtain residency slots before any hospital located in the next (that is lower) level priority category, even if the first hospital meets none of the Evaluation Criteria.

Response: As we explained above and also in the proposed rule, we are awarding section 422 cap increases first by level priority category, and then, within each level priority category, by points from the Evaluation Criteria on the CMS Evaluation Form, per hospital program. Thus, the commenter is correct; in the case where Hospital A qualified to be in level priority category one for a program, but scores no points on the Evaluation Criteria on the CMS Evaluation Form for that program, and Hospital B qualifies to be in level priority category two for a program, and scored 5 points on the Evaluation Criteria on the CMS Evaluation Form for a program, Hospital A will receive the section 422 cap increase before Hospital B, because Hospital A qualified to be in the higher level priority category.

Comment: Two commenters believed that CMS should include consideration of children's hospitals among the evaluation criteria on the CMS Evaluation Form. Specifically, the commenters proposed that we add an evaluation criterion to give a point to hospitals that treat a "predominantly pediatric patient population." One commenter also proposed that we add another evaluation criterion to give another point for hospitals that treat "a high percentage of SCHIP [State Children's Health Insurance Program] beneficiaries or uninsured patients."

Response: While we appreciate the commenters' desire to add evaluation criteria and garner additional points for use by children's hospitals when applying to receive section 422 increases to their FTE resident caps, we note that there are already evaluation criteria in the proposed rule (all of which we are finalizing) that may be applicable to children's hospitals. For instance, a children's hospital may be rotating residents for at least 25 percent of the duration of the residency program to a rural area, a rural health clinic, or a federally qualified health center. Or, a children's hospital may be training displaced residents from a closed program, or training residents above its 1996 FTE cap because it was awaiting accreditation of a new program from the ACGME or AOA during the base period for its FTE cap(s), but was not eligible to receive a new program adjustment. In addition to these evaluation criteria, there are several others that children's hospitals may use when applying to receive an increase in their FTE resident caps. Therefore, we are not adopting the commenter's proposal to add evaluation criteria specific to children's hospitals.

Comment: We received several comments on the proposed Evaluation Criterion Three, which states—

"C3: *Evaluation Criterion Three.* The hospital does not qualify for an adjustment to its FTE caps under existing § 413.86(g)(12) for a rural track residency program, but is applying for an increase in its FTE resident cap(s) under section 1886(h)(7)(B) of the Act because it rotates (or in the case of a new program, will rotate) residents for at least 25 percent of the duration of the residency program to any one (or in combination thereof) of the following: a rural area, as defined in section 1886(d)(2)(D)(ii) of the Act and § 412.62(f)(1)(iii) of the regulations; a rural health clinic (RHC), as defined in section 1861(aa)(1) of the Act and § 491.2 of the regulations; or a Federally Qualified Health Center (FQHC), as defined in section 1861(a)(3) of the Act and § 405.2401(b) of the regulations."

Several commenters applauded CMS for proposing this Evaluation Criterion Three. One of the commenters asked CMS to clarify whether this criterion would apply to residents in existing programs, and not just new ones.

Another commenter believed that for allopathic family practice residents, it would be a problem to rotate residents out of the hospital for a period of time greater than 3 months out of the program: "we believe the current threshold requirement of 25 percent time in the current evaluation criterion three is not in keeping with the best data available. 25 percent of time for a family practice training program is 9 months. Our data show that only 3 months training time in rural areas is necessary to show large changes in outcomes. Since the family practice RRC also requires two years of continuity training with the same patient population, most programs, unless they are located in rural areas themselves, or are rural training tracks, cannot meet a 25 percent requirement. We request that this threshold be decreased to a commensurate percentage."

Response: We appreciate the commenters' support of proposed Evaluation Criterion Three. To respond to the first comment concerning whether the criterion would apply to existing residency programs that rotate residents for at least 25 percent of the duration of the program to those locations, we point to the language in the proposed criterion that says "because it rotates (or in the case of a new program, will rotate)." We believe we have included resident rotations for both new and existing residency programs.

In response to the second commenter, we understand the concerns of allopathic family practice programs that may have "continuity" problems from

the RRC where residents are rotated outside of the hospital for 25 percent of the duration of the program, however, as noted in this final rule, we are specifically addressing family practice programs (that is, primary care programs) in Evaluation Criterion 11. Therefore, even if hospitals with family practice programs are not able to fulfill this particular Evaluation Criterion, they may be able to meet Evaluation Criterion 11, among possibly others.

Comment: One commenter addressed the proposed Evaluation Criterion Seven on the CMS Evaluation Form, which states—

“• C7: *Evaluation Criterion Seven.* The hospital is located in any one (or in combination thereof) of the following: a geographic HPSA, as defined in 42 CFR 5.2; a population HPSA, (also defined at 42 CFR 5.2); or a Medicare physician scarcity county, as defined under section 413 of Public Law 108–173.”

The commenter believed that CMS should “continue with this idea, but broaden its approach to include time residents spend training in these areas, not just where the hospital is located.” In addition, this commenter believed that CMS should have another evaluation criterion based upon where the graduates of a residency program go into practice. The commenter states: “[m]any worthwhile programs not located in rural or underserved designated areas produce a fair number of residents who locate their practices in such areas. As such, in keeping with the Congressional intent of this section of statute, it makes sense for CMS to award a priority point for those situations as well.”

Response: We believe it would be duplicative to allow applicant hospitals to receive a point in the evaluation criteria for example rotating residents to a nonhospital setting that is located in a geographic or population HPSA or Medicare physician scarcity county, when the applicant hospitals already will receive a point in the evaluation criteria under Evaluation Criterion Three (as revised in this final rule) for rotating residents for a significant period to a rural area or a FQHC. Therefore, we are adopting the proposed Evaluation Criterion Seven as final.

To address the second comment concerning awarding a point based not on the location of the hospital, but on where the new graduates of programs have their practices, while we appreciate that hospitals believe they have increased the retention of physicians to rural and underserved populations when residents train in their programs; however, it is difficult for the Medicare program to track such

after-the program data for purposes of audit of where particular graduates work after finishing their training. Therefore, we are not adopting the commenter’s suggestion concerning physician retention, as well.

Comment: We received one comment requesting that CMS add an Evaluation Criterion for hospitals that train ophthalmology residents. The commenter states that a high number of Medicare beneficiaries benefit from physicians in this specialty. In another comment, we received a request to address hospitals that train residents in palliative sub-specialty programs.

Response: Unlike geriatrics, primary care, and emergency medicine, we do not believe that the Congress has specified “ophthalmology residency training” or “palliative residency training” for special consideration within the Medicare statute, nor in any Conference Report language. While we believe both ophthalmology and palliative medicine provide services to Medicare patients, since physicians in these areas serve many individuals, not only Medicare beneficiaries, we do not agree to add a new Evaluation Criterion to the CMS Evaluation Form to address ophthalmology or palliative training.

Comment: We received one comment requesting that CMS add an Evaluation Criterion for any hospital that is a state operated public hospital. The commenter requests that, in the alternative, CMS “add an Evaluation Criterion for any hospital that is a (i) public hospital or (ii) the only public hospital in its MSA.”

Response: While we believe that public hospitals serve an important role in health care, particularly, for medically underserved areas of this country, we do not agree to add a new Evaluation Criterion to the CMS Evaluation Form to address public hospitals, specifically. We believe that we may have addressed the needs of some public hospitals by many of the proposed Evaluation Criteria, and some of the new ones that we are finalizing in this final rule, as well. For instance, Evaluation Criteria Seven, which would address many hospitals located in a HPSA or a Medicare physician scarcity county may provide a point for some public hospitals. Other than the evaluation criteria, we do not believe it is appropriate to single out a hospital by type of ownership for special consideration.

Comment: One commenter described the situation of a hospital that is “in partnership” with a FQHC concerning a family practice program, where the FQHC is the sponsor of the residency program, and the hospital “passes

through” every dollar in Medicare direct GME and IME payments the hospital receives to the FQHC, and the hospital was “caught” by the BBA-mandated caps. The commenter requested that CMS add a new evaluation criterion to the CMS Evaluation Form that addresses this situation.

Response: While we are sympathetic to the situation of hospitals clearly serving medically underserved populations (which is generally the case of a residency program that is sponsored by a FQHC), we believe that proposed Evaluation Criteria Three, Five, or Six may address the hospital described by the commenter. Therefore, we decline to address the situation described by the commenter with an Evaluation Criterion on the CMS Evaluation Form in this final rule. However, we would encourage these hospitals to apply for the increase to the caps under section 422.

Comment: We received one comment on the proposed Evaluation Criterion Nine, which concerns awarding a point for hospitals “affiliated with a historically Black medical college.” The commenter disagreed with the CMS proposed interpretation of the Conference Report language that accompanied Public Law 108–173, which stated that the Secretary should consider whether the hospital is a “historically large medical college” in evaluating hospital applications for the increase to their caps under section 422. In the proposed rule, we stated—

“[u]pon consideration of this particular terminology, which, on its face, seems to contradict the three statutory priority categories (that is, rural, “small” urban, and only specialty program in the State), we proposed to view the reference to “historically large medical colleges” as a scrivener’s error, and to read this language to refer to “historically Black medical colleges.” This proposed interpretation accomplishes two goals— first, we believe this interpretation serves the greater policy goal of encouraging residency training for the benefit of medically underserved populations. Second, we believe that this interpretation reflects the Conferees’ intent in the language in the Conference Report.” The commenter believed that the CMS interpretation of the Conference Report terminology is “inaccurate and arbitrary* * *” and that historically large medical colleges” deserve special consideration as they play an important role in educating a large portion of medical students. In some cases these hospitals may be training at a level above their cap and deserve recognition for that.”

Response: We believe our proposed interpretation of the term in the Conference Report, “historically large medical colleges,” is appropriately interpreted to mean “historically Black medical colleges,” as we explained in the proposed rule. We believe historically Black medical colleges serve an important role for medically underserved populations and we would like to award hospitals that train residents that are in programs sponsored by historically Black medical colleges. While we also agree with the commenter that “historically large medical colleges” play an important role in graduate medical education, we do not believe a literal reading of the report language can be consistent with Congress’ explicit statement of priorities at section 1886(h)(7)(B) of the Act. In any case, we believe that we have addressed the issue of large medical college hospitals training residents above their FTE caps with other evaluation criteria addressed in this final rule.

Comment: We received one comment that requested CMS add an Evaluation Criterion for any hospital that has a Medicare Case Mix Index (CMS) greater than 1.70. The commenter believes: “[t]his is an indicator that the hospital is serving severely ill patients who most benefit from being treated in a teaching institution.”

Response: We appreciate the commenter’s suggested Evaluation Criterion, but we have chosen not to adopt it, since a criteria based on severity of illness in general is not necessarily a measurement of the need for additional residents in any specific program.

j. IME Adjustment Formula Multiplier for Redistributed FTE Resident Slots (Section 422(b)(1)(C) of Public Law 108–173) and the Application of Locality-Adjusted National Average Per Resident Amount (PRA)

Section 1886(h)(7)(B)(v) of the Act, as added by section 422 of Public Law 108–173, provides that, with respect to additional residency slots attributable to the increase in the hospital’s FTE resident cap as a result of redistribution of resident positions, the approved FTE resident amount, or PRA, is deemed to be equal to the locality-adjusted national average per resident amount computed for that hospital. In other words, section 1886(h)(7)(B)(v) of the Act requires that, for purposes of determining direct GME payments for portions of cost reporting periods occurring on or after July 1, 2005, a hospital that receives an increase in its direct GME FTE resident cap under

section 1886(h)(7)(B) of the Act will receive direct GME payments with respect to those additional FTE residents using the locality-adjusted national average PRA. Thus, in the May 18, 2004 proposed rule (69 FR 28305), we proposed that a hospital that receives an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act would receive direct GME payments based on the sum of two different direct GME calculations: one that is calculated using the hospital’s actual PRAs (primary care PRA or nonprimary care PRA) applicable under existing § 413.86(e)(4) (proposed to be redesignated as § 413.77(d) in the proposed rule) and the hospital’s number of FTE residents *not* attributable to an FTE cap increase under section 1886(h)(7)(B) of the Act; and another that is calculated using the locality-adjusted national average PRA under existing § 413.86(e)(4)(ii)(B) (proposed to be redesignated as § 413.77(d)(2)(ii) in the proposed rule) inflated to a hospital’s current cost reporting period, and the hospital’s number of FTE residents that is attributable to the increase in the hospital’s FTE resident cap under section 1886(h)(7)(B) of the Act.

Section 422(a) of Public Law 108–173 contains a cross-reference in the new section 1886(h)(7)(B)(v) of the Act to the locality adjusted national average PRA “computed under paragraph (4)(E).” However, section 1886(h)(4)(E) of the Act does not relate to the locality-adjusted national average PRA. Rather, it relates to the circumstances under which a hospital may count FTE resident time spent training in nonhospital sites.

We have concluded that the cross-reference to section 1886(h)(4)(E) of the Act is a legislative drafting error, or scrivener’s error. Instead, we believe the Congress intended to refer to section 1886(h)(2)(E) of the Act, which explicitly provides for the determination of locality-adjusted national average PRAs. Because the drafting error is apparent, and a literal reading of the cross-reference as specified in the statute would produce absurd results, we proposed to interpret the cross-reference to section 1886(h)(4)(E) of the Act in the new section 1886(h)(7)(B)(v) of the Act as if the reference were to section 1886(h)(2)(E) of the Act.

We note that section 1886(h)(7)(B)(v) of the Act, which addresses the applicability of the locality-adjusted national average PRAs with respect to redistributed slots for the direct GME payment, makes no reference to section 1886(h)(4)(G) of the Act, which is the

provision concerning the rolling average count of FTE residents. That is, the statute does not provide for an exclusion from application of the rolling average for residents counted as a result of FTE cap increases under section 1886(h)(7)(B) of the Act. In light of the absence of a specific pronouncement in section 1886(h)(7)(B) of the Act exempting those residents from application of the rolling average, and with no apparent reason to treat residents counted as a result of the FTE cap increases under section 1886(h)(7)(B) of the Act differently for purposes of the rolling average, we had proposed to require that if a hospital increases its direct GME FTE count of residents as a result of an FTE resident cap increase under section 1886(h)(7)(B) of the Act, those FTE residents would be immediately subject to the rolling average calculation. Furthermore, we believed that, given potentially significant shifts of FTE slots among hospitals as a result of section 1886(h)(7) of the Act, the inclusion of FTE residents counted as a result of section 1886(h)(7)(B) of the Act in the rolling average would introduce a measure of stability and predictability, and mitigates radical shifts in direct GME payments from period to period.

Comment: We received several comments on the implementation of section 1886(d)(5)(B) of the Act as modified by section 422(b) of Public Law 108–173, concerning the reduction in the IME adjustment factor, and also section 1886(h)(7)(B)(iv) of the Act, as added by section 422 of Public Law 108–173, concerning the application of the locality adjusted national average PRA, when a hospital receives an increase to its FTE caps for IME and direct GME under section 422. One commenter objected to our application of these two statutory provisions. The commenter stated that “although we recognize that CMS does not have the authority to alter those formula defined in the statute, * * * [we] strongly believe that the Medicare reimbursement formula for all residency positions should be consistent and the section 422 of the [Medicare Modernization Act of 2003] should not have mandated a locality-adjusted national average per resident amount and reduction in the IME factor.”

Other commenters similarly had concerns with the CMS proposed application of the reduced payment rates required for the IME adjustment factor and the locality-adjusted national average PRA. Specifically, these commenters disagreed with the proposed implementation of the rolling average methodology and also the intern

and resident to bed ratio (or "IRB") cap on IME payments, as stated in the proposed rule. The commenters disagreed with the "immediate" application of these two policies to the FTE cap adjusted under section 422. One commenter stated that applying the IRB cap as proposed "* * * effectively reduces a hospital's IME payments below the 50 percent level, and possibly to zero for the first year, and the 3-year rolling average which results in a 3 year phase-in causes additional IME payment delays for these redistributed residents. We believe this IME payment provision as proposed makes it much more difficult for providers to obtain and maintain board approval for commitment of new residency programs when CMS is not even proposing payments at 50 percent of their standard IME payment levels for these redistributed residents." The commenter asked that CMS reconsider the application of the rolling average and the IRB cap to the section 422 FTE increase.

Another commenter, also in support of CMS excepting the application of the rolling average and the IRB cap to the section 422 increase, reminded us that "in the past, CMS [has] created exceptions to the application of the rolling average and the [IRB] cap when there were compelling reasons to do so, even in the absence of a statutory mandate." The commenter gave the examples of the initial years of the new residency program adjustment to the 1996 caps as provided under § 413.79(e) (formerly § 413.86(g)(6)), and the temporary adjustment to the 1996 caps from residents that are displaced from program or hospital closure, as provided under redesignated § 413.79(e) (formerly § 413.86(g)(6)). This commenter also pointed out that it would be a "double penalty" to finalize the rolling average and IRB cap policy as proposed—"the first penalty being a payment rate penalty and the second penalty being an inability to count the residents fully in the first and second years."

In addition, another commenter asked CMS to consider providing a 3-year exemption from the rolling average for IME and direct GME and also the IRB cap for IME payments for any FTEs added as a result of section 422, in a manner similar to the new residency program adjustment to the FTE caps, which allows hospitals to except residents from the rolling average that are in the "initial years" of the new program. The commenter stated that "the current proposed policy [of immediate application of the rolling average and the IRB cap] * * * makes it unnecessarily difficult for qualifying

rural and small city hospitals to properly take advantage of the redistribution process."

Response: We appreciate hospitals' concern with the complexity of receiving different direct GME and IME payments for the residency slots received as per section 422 and the "regular" direct GME and IME payments for the residency slots counted within the hospitals' 1996 FTE caps on the count of residents in accordance with sections 1886(d)(5)(B) and (h)(4) of the Act. As the first commenter correctly states, section 422 of Public Law 108-173 mandates different direct GME and IME payments for the increased slots received under section 422, and CMS has no discretion but to implement these two provisions as written. Due to the complex nature of the different payments for the different FTEs ("section 422 FTEs" and "1996 cap FTEs"), we will refer to the increase a hospital receives in its 1996 FTE cap under section 422 as "the section 422 cap" for purposes of direct GME and IME payments. The section 422 cap will be labeled as such on Worksheets E, Part A and Worksheets E-3, Part IV on the Medicare cost report so that both hospitals and the fiscal intermediaries will be able to more easily determine the different direct GME and IME payments for the different FTEs, depending on whether the FTE residents trained at the hospital are within the hospital's adjusted 1996 FTE cap, or are above that adjusted 1996 FTE cap and, therefore, subject to a section 422 cap.

To address the comments concerning the proposed immediate application of the rolling average to FTEs counted within the section 422 cap for purposes of direct GME and IME payments, and the application of the IRB cap to section 422 FTEs counted for purposes of IME payments, we agree with the commenters that the proposal could create a disincentive for hospitals to apply for the increase to their caps under section 422 because of the "extra-reduced" direct GME and IME payments that would result from the application of the IRB cap and rolling average in the initial years of counting the FTEs within the section 422 caps. We are also concerned that the proposed immediate application of the rolling average and the IRB cap may, as one commenter put it, make it "much more difficult for providers to obtain and maintain board approval for commitment of new residency programs." Furthermore, we believe that the application of the IRB cap and rolling average to residents counted within the section 422 caps would add significantly to the

administrative burdens of both hospitals and fiscal intermediaries to track these residents for purposes of the differing payment rates for IME and direct GME. For these reasons, effective for portions of cost reporting periods and discharges beginning on or after July 1, 2005, CMS will not include the FTEs counted within the section 422 cap in the 3-year rolling average calculation for purposes of direct GME and IME payments. In addition, effective with discharges on or after July 1, 2005, CMS will not apply the IRB cap to the FTEs counted within a hospital's section 422 cap, for purposes of IME payment.

Although one commenter suggested a 3-year exception to the IRB cap and the rolling average, we agree with the commenters that argued that it is appropriate to not apply either of these limitations on the reduced payment authorized by section 1886(h)(7) of the Act.

Because the policies stated above are changed from those stated in the proposed rule at 69 FR 28283 for IME and 69 FR 28305 for direct GME, we provide the following two examples to clarify how the calculations for the payments will work when FTEs are counted within a hospital's section 422 cap:

Example 1: IME adjustment factor. This example illustrates how the IME adjustment factor would be calculated for a hospital that receives an increase to its FTE resident cap as a result of section 1886(h)(7)(B) of the Act. Hospital A has a fiscal year end (FYE) of September 30, and a 1996 IME FTE cap of 20 FTEs. During its FYEs September 30, 2003, September 30, 2004, and September 30, 2005, Hospital A trains 25 FTE residents. Effective for discharges beginning on or after July 1, 2005, under section 1886(h)(7)(B) of the Act, Hospital A receives an increase to its IME cap of 5 FTEs. These additional 5 FTEs are the hospital's IME section 422 cap. The hospital now has an IME 1996 cap of 20 FTEs and an IME section 422 cap of 5 FTEs. Hospital A has maintained an available bed count of 200 beds for FYE September 30, 2004 and continuously through FYE September 30, 2005. The IME adjustment factor formula multiplier for discharges occurring during FY 2005 is 1.42 (as required by section 502(a) of Pub. L. 108-173). The IME adjustment factor formula multiplier for redistributed FTE resident slots is .66 (set by section 422(b)(1)(C) of Pub. L. 108-173). For the FYE September 30, 2005 cost report, the IME adjustment factor is calculated as follows:

Step 1: For discharges occurring October 1, 2004, through September 30, 2005, for residents counted but NOT pursuant to section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: $20+20+20/3=20$.
- Current year resident-to-bed ratio: $20/200=.10$.
- Cap on resident-to-bed ratio (from prior year): $20/200=.10$.

• Compare, and use the lower of, prior year resident-to-bed and current year resident-to-bed ratio: $.10 = .10$.

• Compute IME adjustment factor for FTE residents counted in the 1996 cap: $1.42 \times \{[1+.10]^{.405} - 1\} = 0.0559$

Step 2: For discharges occurring on July 1, 2005 through September 30, 2005 for residents counted as part of the section 422 cap pursuant to section 1886(d)(5)(B)(ix) of the Act:

• Resident-to-bed ratio for 7/1/05—9/30/05: $5/200 = .025$

• Compute IME adjustment factor related to the section 422 cap: $0.66 \times \{[1+.025]^{.405} - 1\} = 0.0066$

Step 3: Compute the combined IME adjustment factor for the hospital (attributable to both the 1996 cap and the section 422 cap):

• For discharges occurring October 1, 2004, through June 30, 2005, the IME adjustment factor for the hospital is 0.0559 (Step 1).

• For discharges occurring July 1, 2005 through September 30, 2005, the combined IME adjustment factor for the hospital is 0.0625 (that is, $0.0559 + 0.0066$) (Step 1 + Step 2).

Since the additional FTEs counted within the section 422 cap are not in the 3-year rolling average calculation or subject to the IRB cap, Hospital A is able to add 0.0066 to the IME adjustment factor for discharges occurring July 1, 2005, through September 30, 2005.

Example 2: Direct GME payment. This example illustrates how the direct GME payment would be calculated for a hospital that receives an increase to its FTE resident cap as a result of section 1886(h)(7)(B) of the Act. For example, Hospital B has a fiscal year end (FYE) of June 30, and a 1996 direct GME FTE cap of 20 FTEs. During its FYEs June 30, 2004 and June 30, 2005, Hospital B trained 20 nonprimary care residents. During FYE June 30, 2006, Hospital B trains 25 nonprimary care FTE residents. Hospital B's FYE June 30, 2006 nonprimary care PRA is \$100,000. The FYE June 30, 2006 locality-adjusted national average PRA for Hospital B is \$84,000. Hospital B's Medicare utilization is 35 percent in FTE June 30, 2006. Effective July 1, 2005, under section 1886(h)(7)(B) of the Act, Hospital B receives an increase to its direct GME cap of 5 FTEs. These additional 5 FTEs are the hospital's direct GME section 422 cap. The hospital now has a direct GME 1996 cap of 20 FTEs and a direct GME section 422 cap of 5 FTEs. For the FYE June 30, 2006 cost report, the direct GME payment is calculated as follows:

Step 1: For residents counted but NOT pursuant to section 1886(h)(7)(B) of the Act:

• Rolling average count: $20+20+20/3 = 20$.

• Direct GME computation: $\$100,000 \times 20 \times .35 = \$700,000$.

Step 2: For residents counted pursuant to section 1886(h)(7)(B) of the Act (the section 422 cap):

• Direct GME computation: $\$84,000 \times 5 \times .35 = \$147,000$.

Step 3: Total direct GME payment for FYE June 30, 2006: $\$700,000 + \$147,000 = \$847,000$.

Comment: One commenter stated that the calculation of the IME payment

relating to additional residents counted as a result of an increase in the hospital's FTE cap received under section 1886(h)(7)(B) of the Act is extremely cumbersome and will require difficult and extensive changes to the Medicare cost report, particularly if the additional residents are to be subject to the rolling average and the resident-to-bed ratio. The commenter suggested that instead of revising Worksheet E, Part A to include this calculation, CMS should consider including this calculation on a separate worksheet, with the results added to Worksheet E, Part A.

Response: First, we note that we are required by section 1886(d)(5)(B)(ix) of the Act to apply a different IME formula multiplier to calculate the IME payment relating to these residents. Therefore, some level of additional complexity is not avoidable. Additionally, we have stated in previous responses concerning the IME calculation relating to residents counted under section 1886(h)(7)(B) of the Act, under our final policy, we are not requiring that these residents be subject to the rolling average and resident-to-bed ratio calculations. Thus, we believe that our final policy substantially reduces the complexity of the proposed calculations that concerned the commenter. Even so, we do realize that the presence of an additional calculation on Worksheet E, Part A for IME (and also on Worksheet E-3, Part IV for direct GME) further complicates an already difficult calculation. We will attempt to revise the worksheets in the simplest and least disruptive manner.

Comment: One commenter discussed the situation of a hospital that was subject to the reductions as required under section 1886(h)(7)(A) of the Act because it was below its 1996 FTE cap, that also applies for the cap increase (that is, the section 422 cap) as provided under section 1886(h)(7)(B) of the Act. The commenter believed that only the "aggregate" FTE amount, that is, the difference in number of positions between the reduction in the cap and the cap increase, both provided under section 422, should be the sole basis for the application of the reduced direct GME and IME payment rates. Using the commenter's reasoning in an example, there is Hospital A, which has a 1996 FTE cap of 100 FTEs on June 30, 2005. Hospital A's resident FTE cap is raised to 110 FTEs as of July 1, 2005 under the section 422 increase. Under the section 422 reductions, Hospital A's cap was lowered to 90 FTEs, also as of July 1, 2005. As per the commenter's proposal, CMS would apply the reduced direct GME and IME payment rates only to 10 FTEs for Hospital A, because 10 FTEs is

the difference in number of positions between Hospital A's reduction in the cap and Hospital A's cap increase. Thus, the commenter suggested that, in the situation of a hospital that was reduced under section 422 for a greater number of FTEs than the hospital received as a section 422 cap, there would be no "redistributed" residents and, thus, there would be no application of the reduced payment rates.

Response: We do not agree with the commenter's suggestion. We believe that sections 1886(h)(7)(A) and (B) of the Act—the section 422 reduction and increase provisions, respectively—are two very different processes that require separate determinations by CMS. The only connections between subparagraphs (A) and (B) are that the cap increases through (B) are made by us through an estimated pool of FTE slots gathered from the reductions made through (A), and that both the reductions under (A) and the increases under (B) are effective July 1, 2005. The similarities end there. We believe the reductions and the increases are stand-alone provisions and that the Congress did not intend that we would use the difference in the number of positions between the reduction in the cap and the cap increase, both provided under section 422, as the "sole basis" for the application of the reduced direct GME and IME payment rates, as the commenter suggested. We believe that a "redistribution" under section 1886(h)(7)(B) of the Act is simply an increase to the adjusted 1996 cap, as reduced where applicable by section 1886(h)(7)(A) of the Act. It is not the difference between the section 422 reduction and the section 422 increase for any one applicant hospital.

Other Issues on the Request for Increase in the FTE caps Under Section 422

Comment: One commenter requested that CMS clarify the question of whether rural hospitals that establish a new residency program are precluded from receiving a new residency program adjustment under § 413.86(g)(6)(i) (redesignated as § 413.79(e)(1)), if the hospitals can also receive an increase to their FTE caps if they apply under section 422. Similarly, another commenter stated that for expansion of rural programs up to 130 percent of their BBA-set cap, it should be made clear that CMS' proposals concerning section 422 do not supersede the BBRA provision, but are in addition to it, "so a rural hospital that wishes to increase its BBA-set cap, may do so up to 130 percent, and may of course use this provision for any positions beyond that number." Finally, several commenters

asking CMS to exclude applicant hospitals from consideration under section 422 if they are eligible for current regulatory exceptions to the 1996 FTE caps.

Response: Rural hospitals may receive an adjustment to their FTE caps for establishing a new residency program under redesignated § 413.79(e)(1), at any time, and are not precluded from requesting the new residency program adjustment even if the hospitals also receive an increase to their FTE caps under section 422. However, we note that hospitals, rural or urban, may not apply for a permanent adjustment to their FTE caps under current Medicare regulations and also apply for an increase to their FTE caps under section 422 for the same new residency program. Though, such hospitals may apply for an increase under section 422 for a different residency program(s).

In response to the second commenter's suggestion, there is nothing that precludes a rural hospital from requesting an increase to its FTE cap under section 422 even if it also received a 130 percent expansion under the BBRA of 1999. We do not believe that when the Congress enacted section 1886(h)(7)(B) of the Act, it intended to limit rural hospital from receiving any additional slots. In fact, the Congress gave rural hospitals priority in the redistribution process.

Comment: One commenter asked whether CMS plans to provide oversight of a hospital's section 422 caps. Specifically, the commenter wanted to know if hospitals could use the FTE cap increase as per section 422 for any program at the applicant hospital, "in spite of receiving them on the basis of demand for starting or expanding a specific specialty program."

Response: As we stated above, once a hospital receives its section 422 cap after applying for the increase as stated in this final rule, beginning July 1, 2005, the section 422 cap is applied to FTEs in any program that the hospital is training in excess of its 1996 FTE cap, regardless of the hospital's program-specific basis for being granted the section 422 cap.

However, we note that, in order to qualify to apply for the increase to its FTE caps under section 422, a hospital must fulfill the demonstrated likelihood criteria on the CMS Evaluation Form (as finalized in this rule). The hospital must complete a CMS Evaluation Form for each residency program for which the hospital requests a FTE cap increase. In addition to a CMS Evaluation Form(s), the hospital must include as part of its application for the section 422 caps an attestation to the truth and veracity for

the information included in the hospitals application. Thus, while the section 422 cap is an aggregate non-program-specific cap, when we determine which hospitals are to receive the section 422 caps, we are basing our determinations on the program-specific information provided by the hospital at the time of the hospital's application.

Comment: Two commenters asked whether both the requests for the increases in the IME cap and the direct GME cap could be on the same hospital application for the section 422 caps.

Response: As we stated above and also in the proposed rule, as part of the requirements that a hospital must fulfill in order to complete an application for the section 422 caps, is the requirement that the applicant hospital must include the total number of requested FTE resident slots (for all residency programs at the hospital) for direct GME or IME, or both (up to 25 FTEs). Thus, both of the increases in the IME and the direct GME cap request (that is, the total number of requested FTE resident slots (for all residency programs at the hospitals)) are required to be on the same hospital application for the section 422 caps.

As stated above, a hospital must submit the following in order to apply for the section 422 caps:

- The name and Medicare provider number of the hospital.
- The total number of requested FTE resident slots (for all residency programs at the hospital) for direct GME or IME, or both (up to 25 FTEs).
- A completed copy of the CMS Evaluation Form for each residency program for which the applicant hospital intends to use the requested increase in the number of FTE residents and source documentation to support the assertions made by the hospital on the Evaluation Form.
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report.

• An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following information in the hospital's application for an increase in its FTE resident cap:

"I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly

of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents."

Comment: One commenter asked why the "resident cap redistribution process" is not included in the proposed regulations text, and that only "summary information" is provided under proposed § 413.79(c)(4).

Response: We proposed only "summary information" at proposed § 413.79(c)(4) because the process for applying for the section 422 caps is a one-time process, not to be repeated, as we understand it. We see no reason to put in all of the steps for applying for the section 422 caps into regulations, as well as our evaluation process of the applications. There may be some hospitals that will apply for the section 422 caps, and other hospitals that will not apply. However, to avoid any misunderstanding as to the process for applying for the section 422 caps, in this final rule, we are revising § 413.79(c)(4) to state "For portions of cost reporting periods beginning on or after July 1, 2005, a hospital may receive an increase in its otherwise applicable FTE resident cap up to an additional 25 FTEs (as determined by CMS) if the hospital meets the requirements and qualifying criteria of section 1886(h)(7) of the Act and implementing instructions issued by CMS, including the preamble to the August 11, 2004, and if the hospital submits an application to CMS within the timeframe specified by CMS."

k. Application of Section 422 to Hospitals That Participate in Demonstration Projects or Voluntary Reduction Programs

Section 1886(h)(7)(B)(vi) of the Act, as amended by section 422(a)(3) of Public Law 108-173, states that "Nothing in this subparagraph shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs * * * under a demonstration project approved as of October 31, 2003." This language is referring to the New York Medicare GME Demonstration Project and the Voluntary Resident Reduction Project (VRRP) under section 402 of Public Law 90-248. In July 1997, 42 New York teaching hospitals participated in the

demonstration project. As there were two entry points for this demonstration, an additional seven hospitals joined the program in July 1998. The purpose of the demonstration project was to test reimbursement changes associated with residency training to determine whether hospitals could use time-limited transition funding to replace and reengineer the services provided by a portion of their residency trainees. In exchange for reducing its count of residents by 20 to 25 percent over a 5-year period, while maintaining or increasing its primary care-to-specialty ratio of residents, a participating hospital (or consortium of hospitals) would receive "hold harmless payments" for 6 years. These payments represented a declining percentage of the Medicare GME reimbursement the participating hospitals would have received had their number of residents not been reduced.

For hospitals that successfully completed the demonstration project, the Balanced Budget Act of 1997 states that if a hospital increases the number of full-time equivalent residents permitted under its reduction plan as of the completion of the plan, it is liable for repayment of the total amounts paid under the demonstration. Following the demonstration's period of performance, which ended June 30, 2003, if a hospital exceeds its post-demonstration cap and trains residents in excess of the FTE levels achieved under the demonstration, the hospital is not permitted to count those excess residents for purposes of Medicare GME payments until such time as the hold harmless funds paid under the demonstration project have been repaid in full.

Similarly, with the VRPP, hospitals could use time-limited transition funding to replace the services provided by a portion of their residents. In exchange for reducing its count of residents by 20 to 25 percent over a 5-year period, while maintaining or increasing its primary care-to-specialty ratio of residents, a VRRP participating hospital would receive "hold harmless payments" for 5 years. These payments represented a declining percentage of the Medicare GME reimbursement the VRRP participating hospital would have received had its number of residents not been reduced.

In the May 18, 2004 proposed rule, we indicated that we believe that the language of section 1886(h)(7)(B)(vi) of the Act precludes the Secretary from redistributing residency positions that are unused due to a hospital's participation in a demonstration project or the VRRP to other hospitals that seek

to increase their FTE resident caps under section 1886(h)(7)(B)(i) of the Act. That is, if we were to specify that hospitals that participated in a demonstration project or the VRRP are subject to possible reductions to their FTE resident caps under section 1886(h)(7)(A)(i) of the Act, any excess slots resulting from reductions made under section 1886(h)(7)(A)(i) of the Act attributable to the demonstration or the voluntary reduction program at these hospitals would not be allocated to the resident pool and redistributed to other hospitals. We also believed that section 1886(h)(7)(B)(vi) of the Act is silent as to whether the Secretary should apply the possible reductions under section 1886(h)(7)(A)(i) of the Act to the FTE resident caps of these hospitals. The Congress recognized the unique status of reductions in FTE resident counts made by these hospitals that participated in a demonstration project under the authority of section 402 of Public Law 90-248, or a VRRP under section 1886(h)(6) of the Act, in which these hospitals received hold-harmless payments from Medicare for reducing the number of residents that they were training. Accordingly, in the May 18, 2004 proposed rule (69 FR 28306), we proposed to recognize the unique status of FTE reductions made by these hospitals, and to apply the discretion that the Congress granted the Secretary under section 1886(h)(7)(A)(ii) of the Act in determining the reference resident level applicable to these hospitals, to determine the extent to which section 1886(h)(7)(A)(i) of the Act applies to these hospitals.

We note that section 1886(h)(7)(B)(vi) of the Act only applies to these hospitals to the extent that a hospital's "reductions in residency positions" were "attributable" to its participation in the demonstration project or the VRRP. In determining the reference resident level for these hospitals, we proposed to adjust the reference resident level for "reductions in residency positions attributable" to participation in the demonstration project or the VRRP. We proposed to define "reductions in residency positions attributable" to participation in the demonstration project or the VRRP as the difference between the number of unweighted allopathic and osteopathic residents training at the hospital at the start of a hospital's participation in the demonstration project or the VRRP, (that is, the base number of residents as defined by the terms of the demonstration project and the VRRP,) and the number of such residents training at the hospital in the

hospital's most recent cost reporting period ending on or before September 30, 2002. We proposed that, in determining any possible adjustments to the reference resident level for hospitals that participated in the demonstration project or the VRRP, we would differentiate between hospitals that withdrew from participation prior to the beginning of the most recent cost reporting period ending on or before September 30, 2002, and hospitals that either have not withdrawn from participation, or withdrew sometime during or after the most recent cost reporting period ending on or before September 30, 2002.

Specifically, we proposed that, if a hospital was participating in the demonstration project or the VRRP at any time during the hospital's most recent cost reporting period ending on or before September 30, 2002, for purposes of determining possible reductions to the FTE resident caps, we would compare the higher of the hospital's base number of residents, and the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, to the hospital's otherwise applicable FTE resident cap. If the higher of the base number of residents or the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, is still less than the otherwise applicable FTE resident cap, we proposed to reduce the hospital's FTE resident cap amount by 75 percent of the difference, effective July 1, 2005. We also proposed to use those slots in the redistribution process under section 1886(h)(7)(B) of the Act since those slots are not "attributable" to participation in the demonstration project or the VRRP.

Under section 1886(h)(7)(A)(ii)(II) of the Act, a hospital may submit a timely request to use its cost report that includes July 1, 2003, for purposes of determining the reference resident level if the hospital has an expansion of an existing program that is not reflected on the hospital's most recent settled cost report. If a hospital that was still participating in the demonstration project or the VRRP at some time during its most recent cost reporting period ending on or before September 30, 2002, had an expansion of an existing program that is not reflected on its most recent settled cost report, and the resident level for its cost reporting period that includes July 1, 2003, is higher than the resident level for the most recent cost reporting period ending on or before September 30, 2002, and is higher than the base number of residents, we anticipate that the hospital would submit a timely request that its resident

level from its cost reporting period that includes July 1, 2003, be compared to its otherwise applicable FTE resident cap, for purposes of determining a possible reduction to the hospital's FTE resident cap. We believe that under the proposed policy discussed above, a hospital would only request that we utilize its cost reporting period that includes July 1, 2003, if the number of allopathic and osteopathic residents it trained in that cost reporting period is higher than its base number of residents and its base number of residents is less than its FTE resident cap. If we grant the hospital's request that we utilize its cost reporting period that includes July 1, 2003, and the resident level for that period is less than the FTE resident cap, we would reduce the FTE resident cap by 75 percent of the difference between the two numbers. We also proposed to use those slots in the redistribution process under section 1886(h)(7)(B) of the Act, because those slots are not "attributable" to participation in the demonstration project or the VRRP.

If a hospital withdrew from participation in the demonstration project or the VRRP prior to its most recent cost reporting period ending on or before September 30, 2002, we proposed that such a hospital would be subject to the procedures applicable to all other hospitals for determining possible reductions to the FTE resident caps. However, we note that such a hospital may still apply for an increase to its FTE caps as specified under section 1886(h)(7)(B) of the Act (the proposals for applying for the increase are described above).

Comment: One commenter was appreciative of the fact that CMS acknowledged that section 1886(h)(7)(B)(vi) of the Act only applies to hospitals that participated in the demonstration project to the extent that a hospital's "reductions in residency positions" were attributable to its participation in the demonstration project, and that, in determining the reference resident level for these hospitals, CMS proposed to adjust the reference resident level for reductions in residency positions attributable to participation in the demonstration project. The commenter supported our proposal that, for a hospital that was participating in the demonstration project during the most recent cost reporting year ending on or before September 30, 2002, CMS would compare the higher of the hospital's base number of residents, and the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, to the hospital's otherwise applicable FTE

resident cap. However, the commenter requested that CMS expand upon its proposal to allow additional hospitals that do not meet the proposed criteria to demonstrate that certain reductions were also "attributable" to their participation in the demonstration project and, therefore, should be exempt from reduction to their FTE resident caps, for the following reasons: First, some hospitals withdrew prior to their most recent cost reporting period ending on or before September 30, 2002, because they realized that remaining in the demonstration project and maintaining reduced resident counts would compromise their educational and patient care missions in the long run. Second, because the terms and conditions of the demonstration project "front-loaded" the hold harmless payments by means of a declining percentage of the hospital's usual Medicare GME reimbursement, all demonstration hospitals gained incentivized to make as large a reduction as possible in the early years of the demonstration project." The commenter noted that, while some hospitals that withdrew prior to their most recent cost reporting period ending on or before September 30, 2002, were able to rebuild their residency programs close to or at the pre-demonstration project level, other hospitals have only just begun or are still in the planning stages for rebuilding their programs. The commenter further stressed the point that section 1886(h)(7)(B)(vi) of the Act, which prohibits the redistribution of reductions in residency positions attributable to voluntary reduction programs, does not specify a timeframe within which those hospitals need to refill those positions, and that, therefore, CMS should not impose such a criterion that differentiates between hospitals that withdrew from participation prior to the beginning of the most recent cost reporting period ending on or before September 30, 2002, and hospitals that either have not withdrawn from participation, or withdrew sometime during or after the most recent cost reporting period ending on or before September 30, 2002.

The commenter recommended a multi-part criterion for hospitals that withdrew prior to the most recent cost reporting period ending on or before September 30, 2002, to demonstrate that particular resident reductions were attributable to the demonstration project and should be exempted from redistribution. The criterion focused on a two-part test for exemption from redistribution: hospital eligibility and residency program eligibility. The

commenter suggested that a residency program's eligibility for consideration under the second-level criterion would be dependent on a hospital's satisfaction of the first-level criterion.

The commenter proposed that a hospital would have to meet the following criteria to prove the "first level criterion" for hospital eligibility:

- The hospital participated in demonstration project and withdrew prior to the most recent cost reporting period ending on or before September 30, 2002;
- The hospital's resident FTE count declined between the demonstration project base year and the point at which the hospital withdrew from the demonstration project; and
- The hospital's applicable FTE resident count in the hospital's reference resident level year is below both the hospital's demonstration project base year FTE resident count and the hospital's otherwise applicable FTE resident cap number.

The commenter proposed that the hospital would have to meet the following criteria to prove the "second level criterion" of residency program eligibility:

- The residency program was in operation during the base year for the demonstration project.
- The FTE resident count for that particular residency program declined between the demonstration project base year and the point at which the hospital withdrew from the demonstration project.
- The FTE resident count for that particular residency program in the hospital's reference resident level year is below both (a) the FTE resident count for that particular residency program during the base year for the demonstration project, and (b) the FTE resident count for that particular residency program during the most recent cost reporting period ending on or before December 31, 1996.

While the commenter believed that satisfaction of these two criteria prove that these reduced resident positions are attributable to demonstration project and should be exempt from redistribution, the commenter indicated that it would be pleased to work with CMS to develop basic documentation requirements to support the exemption should CMS believe such a requirement is needed. The commenter also noted that hospitals that withdrew from the demonstration project prior to the most recent cost reporting period ending on or before September 30, 2002, might have, in certain instances, added resident positions in departments other than where resident reductions

attributable to the demonstration project were made. Therefore, in order to ensure that the number of individual reduced residency position eligible for exemption does not exceed the appropriate number of positions, the number of exemptions should be "capped" at the difference between (i) the number of FTE residents in the hospital's reference resident level year, and (ii) the lower of the hospital's demonstration project base year FTE resident count and the hospital's otherwise applicable FTE resident cap number.

The commenter concluded that it recognizes that CMS may not be able to address all details of its recommended methodology in the final rule, and expressed hope that time constraints would not preclude CMS from giving ample consideration to the reasonableness of its recommendation and its consistency with the relevant provisions within section 422 of Public Law 108-173.

Response: As we explained in the May 18, 2004 proposed rule, while we believe that the language of section 1886(h)(7)(B)(vi) of the Act concerning hospitals that participated in the New York Medicare GME demonstration project or the VRRP precludes the Secretary from redistributing residency positions that are unused due to a hospital's participation in a demonstration project or the VRRP to other hospitals that seek an increase in their FTE resident caps under section 1886(h)(7)(B)(i) of the Act, we also believe that section 1886(h)(7)(B)(vi) of the Act is silent as to whether the Secretary should apply the possible reductions under section 1886(h)(7)(A)(i) of the Act to the FTE resident caps of these hospitals. As the commenter noted, we proposed that, in determining the reference resident level for these hospitals, we would adjust the reference resident level for reductions in residency positions attributable to participation in the demonstration project or the VRRP. In making this proposal, we considered the potential operational difficulties that would be imposed on both hospitals and the fiscal intermediary if we were to require that each hospital document reductions attributable to the demonstration project, whether at the hospital level, or at the program level. Thus, to avoid undue administrative burden, and in absence of a clearly specified timeframe or cut off point for reductions attributable to participation in the demonstration or the VRRP in section 1886(h)(7)(B)(vi) of the Act, we proposed to use the hospital's most recent cost reporting period ending on

or before September 30, 2002, which is the cost reporting period the Secretary is first directed to use under section 1886(h)(7)(A)(ii) of the Act, to determine any possible adjustments to the reference resident level for hospitals that participated in the demonstration project or the VRRP. Specifically, we proposed to differentiate between hospitals that withdrew from participation prior to the beginning of the most recent cost reporting period ending on or before September 30, 2002, and hospitals that either have not withdrawn from participation, or withdrew sometime during or after their most recent cost reporting period ending on or before September 30, 2002. We believe it is necessary to establish a timeframe for a hospital's participation in a demonstration or VRRP because, at some point after withdrawal, it can no longer be said that reductions in the number of FTE residents are attributable to participation in a demonstration or VRRP. We believe that using the most recent cost reporting period ending on or before September 30, 2002, as the delineator for determining which hospitals may receive possible adjustments to their reference resident levels was clear, administratively feasible, had basis in the statute, and would be a reasonable reflection of which reductions were attributable to participation in a demonstration or VRRP. Therefore, we strongly disagree with the commenter's assertion that our proposed use of this cost reporting period was a "bright line" distinction that implied that there was some "predetermined maximum amount of time" for hospitals that participated in a demonstration project to refill their vacated resident positions. In fact, those hospitals could refill, or not refill, those slots as they saw fit. Furthermore, to the extent that a hospital (involved in the demonstration project or otherwise) may have planned to increase its resident counts in the future, these plans are not recognized under section 1886(h)(7)(A) of the Act, which requires 75 percent of any "unused" slots must be "redistributed." The Congress did, however, recognize the unique status of reductions in FTE resident counts attributable to a hospital's participation in a demonstration project or the VRRP in the statute at section 1886(h)(7)(B)(vi) of the Act. Therefore, we do not believe our proposal would allow resident positions to be redistributed in "some wholesale manner," as the commenter suggested.

However, we do acknowledge the commenter's comprehensive and clearly articulated recommended methodology

for documenting, both at the hospital level, and at the program-specific level, that select unused resident positions were attributable to the demonstration project, and should be exempted from redistribution. We note that hospitals, including those that participated in the demonstration, may reduce their FTE resident counts for many possible reasons. Thus, it would be impossible to determine with certainty, under any possible methodology, that a particular reduction in the number of FTE residents is purely attributable to participation in the demonstration or VRRP. Although we have considered various ways of documenting reductions in FTE resident counts attributable to participation in the demonstration project, we decided that any possible improvement in the definition of "attributable to" reductions would be offset by the difficulty for hospitals to produce this detailed, program-specific documentation, and the significant additional audit workload that would be imposed on the fiscal intermediary. In addition, we note that the commenter's suggested methodology seems to focus solely on reductions in resident positions that occurred in specific programs between the time that the hospitals entered the demonstration project and the time that they withdrew. We believe a more credible method of demonstrating that reductions should be exempt from redistribution would be to document what has happened in those programs since the time that the hospital withdrew from the demonstration project, especially for those hospitals that ended participation in the demonstration in earlier years, and have had more time to add back to their FTE resident count those reductions that were solely attributable to participation in the demonstration. We believe evidence that the hospital's resident counts have grown since its withdrawal more convincingly advocates for an exemption from reduction for those resident slots, as opposed to emphasis on the number of slots that had been reduced prior to withdrawal. Thus, while we considered the commenter's recommendation that the hospitals should be required to supply program-specific information from the reference cost reporting period, the base year for the demonstration project, and for the most recent cost reporting period ending on or before December 31, 1996, we are not inclined to impose such detailed documentation requirements for the purpose of determining which of a hospital's reductions in FTE resident counts are attributable to participation in the

demonstration project, and we question whether this data could necessarily be conclusive. Accordingly, we are not adopting the commenter's suggested multi-part methodology.

However, in light of the comments, and after reviewing the proposed policy, we have decided that, in finalizing our policy, we will further consider the length of time a hospital participated in the demonstration project or the VRRP before it withdrew. Specifically, we will provide the same protection that we proposed for hospitals that were still participating in the demonstration project during the cost reporting period ending on or before September 30, 2002, to hospitals that withdrew prior to that cost reporting period if the period of time the hospital participated in the demonstration project is longer than the period of time the hospital has been withdrawn from the demonstration project. For instance, the maximum amount of time that a hospital entering the demonstration project in 1997 could participate in the demonstration project was 6 years (from July 1997 to June 2003). A hospital that participated in the demonstration for more than 3 years would necessarily have participated in the demonstration for more years than it did not (that is, it would have been withdrawn from the demonstration for less than 3 years). We note that, for those hospitals entering the demonstration project at the second entry point in 1998, the maximum amount of time those hospitals could participate in the demonstration project was 5 years. If a hospital participated in the demonstration for a greater period of time than the time period that has elapsed since it withdrew from the demonstration project, we acknowledge that the hospital may not have had a sufficient amount of time to refill its residency slots to its base year level by its cost report that includes July 1, 2003. Therefore, in this final rule, we are finalizing our policy with respect to hospitals that participated in a demonstration project or the VRRP to state that, if a hospital participated in the demonstration project or the VRRP for a longer period of time than it has been withdrawn from the demonstration project or the VRRP, for purposes of determining possible reductions to the FTE resident caps, we would compare the higher of the hospital's allopathic and osteopathic base number of residents for the demonstration project or the VRRP, or the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, to the hospital's otherwise applicable FTE resident cap. If the

higher of the allopathic and osteopathic base number of residents or the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, is still less than the otherwise applicable FTE resident cap, we would reduce the hospital's FTE resident cap amount by 75 percent of the difference, effective July 1, 2005. We will also include those cap reductions in the redistribution process under section 1886(h)(7)(B) of the Act because those reductions are not "attributable" to participation in the demonstration project or the VRRP.

Although hospitals that participated in the demonstration project for less time than they have been withdrawn from the demonstration project may also have reduced their FTE resident counts at one point, we believe that those hospitals (particularly those that withdrew from the demonstration project after realizing, as the commenter states, that their educational and patient care missions would be compromised in the "long run"), should have been able to increase their FTE resident counts to their base year levels. If not by their most recent cost reporting period ending on or before September 30, 2002 then in time to qualify to make a timely request to use its cost report that includes July 1, 2003 under section 1886(h)(7)(A)(ii)(II) of the Act. We emphasize that the Congress recognized that, for a variety of reasons, a hospital's FTE resident count on its most recent cost reporting period ending on or before September 30, 2002, might not be as high as it typically is, or that its FTE resident count may have increased after its most recent cost report ending on or before September 30, 2002. Under sections 1886(h)(7)(A)(ii)(II) and (III) of the Act, Congress provided for the possibility that hospitals may have expanded existing programs or may have planned to start new programs, by allowing hospitals the option to use their cost report that includes July 1, 2003 for expansions of existing programs, or to adjust the reference resident level in the case of newly approved programs. We believe hospitals that withdrew early (that is, those that withdrew so early from the demonstration that the time they were participating was shorter than the time they were not), and are committed to maintaining their residency programs consistent with its educational and patient care missions would have been able to substantially restore their residency programs by their cost report that includes July 1, 2003. Those hospitals that participated in the demonstration project for a lesser

amount of time than they have been withdrawn and, since their withdrawal have been increasing their resident counts, could have availed themselves of the option to submit a timely request by June 14, 2004, to use their cost report that includes July 1, 2003, as the reference cost report.

In summary, we are finalizing our policy with respect to hospitals that participated in a demonstration project or the VRRP to state that if a hospital participated in the demonstration project or the VRRP for a longer period of time than the time period that it has been withdrawn from the demonstration project or the VRRP, for purposes of determining possible reductions to the FTE resident caps, we would compare the higher of the hospital's allopathic and osteopathic base number of residents, and the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, to the hospital's otherwise applicable FTE resident cap. If the higher of the allopathic and osteopathic base number of residents or the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, is still less than the otherwise applicable FTE resident cap, we would reduce the hospital's FTE resident cap amount by 75 percent of the difference between the higher number and the otherwise applicable cap, effective July 1, 2005. We would also include those slots in the redistribution process under section 1886(h)(7)(B) of the Act since those slots are not "attributable" to participation in the demonstration project or the VRRP.

Under section 1886(h)(7)(A)(ii)(II) of the Act, a hospital may submit a timely request to use its cost report that includes July 1, 2003, for purposes of determining the reference resident level if the hospital has an expansion of an existing program that is not reflected on the hospital's most recent settled cost report. Accordingly, if a hospital that was participating in the demonstration project or the VRRP for a greater amount of time than it has been withdrawn from participation in the demonstration project or the VRRP, had an expansion of an existing program that is not reflected on its most recent settled cost report, and the hospital submitted (and CMS approved) a timely request that its resident level from its cost reporting period that includes July 1, 2003, be compared to its otherwise applicable FTE resident cap, we would compare the higher of the hospital's allopathic and osteopathic base number of residents, and the resident level in the hospital's cost reporting period that includes July 1, 2003, to the hospital's

otherwise applicable FTE resident cap. If the higher of the allopathic and osteopathic base number of residents or the resident level in the hospital's cost reporting period that includes July 1, 2003 is still less than the otherwise applicable FTE resident cap, we would reduce the hospital's FTE resident cap amount by 75 percent of the difference between the higher number and the otherwise applicable cap, effective July 1, 2005. We would also include those slots in the redistribution process under section 1886(h)(7)(B) of the Act since those slots are not "attributable" to participation in the demonstration project or the VRRP.

If a hospital participated in the demonstration project or the VRRP for an amount of time that is less than the amount of time that has elapsed since it withdrew from the demonstration project or the VRRP, such a hospital would be subject to the procedures applicable to all other hospitals for determining possible reductions to the FTE resident caps. However, we note that such a hospital may still apply for an increase to its FTE caps as specified under section 1886(h)(7)(B) of the Act.

We are also clarifying one point concerning the "base number" of residents. In the May 18, 2004 proposed rule, we explained that for purposes of determining whether the FTE resident caps of hospitals that participated in the demonstration project or the VRRP would be reduced, we would determine the "difference between the number of unweighted *allopathic and osteopathic* residents training at the hospital at the start of a hospital's participation in the demonstration project or the VRRP, (that is, *the base number of residents as defined by the terms of the demonstration project and the VRRP*), and the number of these residents training at the hospital in the hospital's most recent cost reporting period ending on or before September 30, 2002" (69 FR 28307, emphasis added). However, we inadvertently overlooked the fact that the demonstration project and the VRRP applied to dental and podiatric residents, in addition to allopathic and osteopathic residents. Thus, for hospitals that were training dental and podiatric residents at the start of their participation in the demonstration project or the VRRP, these residents were also included in the base number of residents. Because FTE resident caps apply only to allopathic and osteopathic residents, we are clarifying that, for purposes of determining possible reductions to the FTE resident caps of a hospital that participated in the demonstration project or the VRRP, any dental and podiatry FTE residents

should be subtracted from a hospital's base number of FTE residents. If a hospital participated in the demonstration project or the VRRP for a longer period time than it was not participating, for purposes of determining possible reductions to the FTE resident caps, we would compare the higher of the hospital's base number of residents, excluding any dental and podiatric residents, and the reference resident level, to the hospital's otherwise applicable FTE resident cap.

l. Application of Section 422 to Hospitals That File Low Utilization Medicare Cost Reports

In general, section 422 of Public Law 108-173 applies to hospitals that are Medicare-participating providers and that train residents in approved residency programs. However, because Medicare-participating children's hospitals primarily serve a non-Medicare population and, therefore, receive minimal Medicare payments relative to other Medicare-participating hospitals, some children's hospitals choose (with approval from their fiscal intermediaries) to submit low utilization (abbreviated) Medicare cost reports. Typically, such low utilization cost reports do not include the information that would be necessary for us to calculate Medicare GME payments, such as FTE resident counts and caps. Thus, children's hospitals that submit these low utilization cost reports do not receive Medicare GME payments.

Under section 1886(h)(7)(A) of the Act, as added by section 422(a) of Public Law 108-173, in the May 18, 2004 proposed rule (69 FR 28307), we proposed that determinations as to whether, and by how much, a children's hospital's FTE resident cap will be reduced will be made using the same methodology (that is, utilizing the same reference cost reporting periods and the same reference resident levels) that we proposed for other Medicare-participating teaching hospitals. We note that the low utilization cost reports may be filed with or without Worksheet E-3, Part IV (the worksheet on which the Medicare direct GME payment is calculated). If a children's hospital files a low utilization cost report in a given cost reporting period, and does not file the Worksheet E-3, Part IV, for Medicare purposes, that hospital is not considered by Medicare to be a teaching hospital in that cost reporting period. (We realize that a children's hospital that files a low utilization cost report may have a "resident cap" that is applicable for payment purposes under the Children's Hospital Graduate Medical Education (CHGME) Payment

Program, administered by the Health Resources and Services Administration (HRSA), but this resident cap is not the Medicare FTE resident cap.) As stated in the One-Time Notification published on April 30, 2004 (Transmittal 77, CR 3247), if a children's hospital filed a low utilization cost report in its most recent cost reporting period ending on or before September 30, 2002, and did not file the Worksheet E-3, Part IV, there could be no reduction under section 1886(h)(7)(A) of the Act because there is no reference resident level for such a hospital. This would be the case even in instances where such a children's hospital has a FTE resident cap (for example, from 1996) that is recognized for Medicare purposes, because there would still be no reference resident level for its most recent cost reporting period ending on or before September 30, 2002, on which to determine a possible reduction to the children's hospital FTE resident cap.

Although section 1886(h)(7)(A) of the Act does not apply to children's hospitals that filed a low utilization cost report (and no Worksheet E-3, Part IV) for the most recent cost reporting period ending on or before September 30, 2002, we proposed that, regardless of how a children's hospital has previously filed its Medicare cost report (that is, a full cost report or an abbreviated one), or how it is treated for CHGME payment purposes, a children's hospital would be eligible to apply for an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act, subject to the same demonstrated likelihood and evaluation criteria proposed above for all hospitals. However, we proposed that, in order to receive an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act, effective July 1, 2005, in addition to complying with the proposed application requirements described above, the hospital must file Worksheet E-3, Part IV, with its Medicare cost report for its cost reporting period that includes July 1, 2005. We proposed that the children's hospital comply with this requirement because section 422 is intended to allow a hospital to increase its FTE counts for purposes of Medicare GME payments. We do not believe it would be appropriate to grant an increase in a hospital's FTE resident cap under section 1886(h)(7)(B) of the Act if the hospital does not use the slots for Medicare purposes (but only for purposes of the CHGME Payment Program) as would be evidenced by not filing a Worksheet E-3, Part IV.

Comment: Several commenters requested that we exempt all children's hospitals or hospitals filing a low

utilization Medicare cost report, or both, from possible reductions to FTE resident caps under section 422 of Public Law 108–173. The commenters pointed out that Medicare-participating children’s hospitals primarily serve a non-Medicare population and may choose (with approval from their fiscal intermediary) to submit low utilization (abbreviated) cost reports. They added that, although not a required part of a low utilization Medicare cost report, some children’s hospitals may have filed Worksheet E–3, Part IV with the cost report. The commenters indicated that Worksheet E–3, Part IV details the hospital’s FTE resident count and FTE resident cap for direct GME purposes and that CMS proposed to apply the provisions of section 1886(h)(7)(A) of the Act if the low utilization filer had filed Worksheet E–3, Part IV for the reference cost reporting period. The commenters believed it would be unfair to distinguish between low utilization filers based on the inclusion of Worksheet E–3, Part IV and, therefore, possibly make reductions to the FTE resident cap for some low utilization filers and not for others. They requested that we deem submission of Worksheet E–3, Part IV to be irrelevant to whether FTE reductions apply to any low utilization filers. Another commenter requested that we not apply FTE resident cap reductions to children’s hospitals that submitted low utilization reports in the 1996 base year.

Response: We believe the commenters have taken the policy regarding low utilization filers out of context. Low utilization cost reports may be filed with or without Worksheet E–3, Part IV. The proposed rule does not exempt any of these low utilization filers from the provisions of section 422. Rather, as we stated in the May 18, 2004 proposed rule (69 FR 28308), “if a children’s hospital filed a low utilization cost report in its most recent cost reporting period ending on or before September 30, 2002, and did not file the Worksheet

E–3, Part IV, there could be no reduction under section 1886(h)(7)(A) of the Act *because there is no reference resident level for such a hospital.*” (Emphasis added.) Our policy focuses on the existence of a reference resident level rather than if the hospital is filing a low utilization cost report. Therefore, as we stated in the proposed rule, section 1886(h)(7)(A) of the Act does not apply to children’s hospitals that filed a low utilization cost report *and* did not file Worksheet E–3, Part IV because, for these hospitals, no reference FTE resident count exists. Furthermore, we do not have the authority to exempt hospitals from possible reductions under section 422. The only hospitals that are exempted by statute are rural hospitals with fewer than 250 beds, as explicitly mandated by section 1886(h)(7)(A)(i)(II) of the Act. Therefore, we do not have the authority to exempt children’s hospitals that file a low utilization cost report either in the reference year or in the 1996 base year.

Comment: One commenter noted that children’s hospitals that file low utilization cost reports may not have filed Worksheet E–3, Part IV and, therefore, may not have the prior and penultimate years’ FTE resident counts necessary to calculate the rolling average FTE resident count after receiving an increase in FTE resident caps in accordance with section 422 of Public Law 108–173. The commenter proposed that if a children’s hospital has not filed Worksheet E–3, Part IV with its low utilization cost reports, the hospital include supporting documentation, such as the prior periods’ Form HRSA–99 forms with the request for an increase in its FTE resident cap, for the purposes of computing the rolling average.

Response: We agree with the commenter that a children’s hospital that files low utilization cost reports without Worksheet E–3, Part IV must supply whatever supporting documentation as may be deemed

necessary to the financial intermediary in order to calculate a 3-year rolling average FTE resident count. However, we note, that as explained earlier in this final rule, we excluded any FTE resident cap increases that a hospital may receive as a result of section 422 (the section 422 cap) from the rolling average determination. Therefore, the process of collecting documentation necessary for calculating a rolling average would only apply to calculation of the number of residents at the hospital that are subject to a hospital’s 1996 FTE resident cap, not to FTE residents counted for purposes of the section 422 cap.

Comment: One commenter requested that CMS emphasize that the redistribution of FTE resident cap slots under section 1886(h)(7)(A) of the Act applies only to the Medicare program. The commenter pointed out that many children’s hospitals qualify for annual grants under the federal Children’s Hospitals GME (CHGME) Payment Program, which is administered by the Health Resources and Services Administration (HRSA). The commenter added that, by statute, HRSA determines the FTE resident counts for CHGME payment purposes based on Medicare rules regarding counting FTE residents (42 U.S.C 256e(c)(1)(B)). The commenter believed it would be inappropriate for HRSA to enact any provisions of Public Law 108–173 that would result in reductions (or increases) to children’s hospital’s FTE resident cap and requested that CMS clearly explain that section 1886(h)(7) of the Act applies only to the Medicare program.

Response: While we appreciate the commenter’s concerns regarding the effects of section 422 of Public Law 108–173 on the CHGME Payment Program, we have no authority to limit HRSA’s use of CMS’ determinations. All comments on CHGME should be directed to HRSA.

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m. CMS Evaluation Form

CMS Evaluation Form
As Part of the Application for the Increase in a Hospital's FTE Cap(s)
under Section 422 of the Medicare Modernization Act of 2003

Directions: Please fill out the information below for each residency program for which the applicant hospital intends to use the increase in its FTE cap(s). The applicant hospital is responsible for complying with the other requirements listed in the FY 2005 hospital inpatient prospective payment system rule in order to complete its application for the increase in its FTE cap(s) under section 422 of Public Law 108-173.

NAME OF HOSPITAL: _____

MEDICARE PROVIDER NUMBER: _____

NAME OF SPECIALTY TRAINING PROGRAM: _____

(Check one): Allopathic Program Osteopathic Program

NUMBER OF FTE SLOTS REQUESTED FOR PROGRAM:

Direct GME: _____ **IME:** _____

Section A: Demonstrated Likelihood of Filling the FTE Slots

(Place an "X" in the box for the applicable criterion and subcriteria.)

A1: Demonstrated Likelihood Criterion 1. The hospital intends to use the additional FTEs to establish a new residency program (listed above) on or after July 1, 2005 (that is, a newly approved program that begins training residents at any point within the hospital's first three cost reporting periods beginning on or after July 1, 2005).

(1) Hospital will establish this newly approved residency program. **(Check at least one of the following, if applicable.)**

Application for approval of the new residency program has been submitted to the ACGME, AOA or the ABMS by December 1, 2004. **(Copy attached.)**

- The hospital has submitted an institutional review document or program information form concerning the new program in an application for approval of the new program by December 1, 2004. **(Copy attached.)**

- The hospital has received written correspondence from the ACGME, AOA or ABMS acknowledging receipt of the application for the new program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit). **(Copy attached.)**

- (2) Hospital will likely fill the slots requested. **(Check at least one of the following, if applicable.)**
 - The hospital's existing residency programs had a resident fill rate of at least 85 percent in each of program years 2001 through 2003. **(Documentation attached.)**

 - The specialty program (listed above) has a resident fill rate either nationally, within the State, or within the MSA in which the hospital is located, of at least 85 percent. **(Documentation attached.)**

- A2: Demonstrated Likelihood Criterion 2. The applying hospital intends to use the additional FTEs to expand the existing residency training program that is listed above (that is, to increase the number of FTE resident slots in the program) on or after July 1, 2005, and before July 1, 2008.
 - (1) Hospital intends to expand an existing program. **(Check at least one of the following, if applicable.)**
 - The appropriate accrediting body (the ACGME, AOA or ABMS) has approved the hospital's expansion of the number of FTE residents in the program. **(Documentation attached.)**

 - The American Osteopathic Association Residency Match Program has accepted or will be accepting the hospital's participation in the match for the existing program that will include additional resident slots in that residency training program. **(Documentation attached.)**

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- The hospital has submitted an institutional review document or program information form for the expansion of the existing residency training program by December 1, 2004. **(Copy attached.)**
- (2) Hospital will likely fill the slots of the expanded residency program. **(Check at least one of the following, if applicable.)**
- Hospital has other previously established residency programs, with a resident fill rate of at least 85 percent in each of program years 2001 through 2003.) **(Documentation attached.)**
- Hospital is expanding an existing program in a particular specialty with a resident fill rate either nationally, within the State, or within the MSA in which the hospital is located, of at least 85 percent. **(Documentation attached.)**
- Hospital is expanding a program in order to train residents that need a program because another hospital in the State has closed a similar program, and the applying hospital received a temporary adjustment to its FTE cap(s) (under the requirements of §413.79(h)). **(Documentation attached.)**
- A3: Demonstrated Likelihood Criterion 3. Hospital is applying for an increase in its FTE resident cap because the hospital is already training residents in an existing residency training program(s) in excess of its direct GME FTE cap or IME FTE cap, or both. **(Copies of EACH of the following attached.)**
- Copies of the most recent as-submitted Medicare cost reports documenting on Worksheet E, Part A and Worksheet E3, Part IV the resident counts and FTE resident caps for both direct GME and IME for the relevant cost reporting periods.
 - Copies of the 2004 residency match information concerning the number of residents at the hospital in its existing programs.

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- Copies of the most recent accreditation letters on all of the hospital's training programs in which the hospital trains and counts FTE residents for direct GME and IME.

Section B. Level Priority Category

(Place an "X" in the appropriate box that is applicable to the level priority category that describes the applicant hospital.)

- B1: First Level Priority Category: The hospital is a rural hospital as of October 1, 2004 and has the only specialty training program in the State (for the program requested on this CMS Evaluation Form).
- B2: Second Level Priority Category: The hospital is a rural hospital as of October 1, 2004 only.
- B3: Third Level Priority Category: The hospital is in an other than large urban area, as of October 1, 2004, and the request is for only specialty program in the State (for the program requested on this CMS Evaluation Form).
- B4: Fourth Level Priority Category: The hospital is in an other than large urban area, hospital, as of October 1, 2004.
- B5: Fifth Level Priority Category: The hospital request is for the only specialty training program in the State (for the program requested on this CMS Evaluation Form).
- B6: Sixth Level Priority Category: The hospital meets none of the statutory priority criteria.

Section C. Evaluation Criteria

(Place an "X" in the box for each criterion that is appropriate for the applicant hospital and for the program for which the increase in the FTE cap is requested.)

- C1: Evaluation Criterion One. The hospital that is requesting the increase in its FTE resident cap(s) has a Medicare inpatient utilization over 60 percent, as reflected in at least two of the hospital's last three most recent audited cost reporting periods for which there is a settled cost report.
- C2: Evaluation Criterion Two. The hospital needs the additional slots to establish a new geriatrics residency program, or to add residents to an existing geriatrics program.

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- C3: Evaluation Criterion Three. The hospital does not qualify for an adjustment to its FTE caps under existing §413.86(g)(12) for a rural track residency program, but is applying for an increase in its FTE resident cap(s) under section 1886(h)(7)(B) of the Act because it rotates (or in the case of a new program, will rotate) residents for at least 25 percent of the duration of the residency program to any one (or in combination thereof) of the following: a rural area, as defined in section 1886(d)(2)(D)(ii) of the Act and §412.62(f)(1)(iii) of the regulations; a rural health clinic (RHC), as defined in section 1861(aa)(1) of the Act and §491.2 of the regulations; or a Federally Qualified Health Center (FQHC), as defined in section 1861(a)(3) of the Act and §405.2401(b) of the regulations.
- C4: Evaluation Criterion Four. In portions of cost reporting periods prior to July 1, 2005, the hospital qualified for a temporary adjustment to its FTE cap under existing §413.86(g)(9) because it was training displaced residents from either a closed program or a closed hospital, and, even after the temporary adjustment, the hospital continues to train residents in the specialty(ies) of the displaced residents and is above the hospital's direct GME FTE cap or IME FTE cap, or both, for that reason.
- C5: Evaluation Criterion Five. The hospital is above its FTE caps because it was awaiting accreditation of a new program from the ACGME or the AOA during the base period for its FTE cap(s) but was not eligible to receive a new program adjustment as stated under existing §413.86(g)(6)(ii).
- C6: Evaluation Criterion Six. The hospital is above its FTE resident caps because, despite qualifying for an FTE cap adjustment for a new program under §413.86(g)(6)(i) or (g)(6)(ii), it was unable to "grow" its program to the full complement of residents for which the program was accredited before the hospital's FTE resident cap was permanently set beginning with the fourth program year of the new program.
- C7: Evaluation Criterion Seven. The hospital is located in any one (or in combination thereof) of the following: a geographic HPSA, as defined in 42 CFR 5.2; a population HPSA, (also defined at 42 CFR 5.2); or a Medicare physician scarcity county, as defined under section 413 of Public Law 108-173.

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- C8: Evaluation Criterion Eight. The hospital is in a rural area (as defined under section 1886(d)(2)(D)(ii) of the Act) and is a training site for a rural track residency program (as specified under §413.86(g)(12), but is unable to count all of the FTE residents training at the rural hospital in the rural track because the rural hospital's FTE cap is lower than the hospital's unweighted count of allopathic or osteopathic FTE residents beginning with portions of cost reporting periods on or after July 1, 2005.

- C9: Evaluation Criterion Nine. The hospital is affiliated with a historically Black medical college.

- C10: Evaluation Criterion Ten: The hospital is training residents in residency program(s) sponsored by a medical school(s) that is designated as a Center of Excellence for Underserved Minorities (COE) under section 736 of the Public Health Service Act in FY 2003.

- C11: Evaluation Criterion Eleven: The hospital needs the additional slots to establish a new primary care residency program, or to expand an existing primary care residency program, as primary care is defined under 413.75(b).

- C12: Evaluation Criterion Twelve: The hospital is above its direct GME and/or IME FTE cap on the count of residents, as stated in the Medicare cost report on the worksheets E, part A or the worksheets E3, part IV, in the hospital's most recently as submitted Medicare Cost Report.

- C13: Evaluation Criterion Thirteen: The hospital's FTE resident cap was reduced under section 1886(h)(7)(A)(i) of the Act because the resident level in its reference cost report equaled or was above its FTE resident cap as it knew its FTE resident cap to be at that time, but as a result of a resolution to an appeal concerning the FTE resident cap, the FTE resident cap was later increased to an amount that is greater than the reference resident level.

- C14: Evaluation Criterion Fourteen: The hospital is above its cap and needs the additional slots to establish a new emergency medicine residency program or expand an existing emergency medicine residency program. The emergency medicine residency program includes training in bio-terrorism preparedness.

- C15: Evaluation Criterion Fifteen: The hospital's FTE resident cap was reduced under section 1886(h)(7)(A)(i) and:
 - The hospital started a new program(s) that was accredited before January 1, 2002;
 - The new program was in operation during the reference cost reporting period; and
 - The program has been in operation (training residents) for three or fewer years by July 1, 2003.

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n. Application Process and CMS Central Office and Regional Office Mailing Addresses for Receiving Increases in FTE Resident Caps

In order for hospitals to be considered for increases in their FTE resident caps, each qualifying hospital must submit a timely application. The following information must be submitted on applications to receive an increase in FTE resident caps:

- The name and Medicare provider number of the hospital.
- The total number of requested FTE resident slots for direct GME or IME, or both, up to 25 direct GME FTE and 25 IME FTE per hospital.
- A completed copy of the CMS Evaluation Form for each residency program for which the hospital intends to use the requested increase in FTE residents. This form can be found at: <http://www.cms.hhs.gov/forms/>.
- Source documentation to support the assertions made by the hospital on the CMS Evaluation Form. For example: if the hospital indicates on the Evaluation Form that it is located in a Geographic Health Professions Shortage Area (HPSA), the hospital would include documentation to support that assertion.
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report.
- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following information:

"I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents."

The completed application and supporting documentation (as described

above) must be submitted to the CMS Central Office and the CMS Regional Office for the region in which the applicant hospital is located. The application must be received on or before December 1, 2004. The addresses of the CMS central office and regional offices are listed below.

We note that some hospitals' FTE counts will be subject to audit for the purposes of section 1886(h)(7)(A) of the Act and those audits may not be completed by December 1, 2004. Because the results of such an audit may be a factor in a hospital's decision whether to request an increase in its FTE resident cap, we will allow a later date for those hospitals to apply for increases in their FTE resident caps. Therefore, if a hospital's resident level is audited for the purposes of section 1886(h)(7)(A) of the Act, and that hospital also wishes to apply for an increase in its FTE resident cap(s), that hospital must submit a completed application to CMS that is received on or before March 1, 2005.

CMS Central and CMS Regional Office Mailing Addresses for Applications for Increases in FTE Resident Caps:

Central Office: Centers for Medicare and Medicaid Services (CMS), Director, Division of Acute Care, 7500 Security Boulevard, Mail Stop C4-08-06, Baltimore, Maryland 21244.

Region I (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont): Centers for Medicare and Medicaid Services (CMS), Associate Regional Administrator, Division of Medicare Financial Management, Region I, JFK Federal Building, Room 2325, Boston, MA 02203, Phone: (617) 565-1185.

Region II (New York, New Jersey, U.S. Virgin Islands, and Puerto Rico): Centers for Medicare and Medicaid Services (CMS), Associate Regional Administrator, Division of Medicare Financial Management, Region II, 26 Federal Plaza, 38th Floor, New York, NY 10278, Phone: (212) 264-3657.

Region III (Delaware, Maryland, Pennsylvania, Virginia and West Virginia, and the District of Columbia): Centers for Medicare and Medicaid Services (CMS), Associate Regional Administrator, Division of Medicare Financial Management, Region III, Public Ledger Building, Suite 216, 150 South Independence Mall West, Philadelphia, PA 19106, Phone: (215) 861-4140.

Region IV (Alabama, North Carolina, South Carolina, Florida, Georgia, Kentucky, Mississippi, and Tennessee): Centers for Medicare and Medicaid Services (CMS), Associate Regional Administrator, Division of Medicare

Financial Management, Region IV, Atlanta Federal Center, 61 Forsyth Street, SW., Suite 4T20, Atlanta, GA 30303-8909, Phone: (404) 562-7500.

Region V (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin): Centers for Medicare and Medicaid Services (CMS), Associate Regional Administrator, Division of Medicare Financial Management, Region V, 233 North Michigan Avenue, Suite 600, Chicago, IL 60601, Phone: (312) 886-6432.

Region VI (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas): Centers for Medicare and Medicaid Services (CMS), Associate Regional Administrator, Division of Medicare Financial Management, Region VI, 1301 Young Street, Suite 714, Dallas, TX 75202, Phone: (214) 767-6423.

Region VII (Iowa, Kansas, Missouri, and Nebraska): Centers for Medicare and Medicaid Services (CMS), Associate Regional Administrator, Division of Medicare Financial Management, Region VII, Richard Bolling Federal Building, Room 235, 601 East 12th Street, Kansas City, MO 64106.

Region VIII (Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming): Centers for Medicare and Medicaid Services (CMS), Associate Regional Administrator, Division of Medicare Financial Management, Region VIII, Colorado State Bank Building, 1600 Broadway, Suite 700, Denver, CO 80202, Phone: (303) 844-2111.

Region IX (Arizona, California, Hawaii, and Nevada and Territories of American Samoa, Guam and the Commonwealth of the Northern Mariana Islands): Centers for Medicare and Medicaid Services (CMS), Associate Regional Administrator, Division of Medicare Financial Management, Region IX, 75 Hawthorne St., Suite 408, San Francisco, CA 94105, Phone: (415) 744-3501.

Region X (Alaska, Idaho, Oregon, and Washington): Centers for Medicare and Medicaid Services (CMS), Associate Regional Administrator, Division of Medicare Financial Management, Region X, 2201 Sixth Avenue, MS-40, Seattle, WA 98121, Phone: (206) 615-2306.

3. Direct GME Initial Residency Period (New § 413.79, a Redesignation of Existing § 413.86(g))

a. Background

As we have generally described above, the amount of direct GME payment to a hospital is based in part on the number of FTE residents who are training at the hospital during a year.

The number of FTE residents training at a hospital, and thus the amount of direct GME payment to a hospital, is directly affected by CMS policy on how "initial residency periods" are determined for residents.

Section 1886(h)(5)(A) of the Act defines "approved medical residency training program" as "a residency or other postgraduate medical training program, participation in which may be counted toward certification in a specialty or subspecialty." This provision is implemented in regulations at existing § 413.86(b). In accordance with section 1886(h)(5)(I) of the Act, the term "resident" is defined to include "an intern or other participant in an approved medical residency training program." Existing § 413.86(b) defines "resident" as an "intern, resident, or fellow who participates in an approved medical residency training program * * * as required in order to become certified by the appropriate specialty board."

Section 1886(h)(4)(C)(ii) of the Act provides that while a resident is in the "initial residency period," the resident is weighted at 1.00 (existing § 413.86(g)(2) of the regulations). Section 1886(h)(4)(C)(iii) of the Act requires that if a resident is "not in the resident's initial residency period," the resident is weighted as .50 FTE resident (existing § 413.86(g)(3) of the regulations).

Section 1886(h)(5)(F) of the Act defines "initial residency period" as the "period of board eligibility," and, subject to specific exceptions, limits the initial residency period to an "aggregate period of formal training" of no more than 5 years for any individual. Section 1886(h)(5)(G) of the Act generally defines "period of board eligibility" for a resident as "the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training." Existing § 413.86(g)(1) of the regulations generally defines "initial residency period" as the "minimum number of years required for board eligibility." Existing § 413.86(g)(1)(iv) provides that "time spent in residency programs that do not lead to certification in a specialty or subspecialty, but that otherwise meet the definition of approved programs * * * is counted toward the initial residency period limitation." Section 1886(h)(5)(F) of the Act further provides that "the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program."

The initial residency period is determined as of the time the resident

enters the "initial" or first residency training program and is based on the period of board eligibility associated with that medical specialty. Thus, this provision limits the amount of direct GME that Medicare pays a hospital for a resident who switches specialties to a program with a longer period of board eligibility or completes training in a specialty and then continues training in a subspecialty (for example, cardiology and gastroenterology are subspecialties of internal medicine).

b. Direct GME Initial Residency Period Limitation: Simultaneous Match Issue

We understand there are numerous programs, including anesthesiology, dermatology, psychiatry, and radiology, that require a year of generalized clinical training to be used as a prerequisite for the subsequent training in the particular specialty. For example, in order to become board eligible in anesthesiology, a resident must first complete a generalized training year and then complete 3 years of training in anesthesiology. This first year of generalized residency training is commonly known as the "clinical base year." Commonly, the clinical base year requirement is fulfilled by completing either a preliminary year in internal medicine (although the preliminary year can also be in other specialties such as general surgery or family practice), or a transitional year program (which is not associated with any particular medical specialty).

In many cases, during the final year of medical school, medical students apply for training in specialty programs. Typically, a medical student who wants to train to become a specialist is "matched" to both the clinical base year program and the residency training specialty program at the same time. For example, the medical student who wants to become an anesthesiologist will apply and "match" simultaneously for a clinical base year in an internal medicine program for year 1 and for an anesthesiology training program in years 2, 3, and 4.

Based on our interpretation of the statute, our policy is that the initial residency period is determined for a resident based on the program in which he or she participates in the resident's first year of training, without regard to the specialty in which the resident ultimately seeks board certification. Therefore, for example, a resident that chooses to fulfill the clinical base year requirement for an anesthesiology program with a preliminary year in an internal medicine program will be "labeled" with the initial residency period associated with internal

medicine, or 3 years (3 years of training are required to become board eligible in internal medicine), even though the resident may seek board certification in anesthesiology, which requires a minimum of 4 years of training to become board eligible. As a result, this resident would be weighted at 0.5 FTE in his or her fourth year of training for purposes of direct GME payment.

We understand that some hospitals have been assigning residents that complete a clinical base year in a different specialty from the one in which they ultimately train an initial residency period and a weighting factor based on the specialty associated with second program year in which the residents train. As a result, some residents have been assigned a weighting factor of 1.0 FTE for years beyond their initial residency periods, rather than the applicable 0.5 FTE weighting factor. This error results in Medicare overpayments, the size of which is dependent upon the hospital's direct GME PRA and its Medicare utilization. In addition, we have received numerous requests from the health care industry to revise our policy concerning the initial residency period for residency programs that require a clinical base year because some entities in the industry believe that our current policy is unfair to those individuals who "match" simultaneously for both a preliminary year (for example, the clinical base year in internal medicine) and the longer specialty residency program (for example, anesthesiology, dermatology, or radiology).

To address these concerns, in the May 18, 2004 proposed rule (69 FR 28311), we indicated that we were considering making a change in policy that addresses these "simultaneous match" residents. Specifically, we were considering a policy that, if a hospital can document that a particular resident matches simultaneously for a first year of training in a clinical base year in one medical specialty, and for additional year(s) of training in a different specialty program, the resident's initial residency period would be based on the period of board eligibility associated with the specialty program in which the resident matches for the subsequent year(s) of training and not on the period of board eligibility associated with the clinical base year program, for purposes of direct GME payment. In addition, we considered a new definition of "residency match" to mean, for purposes of direct GME, a national process by which applicants to approved medical residency programs are paired with programs on the basis of

preferences expressed by both the applicants and the program directors.

This policy could apply regardless of whether the resident completes the first year of training in a separately accredited transitional year program or in a preliminary (or first) year in another residency training program such as internal medicine.

Under this policy, hospitals would apply a weight of 1.0 FTE (instead of 0.5) for an additional year or two to some residents who, as a prerequisite for training in a specialty program, complete a first year of training in a different specialty program. This would probably cause an increase in direct GME payments. This provision would apply to such programs as anesthesiology, dermatology, radiology, and physical medicine and rehabilitation. In 2004, there were approximately 1,840 residents in these specialties that would be affected by this proposal, as compared to the approximately 83,000 residents in total for whom Medicare makes direct GME payments. Under current policy, these 1,840 residents would be weighted at 0.5 FTE in their 4th year (and 5th year, if applicable) of training. Therefore, direct GME spending for these 1,840 residents should currently be \$26.5 million ($1,840 \times 0.5 \times 82,249^9 \times .35^{10}$). We indicated in the proposed rule that, under the policy we are considering, direct GME spending would be twice that amount at \$53 million ($1,840 \times \$82,249 \times .35$). However, because we believe a number of fiscal intermediaries may have been applying current policy incorrectly and instead have been weighting approximately 920 residents at 1.0 in their 4th year (and 5th year, if applicable) of training, the cost of this change would be expected to be closer to \$13.25 million ($920 \times 0.5 \times \$82,249 \times .35$). We provided this cost impact analysis to the public for its information in consideration of any such proposed change.

We note that in the Conference Committee report that accompanied Public Law 108–173, the Committee stated that “The conferees also clarify that under section 1886(h)(5)(F) of the Act, the initial residency period for any residency for which the ACGME requires a preliminary or general clinical year of training is to be determined in the resident’s second year of training.” (Conference Committee Agreement Accompanying Public Law 108–173, 108 Cong., 2d Sess., 276

(2003)) The Conference Committee included this language as part of its explanation of section 712 of Public Law 108–173, which clarifies an exception to the initial residency period for geriatric fellowship programs (see section IV.O.3.c. of this preamble). We indicated in the proposed rule that we were considering making a policy change for determining the initial residency period for a resident who participates in a clinical base year program based on the resident’s second year of training, as the Conference Committee suggests. However, we understand that not all residents who participate in the clinical base year programs simultaneously match in specialty training programs before the residents’ first year of training. Thus, if we were to propose a “second year” policy, there would be no way to distinguish in the second year of training among those residents who simultaneously matched in a specialty program prior to their first year of training; those residents who did not match simultaneously, but participated in a clinical base year and then continued on to train in a different specialty; and those residents who simply switched specialties in their second year. As we have stated earlier, the initial residency period is to be determined based on the “initial” or first program in which a resident trains. Section 1886(h)(5)(F) of the Act provides that “the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program.” (Emphasis added.)

Therefore, we indicated in the proposed rule that we believe it is appropriate for us to consider changes to the “simultaneous match” policy that would allow for documentation that the residents’ training program is arranged to continue in another medical specialty after the resident completes the clinical base year. However, we also specifically solicited comments concerning the issue of how to establish the initial residency period for a resident who does not match simultaneously for the first and second year, completes the first year in a preliminary program in one specialty, and then continues his or her training in a different specialty program that requires completion of a clinical base year.

In the proposed rule, we note that if we were to propose this change in the initial residency period policy, the change, if finalized, could result in an adjustment to the PRA applicable for the direct GME payments made to the hospital for a resident in a clinical base year. By treating the first year as part of

a nonprimary care specialty program (for example, anesthesiology), the hospital would be paid at the lower nonprimary care PRA rather than the higher primary care PRA, which would be used for residents training in a clinical base year in a primary care program (for example, internal medicine). We noted in conjunction with our proposal that the initial residency period would be established based upon the period of board eligibility for the specialty program for residents who simultaneously match with a clinical base year and a specialty program that we believe all of the programs that require a clinical base year are nonprimary care specialties. Because we were considering a policy change that the initial residency period would be based upon the period of board eligibility for the specialty program rather than the clinical base year, we indicated that we would also consider a policy change that the nonprimary care PRA would apply for the duration of their initial residency period.

Thus, as we indicated in the proposed rule, we are considering making the above policy changes to address the clinical base year initial residency period issue. We specifically solicited comments on the changes we were considering to the existing initial residency period policy and other approaches to address this issue, particularly those that do not increase Medicare expenditures.

Comment: We received many comments commending CMS for the proposed policy discussion concerning residency training in specialties that require a clinical base year. One commenter stated that “we agree that, for purposes of direct GME payment, a resident’s initial residency period should be based on the period of board eligibility associated with the specialty program in which the resident matches for the subsequent year(s) of training and not on the period of board eligibility associated with the clinical base year program.”

However, many commenters believed that instead of a “simultaneous match” policy, CMS should adopt as final the policy stated in the Conference Committee report that accompanied Public Law 108–173, in which the conferees clarified that the initial residency period for any residency “for which ACGME requires a preliminary or general clinical year of training is to be determined in the resident’s second year of training.” (Conference Committee Agreement Accompanying Public Law 108–173, 108 Cong., 2d Sess., 276 (2003)). Many commenters further

⁹ \$82,249 is the estimated national average per resident amount for FY 2005.

¹⁰ .35 is the estimated average Medicare utilization.

stated that “CMS should make a clear statement that for a resident whose first year of training is completed in a program that provides a general clinical base year as required by the ACGME for certain specialties, an IRP should be assigned in the second year based on the specialty the resident enters in the second year of training.” The commenters believed that not having a “second year” policy for determining the IRP for those residents that must complete a clinical base year “violates the statute, does not reflect congressional intent, and results in inequitable payments to teaching hospitals for residents training in certain specialties.”

Response: We appreciate the comments that compliment our proposal to clarify the direct GME policy on determining the IRP for residents that complete a clinical base year of training and simultaneous match in the clinical base year program and the specialty training program. We understand the provider community’s enthusiasm for a “second year” policy for determining the IRP for residents who must complete a clinical base year. However, as we have stated above and also in the proposed rule, we believe that if we were to propose a “second year” policy, there would be no way to distinguish among those residents in their second year of training who simultaneously match in a specialty program prior to their first year of training; those residents who participated in a clinical base year and then continued on in a specialty; and those residents who simply switched specialties in their second year. We believe that the proposed simultaneous match policy is more consistent with congressional intent, as stated in the statute. As we discussed above, and also in the proposed rule, we believe the statute requires that the initial residency period be determined based on the “initial” or first program in which a resident trains. Section 1886 (h)(5)(F) of the Act provides that “the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program.” (Emphasis added.) Thus, we believe that our proposed “simultaneous match” policy will allow for auditable documentation of the residents’ intent upon entering the clinical base year and is therefore appropriate.

We stated in the proposed rule that we believe “it is appropriate for us to consider changes to the ‘simultaneous match’ policy that would allow for documentation that the residents’ training program is arranged to continue

in another medical specialty after the resident completes the clinical base year” (69 FR 28312). We have not heard from the public on how a “second year” policy could be documented at the time the resident enters the residency program (that is, the clinical base year), so that we may distinguish between residents who fully intend to complete a different medical specialty at the start of the clinical base year and other residents who complete a clinical base year. We recognize that there may be some disparity in counting residents for direct GME who simultaneously match in a clinical base year and a different specialty, and those residents who complete a clinical base year and then go on to a different specialty program. However, we believe the policy we proposed will be effective in correcting the problem of many of the residents who are “caught” by our IRP policies. Therefore, we believe it is appropriate to finalize the simultaneous match policy to state at § 413.79(a): “effective October 1, 2004, if a hospital can document that a particular resident matches simultaneously for a first year of training in a clinical base year, and for a second year of training in the specialty program in which the resident intends to seek board certification, the resident’s initial residency period would be based on the specific specialty program for the subsequent year(s) of training in which the resident matches and not on the clinical base year program.”

Comment: Similar to the comments above, one commenter stated that it did not believe the statute requires CMS to determine the IRP for residents who must complete a clinical base year of training in the first year of the resident’s first year of training, and advocated a second year IRP policy for such residents. The commenter noted that CMS’s policy allowing the initial residency period to be determined in the second year for residents training in transitional year programs “is clear evidence that such a timeframe is permissible under the statute.”

Response: As stated above, we believe that our proposed simultaneous match policy is the more appropriate policy to finalize than a second year policy for residents training in a clinical base year. The statute requires that the initial residency period be determined based on the “initial” or first program in which a resident trains. Section 1886 (h)(5)(F) of the Act provides that “the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program.” (Emphasis added.) The simultaneous match policy will allow for hospitals to document the

residents’ intent upon entering the clinical base year, as the statute requires.

As we mentioned above and also in the proposed rule, the clinical base year requirement can be fulfilled by residents that train in preliminary medicine, which is the first year of an internal medicine residency, or transitional years programs, which are unaffiliated with a particular specialty. For a resident that matches in a transitional year program and simultaneously matches in a specialty training program, Medicare will use the specialty training program to determine that resident’s IRP. In the limited circumstance where a resident trains in the transitional year program, without simultaneously matching in a specialty program, Medicare is simply unable to determine what specialty the resident has “entered” for purposes of determining that resident’s IRP. The earliest moment that Medicare is able to determine such a resident’s IRP is when the resident “enters” the specialty program—the resident’s second year of training. Thus, in the limited circumstance of a resident that trains in a transitional year program that is unaffiliated with a particular specialty and does not simultaneously match in a specialty program, Medicare will look to the resident’s second year of training as when the resident has “entered” the residency program for purposes of determining the IRP. We note that this situation of the transitional year program is substantially different from the situation where the resident begins training in a specialty, for example, internal medicine, as the resident’s clinical base year. In the latter case, we are able to establish an initial residency period based on the number of years required for certification in that specialty and have no need to wait until the second year.

Comment: One commenter believed that our proposed definition of “residency match,” a national process by which applicants to approved medical residency programs are paired with programs on the basis of preferences expressed by both the applicants and the program directors, is unclear and ambiguous in regard to residents who are in a required clinical base year training program. The commenter requested clarification from CMS.

Response: We are finalizing a policy with this final rule that states that, effective October 1, 2004, if a hospital can document that a particular resident has matched simultaneously for a first year of training in a clinical base year, and for a second year of training in the

specialty program in which the resident intends to seek board certification, the resident's initial residency period (IRP) will be based on the specific specialty program in which the resident matched for the subsequent year(s) of training, and not based on the clinical base year program, for purposes of direct GME payment. We understand that the term, "residency match" is commonly used by both providers and residents. We are defining "residency match" to mean, for purposes of Medicare direct GME, a national process carried out by the National Residency Matching Program (NRMP), the San Francisco Matching Program, the Urology Matching Program, or the American Osteopathic Association Residency Match Program by which applicants to approved medical residency programs are formally paired with programs on the basis of preferences expressed by both the applicants and the program directors.

Comment: Several commenters noted that they "had no knowledge of any prior CMS policy that is in any way conflicted with the provisions of the legislative history." These commenters state it was "always" their understanding that the IRP was set in the second year for residents that have undertaken a clinical base year during their first year of residency. The commenters also state that the fiscal intermediaries servicing the hospitals have "never expressed disagreement with this policy."

Similarly, another commenter specifically requested that CMS not implement the proposed clarification to apply the possibly shorter initial residency period for the specialty associated with the clinical base year prior to portions of cost reporting periods on or before October 1, 2004.

Finally, another commenter stated that CMS "has never previously issued any formal rule regarding how clinical base year training affects the determination of the initial residency period."

Response: We believe that we have consistently held to our policy concerning the determination of the IRP for residents that complete a clinical base year. We have stated that section 1886(h)(5)(F) of the Act provides that "the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program." (Emphasis added.) Thus, until the effective date of this final rule, our policy has been that, for a resident that completes a clinical base year, the initial residency period for this resident is determined based on the period of board eligibility for the

specialty associated with the first (that is, clinical base year) program. We are prospectively changing this policy in this final rule for those residents that simultaneously match, as explained further in this preamble, effective October 1, 2004.

To address the commenter's point concerning the actions of the fiscal intermediaries on this policy, we are not in a position to specifically respond at this time regarding how some intermediaries may have determined initial residency periods for particular residents. However, we understand that there are many teaching hospitals around the country that have been determining IRPs for residents that complete clinical base years correctly (that is, based on our longstanding policy that has been in effect until this final notice). In this rule, we are responding to comments regarding our proposed policy and prospectively revising our current policy. There are other avenues, outside of this final rule, through which the commenter's concerns regarding our current policy could be appropriately addressed.

Comment: We received several comments on our proposal to apply the non-primary care PRA for the duration of the initial residency period for residents that simultaneously matched in a clinical base year program and a longer specialty program. The commenters believed that there is "nothing in the MMA's legislative history that would indicate that such an adjustment is necessary. Accordingly, it is unclear why any change to this policy would now be required."

Response: We proposed a policy change to determine the initial residency period for residents that simultaneously match for both a clinical base year and a subsequent specialty program based upon the period of board eligibility for the subsequent specialty program, that is, the program in which the resident will seek certification. We believed, and continue to believe, it is appropriate to propose a policy that treats residents consistently in terms of the specialty program in which they are considered to be training. When the specialty program for which the resident simultaneously matches for the second year is a non-primary care specialty, under our policy as revised under this final rule, we would assign the IRP in the resident's first year of training based on the period of board eligibility associated with the non-primary care specialty. Thus, we believe it is consistent to apply the non-primary care PRA for that resident's FTE time, even during the first, clinical base year of

training and we are finalizing this policy at § 413.77(f) of the regulations.

Comment: We received one comment which stated that there are teaching hospitals that have "historically called the first year of training for these complex specialties a "general clinical year," instead of a "transitional year * * *." For this reason, the commenter states the hospitals are "significantly, adversely affected by not being allowed to count the full value of FTEs training in these specialties, when, in fact, there is no difference between a "general clinical year" and a "transitional year." This "penalty for semantics" is illogical, and obviously, unfair."

Another commenter described the general practice residency (GPR) for dentistry. The commenter states that the GPR program should be treated as a transitional year program (like an allopathic program), with the initial residency period for a resident who completes a GPR program determined by the IRP for the program the resident enters next, that is, the specialty program.

Response: In contrast to other comments received, we believe the above commenters are describing a situation where hospitals were aware of our current policy on determining the initial residency period for residents that complete a clinical base year. As we stated above, and also in the proposed rule, we believe there are stand-alone transitional year programs that are separately accredited one-year programs unaffiliated with a particular specialty. There are also other clinical base year programs, which are affiliated with a particular medical specialty and when a resident completes a year of training in that program, that year could be counted toward board certification in that specialty. We do not know the nature of the programs the commenters have labeled as a "general clinical year," and, "general practice residency," therefore, cannot respond to the commenters' specific circumstances. We note that the distinction between a transitional year program, which is not associated with any particular medical specialty, and other clinical base year programs that are associated with a particular specialty and participation in which can be counted toward board certification in that specialty, remains applicable regardless of "semantics" or the "terminology" a hospital uses for its clinical base year programs. Thus, "semantics" or terminology is not the basis on which a fiscal intermediary should determine the initial residency period of a particular resident.

Comment: One commenter argued strongly for the adoption of a "second

year policy” (that is, a policy under which the IRP for all residents would be established based upon the period of board eligibility for the specialty in which the resident trains in the second residency year). The commenter stated that, “CMS proposal suffers from the practical difficulty that determining intent [of the resident] can be difficult. Many times, intent is not communicated in writing, or even orally, and can only be inferred by facts and circumstances * * * [t]he best evidence of a resident’s ‘intent’ is where the resident goes after a clinical base year.”

Response: We agree with the commenter that “intent” of the resident can indeed be difficult for us to determine, which is, in part, why our policy has been based upon the first, or initial, program in which the resident trains, (which can be determined and documented). We disagree with the commenter that “[t]he best evidence of a resident’s intent is where the resident goes after a clinical base year,” because we believe the best evidence of a resident’s intent is the program in which the resident actually trains in the first year of residency. After significant deliberation and reflection on the comments, we also believe documentation that a resident has matched simultaneously for a first year of generalized training and a specialty program that begins thereafter is also sufficient evidence of a resident’s intent to continue training in the specialty program, and not in the specialty associated with the generalized clinical base year. Therefore, we are adopting as our final policy the policy that we solicited for comments in the proposed rule. Specifically, if a hospital can document that a resident matched simultaneously, we will determine the resident’s IRP in the first year based upon the period of board eligibility for the specialty program the resident had “matched” to enter in the second year.

Comment: We received one comment that cited the language in section 1886(h)(5)(F) of the Act: “enters the residency program” (emphasis added by the commenter) as evidence that the statute allows CMS to establish the IRP in the second training year in all cases. The commenter stated that the statutory language “can just as easily be interpreted as referring to entering [the longer, specialty program] as to entering the clinical base year or transitional year.”

Response: With this final rule, we are changing our policy regarding the determination of the IRP for residents that match simultaneously for a clinical base year and subsequent specialty program. Specifically, if hospitals can

document that a resident matched simultaneously, we will determine the resident’s IRP in the first year based upon the period of board eligibility for the specialty program the resident is “matched” to enter in the second year. We do not believe we always wait to establish a resident’s IRP in the second year of training when a resident will have “entered” a residency training program in the first year. Where there is no documentation available in the first year of training to demonstrate that a resident intends to continue training, after completing the first year, in a different medical specialty and, ultimately, to obtain board certification in that specialty, we continue to believe it is appropriate to assign the IRP based on the specialty associated with the first year of residency training.

Comment: We received one comment that noted that the proposed rule did not include an implementation date.

Response: We are stating in this final rule that the implementation date for the policy change regarding the initial residency period for “simultaneous match” residents is for portions of cost reporting periods occurring on or after October 1, 2004.

Comment: One commenter implied that CMS should not consider the costs of the proposed IRP policy as estimated by CMS in the proposed rule in determining whether the proposal should be finalized, since CMS did not account for all of the factors that may serve to offset some of the costs of the proposed IRP policy. For instance, the commenter said that CMS did not take into account the savings resulting from the proposal to require that the non-primary care PRA be applied by hospitals to residents training in their clinical base year and for the duration of their training in that specialty. The commenter added that savings could result from the application of the possible “simultaneous match” policy to residents who begin their training in a specialty such as surgery, which requires a minimum of five years for board eligibility, and subsequently pursue training in a specialty that requires four years of training for board eligibility, since these residents would actually see a decrease in the number of years in which they would be weighted at 1.0 FTE under the proposed policy. The commenter also recommended that, rather than comparing the present costs of direct GME payments to the projected costs subsequent to implementation of the policy, CMS should compare the projected costs of not implementing the policy against the projected costs resulting from implementation. The commenter believed that the

incremental difference between implementation and non-implementation of the proposed policy is likely far smaller than estimated in the proposed rule since, even if CMS were not to implement the policy under consideration, hospitals would now be aware of the current policy, which would lead to an increase in positions in transitional year programs.

Response: We acknowledge the points raised by the commenter, but note that the commenter’s concerns are moot since, as explained in response to previous comments, we have decided to adopt the “simultaneous match” policy as final in this final rule.

c. Exception to Initial Residency Period for Geriatric Residency or Fellowship Programs (Section 712 of Pub. L. 108–173 and Redesignated § 413.79(a) (a Redesignation of Existing § 413.86(g)(1))

As explained further below, under Medicare direct GME payment rules, the initial residency period is generally defined as the minimum number of years of training required for a resident to become board eligible in a specialty (not to exceed 5 years) and is established at the time the resident enters his or her first training program. For purposes of direct GME payments, a resident’s full-time equivalent (FTE) training time is weighted at 1.0 during the initial residency period and 0.5 for training that continues beyond the initial residency period. Section 1886(h)(5)(F) of the Act generally limits a resident’s initial residency period to no longer than 5 years. That section also provides an exception that allows FTE training time spent by residents in an approved geriatric residency program to be treated as part of the resident’s initial residency period, that is, weighted at 1.0 FTE for up to an additional 2 years after conclusion of the otherwise applicable initial residency period.

We understand, based on information provided by the American Geriatric Society (AGS), that in 1998, the American Board of Internal Medicine and the American Board of Family Physicians (hereinafter “the Boards”) reduced the minimum number of years of formal training required for residents to become board eligible in geriatrics from 2 years to 1 year. As a result, the initial residency period, and full direct GME funding for residents in geriatric training programs, would be limited to 1 year.

However, we understand that many teaching hospitals continue to run geriatric residency or fellowship programs of at least 2 years in length (some are even 3 years). We also understand that, despite the decrease in

the minimum requirements for board eligibility, the Accreditation Council for Graduate Medicare Education (ACGME) continues to accredit some geriatric training programs for the full duration of the fellowships. For example, if a hospital's geriatric fellowship is 3 years in length, the program may continue to be accredited by the ACGME for the full 3 years, but the FTE time spent by a resident training in the geriatric program would be weighted at 1.0 for the first year of the resident's training and at 0.50 for the second and third year of the fellowship. (However, we note that FTE residents' time is not weighted for purposes of IME payments.)

Effective October 1, 2003, section 712 (a) of Public Law 108-173 clarified that Congress intended to provide an exception to the initial residency period for purposes of direct GME payments for geriatric residency or fellowship programs such that "where a particular approved geriatric training program requires a resident to complete 2 years of training to initially become board eligible in the geriatric specialty, the 2 years spent in the geriatric training program are treated as part of the resident's initial residency period, but are not counted against any limitation on the initial residency period." Therefore, in the May 18, 2004 proposed rule (69 FR 28312), we proposed that, effective for cost reporting periods beginning on or after October 1, 2003, if a resident is training in an accredited geriatric residency or fellowship program of 2 (or more) years in duration, hospitals may treat training time spent during the first 2 years of the program as part of the resident's initial residency period and weight the resident's FTE time at 1.0 during that period, regardless of the fact that the minimum number of years of training required for board eligibility in geriatrics is only 1 year. We noted that the statutory language quoted above does not allow a hospital to treat time spent by a resident in the second year of geriatric training as part of the resident's initial residency period in the case where the resident trained in a geriatric residency or fellowship program that is accredited as a 1-year program because, in that case, the resident could be board eligible after only 1 year of training.

Even though the Congress gave the Secretary authority to implement section 712 of Public Law 108-173 through an interim final rule with comment period, we chose to provide instructions in a One-Time Notification (OTN) to fiscal intermediaries and providers (Transmittal 61, CR 3071), "Changes to the FY 2004 Graduate

Medical Education (GME) Payments as Required by the Medicare Modernization Act of 2003 (MMA), Pub. L. 108-173," issued on March 12, 2004, and indicated in the proposed rule that we are implementing the statutory provision in our regulations through the notice and comment rulemaking process. We proposed to revise proposed redesignated § 413.79(a) (a redesignation of § 413.86(g)(1)) to incorporate the provision of section 712(a) of Pub. L. 108-173. We received no comments on this proposed change in regulation. Therefore, we are adopting the proposed regulation without modification.

4. Per Resident Amount: Extension of Update Limitation on High-Cost Programs (Section 711 of Pub. L. 108-173 and § 413.77(d)(2)(iii)(B)(3) (a Redesignation of Existing § 413.86(e)(4)(ii)(C)(2)(iii))

Section 1886(h)(2) of the Act, as amended by section 311 of the Balanced Budget Refinement Act (BBRA) of 1999 (Pub. L. 106-113), establishes a methodology for the use of a national average per resident amount (PRA) in computing direct GME payments for cost reporting periods beginning on or after October 1, 2000, and on or before September 30, 2005. Generally, section 1886(h)(2)(D)(ii) of the Act establishes a "floor" for hospital-specific PRAs at 70 percent of the locality-adjusted national average PRA. In addition, section 1886(h)(2)(D)(iv) of the Act establishes a "ceiling" that limits the annual adjustment of a hospital-specific PRA if the PRA exceeded 140 percent of the locality-adjusted national average PRA. Section 511 of the Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106-554) further amended section 1886 (h)(2) of the Act to increase the floor that was established by the BBRA to 85 percent of the locality-adjusted national average PRA. For purposes of calculating direct GME payments, each hospital-specific PRA is compared to the floor and ceiling to determine whether the hospital-specific PRA should be revised. (We direct readers to Program Memorandum A-01-38, March 21, 2001 for historical reference on calculating the floor and ceiling.)

Section 711 of Public Law 108-173 amended section 1886 (h)(2)(D)(iv) of the Act to freeze the annual CPI-U updates to hospital-specific PRAs for those PRAs that exceed the ceiling for FYs 2004 through 2013. Therefore, in the May 18, 2004 proposed rule (69 FR 28313), we proposed that, for cost reporting periods beginning during FY 2004 through FY 2013, we would

calculate a ceiling that is equal to 140 percent of the locality-adjusted national average PRA for each hospital and compare it to each hospital-specific PRA. If the hospital-specific PRA for the preceding year is greater than 140 percent of the locality-adjusted national average PRA "ceiling" in the current fiscal year, the hospital-specific PRA for the current year is frozen at the preceding fiscal year's hospital-specific PRA and is not updated by the CPI-U factor. We note that a hospital may have more than one PRA. Each of a hospital's PRAs must be separately compared to the "ceiling" PRA to determine whether that PRA should be frozen at the level for the previous year or updated by the CPI-U factor.

For example, to determine the applicable PRA for a cost reporting period beginning during FY 2004, we proposed to compare the hospital-specific PRA from the cost reporting period that began during FY 2003 to the FY 2004 locality-adjusted national average PRA for that hospital. If the FY 2003 hospital-specific PRA exceeds 140 percent of the FY 2004 locality-adjusted national average PRA, the FY 2004 hospital-specific PRA is frozen at the level of the FY 2003 hospital-specific PRA and is not updated by the CPI-U factor for FY 2004.

Due to the effective date of the statutory provision of section 711 of Public Law 108-173, we issued a notification to fiscal intermediaries and providers regarding the provision in the OTN issued on March 12, 2004 (Transmittal 61, CR 3071). In the May 18, 2004 proposed rule, to incorporate the changes made by section 711 of Public Law 108-173 in our regulations regarding the determination of PRAs, we proposed to: (1) Revise proposed redesignated § 413.77(d)(2)(iii)(B)(3) (a proposed redesignation of existing § 413.86(e)(4)(ii)(C)(2)(iii)) to make it applicable only to FY 2003; (2) further redesignate proposed newly redesignated § 413.77(d)(2)(iii)(B)(4) (the proposed redesignation of existing § 413.86(e)(4)(ii)(C)(2)(iv)) as § 413.77(d)(2)(iii)(B)(4); and (3) add a proposed new § 413.77(d)(2)(iii)(B)(4).

Comment: One commenter stated that many hospitals incur direct GME costs beyond those reimbursed by Medicare through the PRA due to the difficulties in recruiting physicians to certain areas and the shortages of physicians in certain specialty programs. The commenter stated that the freeze in the inflation updates to the per resident amounts will inhibit a hospital from providing high quality education, and will result in additional physician shortages.

Response: The commenter is referring to section 711 of Public Law 108–173 that freezes the annual CPI–U updates to hospital-specific PRAs for those PRAs that exceed the ceiling for FYs 2004 through 2013. While we are sympathetic to the commenter’s concerns, this provision is statutory and must be implemented as mandated.

5. Residents Training in Nonhospital Settings

a. Background

With respect to reimbursement of direct GME costs, since July 1, 1987, hospitals have been allowed to count the time residents spend training in sites that are not part of the hospital (referred to as “nonprovider” or “nonhospital sites”) under certain conditions. Section 1886(h)(4)(E) of the Act requires that the Secretary’s rules concerning computation of FTE residents for purposes of direct GME payments “provide that only time spent in activities relating to patient care shall be counted and that all the time so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting.” (Section 1886(h)(4)(E) of the Act, as added by section of 9314 of the Omnibus Budget Reconciliation Act of 1986, Pub. L. 99–509.)

Regulations regarding time spent by residents training in nonhospital sites for purposes of direct GME payment were first implemented in the September 29, 1989 final rule (54 FR 40286). We stated in that rule (under § 413.86(f)(3)) that a hospital may count the time residents spend in nonprovider settings for purposes of direct GME payment if the residents spend their time in patient care activities and there is a written agreement between the hospital and the nonprovider entity stating that the hospital will incur all or substantially all of the costs of the program. The regulations at that time defined “all or substantially all” of the costs to include the residents’ compensation for the time spent at the nonprovider setting.

Prior to October 1, 1997, for IME payment purposes, hospitals could only count the time residents spend training in areas subject to the IPPS and outpatient areas of the hospital. Section 4621(b)(2) of the BBA of 1997 (Pub. L. 105–33) revised section 1886(d)(5)(B) of the Act to allow providers to count time residents spend training in nonprovider

sites for IME purposes, effective for discharges occurring on or after October 1, 1997. Specifically, section 1886(d)(5)(B)(iv) of the Act was amended to provide that “all the time spent by an intern or resident in patient care activities under an approved medical residency program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all, or substantially all, of the costs for the training program in that setting.”

In the regulations at §§ 412.105(f)(1)(ii)(C) and 413.86(f)(4) (as issued in the July 31, 1998 **Federal Register**), we specify the requirements a hospital must meet in order to include the time spent by a resident training in a nonhospital site in its FTE count for Medicare reimbursement for portions of cost reporting periods occurring on or after January 1, 1999 for both direct GME and for IME payments. The regulations at § 413.86(b) redefine “all or substantially all of the costs for the training program in the nonhospital setting” as the residents’ salaries and fringe benefits (including travel and lodging where applicable), and the portion of the cost of teaching physicians’ salaries and fringe benefits attributable to direct GME. A written agreement between the hospital and the nonhospital site is required before the hospital may begin to count residents training at the nonhospital site; the agreement must provide that the hospital will incur the costs of the resident’s salary and fringe benefits while the resident is training in the nonhospital site. The hospital must also provide reasonable compensation to the nonhospital site for supervisory teaching activities, and the written agreement must specify that compensation amount.

b. Moratorium on Disallowances of Allopathic or Osteopathic Family Practice Residents Training Time in Nonhospital Settings (Section 713 of Pub. L. 108–173 and Redesignated § 413.78 (a Redesignation of Existing § 413.86(f))

As we mentioned above, under existing § 413.86(f)(4), for portions of cost reporting periods occurring on or after January 1, 1999, the time residents spend in nonhospital settings such as freestanding clinics, nursing homes, and physicians’ offices in connection with approved programs may be included in determining the hospital’s number of FTE residents for purposes of calculating both direct GME and IME payments, if the following conditions are met:

(1) The resident spends his or her time in patient care activities.

(2) There is a written agreement between the hospital and the nonhospital site that indicates that the hospital will incur the costs of the resident’s salary and fringe benefits while the resident is training in the nonhospital site, and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities.

(3) The hospital incurs “all or substantially all” of the costs for the training program in the nonhospital setting. “All or substantially all” means the residents’ salaries and fringe benefits (including travel and lodging where applicable) and the portion of teaching physicians’ salaries and fringe benefits attributable to direct graduate medical education.

In order for the hospital to incur “all or substantially all” of the costs in accordance with the regulations, the actual cost of the time spent by teaching physicians in supervising residents in the nonhospital setting must be compensated by the hospital. The amount of supervisory GME costs is dependent upon the teaching physician’s salary and the percentage of time that he or she devotes to activities related to the residency program at the nonhospital site. As long as there are supervisory costs associated with the nonhospital training, the hospital must reimburse the nonhospital setting for those costs in order to count FTE resident time spent in the nonhospital site for purposes of IME and direct GME payments.

Many hospitals have entered into written agreements with teaching physicians that state that the teaching physician is “volunteering” his or her time in the nonhospital site, and, therefore, the hospital is not providing any compensation to the teaching physician. Other hospitals have paid only a nominal amount of compensation for the supervisory teaching physicians’ time in the nonhospital setting. Because the existing regulations at § 413.86(f)(4) state that the hospital must incur all or substantially all of the direct GME costs, including those costs associated with the teaching physician, regardless of whether the written agreement states that the teaching physician is “volunteering,” we have required that the hospital must pay these costs in order to count FTE residents training in the nonhospital site, as long as these teaching physician costs exist.

However, during the 1-year period from January 1, 2004 through December 31, 2004, section 713 of Public Law 108-173, through a moratorium, allows hospitals to count allopathic or osteopathic family practice residents training in nonhospital settings for IME and direct GME purposes, without regard to the financial arrangement between the hospital and the teaching physician practicing in the nonhospital setting to which the resident is assigned. We implemented section 713 in the One-Time Notification (OTN), "Changes to the FY 2004 Graduate Medical Education (GME) Payments as Required by the Medicare Modernization Act of 2003 (MMA)" (CR 3071, Transmittal 61, issued on March 12, 2004). Generally, to implement the provisions of section 713, we stated in the OTN that, when settling prior year cost reports during this 1-year period, or for family practice residents actually training in nonhospital settings during this 1-year period, the fiscal intermediaries should allow the hospitals to count allopathic and osteopathic family practice residents training in the nonhospital setting for direct GME and IME payment purposes without regard to the financial arrangement between the hospital and the nonhospital site pertaining to the teaching physicians' costs associated with the residency program.

(1) Cost Reports That Are Settled Between January 1, 2004 and December 31, 2004

When fiscal intermediaries settle cost reports during January 1, 2004 through December 31, 2004 (Calendar Year (CY) 2004), a hospital that seeks to count allopathic or osteopathic family practice FTE residents training in a nonhospital setting(s) is allowed to count those FTEs for IME and direct GME purposes, even in instances where the written agreement between the hospital and a teaching physician or a nonhospital site does not mention teaching physician compensation, specifies only a nominal amount of compensation, or states that the teaching physician is "volunteering" his or her time training the residents. For example, when a fiscal intermediary is settling a cost report during CY 2004 that has a fiscal year end of June 30, 2001, the fiscal intermediary will allow the hospital to count family practice FTE residents that trained in a nonhospital setting during the period covered by the June 30, 2001 cost report, regardless of the financial arrangement in place between the hospital and the teaching physician at the nonhospital site during the period covered by the June 30, 2001 cost report.

We note that this moratorium does not apply to cost reports that are not settled during January 1 through December 31, 2004, that do not coincide with, or overlap, the January 1 through December 31, 2004 period. For example, if a cost report for fiscal year ended December 31, 2003 (or June 30, 2003, or others) is not settled during the January 1 through December 31, 2004 period, the moratorium would not apply.

Comment: One commenter expressed concern with the implementation of the moratorium on disallowances of allopathic or osteopathic family practice residents' training time in nonhospital settings. Specifically, the commenter was concerned that fiscal intermediaries may purposely delay audits or the issuance of settled cost reports to avoid the impact of the moratorium. The commenter requested CMS to clearly and firmly direct fiscal intermediaries to settle all cost reports in 2004 that they otherwise would settle and inform intermediaries that they may not take the moratorium into account in determining whether and when to settle cost reports.

Response: We have already addressed the issue of how fiscal intermediaries are to implement this moratorium. In Change Request 3071, Pub. 100-20, Transmittal No. 61, issued to the fiscal intermediaries on March 12, 2004, we stated that, "Scheduling of cost report audit or settlement activities during calendar year 2004 should be done in accordance with normal procedures. If, since January 1, 2004, but before issuance of this OTN, you have settled cost reports and did not allow hospitals to count family practice residents at nonhospital sites where the hospitals did not pay for all of the teaching physician costs, then review such settlements and, if appropriate, reopen and reverse the disallowance. If, as of issuance of this OTN, you have disallowed such residents in the process of settling a cost report, but have not yet issued the Notice of Program Reimbursement (NPR), then reverse the disallowance of those residents. Cost reports that have already been settled prior to January 1, 2004 should not be reopened to allow a hospital to count family practice residents at nonhospital sites where the hospital did not pay for all of the teaching physician costs, even if requested by a hospital."

Therefore, scheduling of audit or settlement activities should be done using normal procedures. Given the above instruction, fiscal intermediaries should not take the moratorium into consideration or delay settlement and audit activities. Because we have instructed fiscal intermediaries to

follow normal procedures, we request that hospitals respect our instructions and refrain from pressuring fiscal intermediaries to settle more cost reports than they would during the normal course of business in an attempt to take advantage of this moratorium.

(2) Family Practice Residents That Are Training in Nonhospital Settings Between January 1, 2004 and December 31, 2004

In addition to allowing family practice residents that trained in nonhospital settings to be counted in cost reports that the fiscal intermediaries settle during the period of January 1, 2004 through December 31, 2004, without regard to the financial arrangements between the hospital and the teaching physician at the nonhospital site, the fiscal intermediaries are to allow family practice residents that actually are or will be training in nonhospital settings during January 1, 2004, through December 31, 2004, without regard to the financial arrangements between the hospital and the teaching physician at the nonhospital site. That is, when fiscal intermediaries settle cost reports that cover service periods of January 1, 2004 through December 31, 2004, a hospital that seeks to count allopathic or osteopathic family practice FTE residents training in a nonhospital setting(s) would be allowed to count those FTEs, even in instances where the written agreement between the hospital and a teaching physician or a nonhospital site does not mention teaching physician compensation, specifies only a nominal amount of compensation, or states that the teaching physician is "volunteering" his or her time training the residents. If a hospital has a fiscal year that is other than a calendar year, the hospital may count the family practice residents training in the nonhospital setting during those portions of its fiscal years that fall within the January 1, 2004 and December 31, 2004 period. For example, when a fiscal intermediary is settling a hospital's June 30, 2004 cost report, the hospital would be allowed to count family practice FTE residents that trained in a nonhospital setting during the period of January 1, 2004 through June 30, 2004, regardless of the financial arrangement between the hospital and the teaching physician at the nonhospital site from January 1 through June 30, 2004. Similarly, when a fiscal intermediary settles the hospital's June 30, 2005 cost report, the hospital would be allowed to count family practice FTE residents that trained in a nonhospital setting during the period of July 1, 2004

through December 31, 2004, regardless of the financial arrangement between the hospital and the teaching physician at the nonhospital site from July 1 through December 31, 2004. (However, we note that family practice residents that train in nonhospital settings beginning January 1, 2005, and after are not subject to the moratorium provided under section 713 of Pub. L. 108–173.)

Because we are interpreting this moratorium to apply to prior period cost reports that are settled during calendar year (CY) 2004, and to cost reports that are settled after CY 2004 that cover training that occurred during the period of January 1, 2004 through December 31, 2004, a gap in applicability of the moratorium may result for family practice residents training in nonhospital settings. For example, a hospital might be permitted to count certain FTE family practice residents that are included in its FY 2001 cost report in accordance with the moratorium because that cost report is settled during CY 2004. However, the hospital might not be permitted to count certain FTE family practice residents in its FY 2002 and FY 2003 cost reports because these cost reports would not be settled during CY 2004 and the moratorium would not apply. The hospital then could be permitted to count certain FTE family practice residents in its FY 2004 cost report in accordance with the moratorium, because the FY 2004 cost report would contain family practice residents who actually trained in a nonhospital setting during CY 2004.

Regardless of whether the fiscal intermediaries are settling prior period cost reports during CY 2004, or settling cost reports after CY 2004 that cover training during the period of January 1, 2004 through December 31, 2004, we emphasize that the moratorium provided in section 713 of Public Law 108–173 only applies for purposes of counting FTE residents in allopathic and osteopathic general family practice programs that were in existence (that is, training residents) as of January 1, 2002 and where the requirement to incur the teaching physician compensation related to direct GME may not have been met. Therefore, in the May 18, 2004 proposed rule (69 FR 28315), for residents training in nonhospital settings, we proposed that the moratorium applies only: (1) To FTE residents in general family practice programs (and not to dental, podiatric, or other allopathic or osteopathic specialty programs); (2) to family practice programs that were in existence as of January 1, 2002; and (3) with the exception of teaching physician

compensation, to training in nonhospital settings that meet the requirements in the existing regulations at § 413.86(f)(4) (proposed to be redesignated as § 413.78(d)).

We did not propose any regulation text changes to address this provision in the proposed rule. We note that section 713(b) of Public Law 108–173 directs the Inspector General of the Department of Health and Human Services to conduct a study of the appropriateness of alternative methodologies for payment of residency training in nonhospital settings and to submit a report to Congress on the results of the study, along with recommendations, as appropriate, by December 8, 2004. We will await the release of the Inspector General's report and may consider additional policy and regulation changes at that time if they are warranted.

Comment: Many commenters expressed strong opposition to CMS' policy regarding IME and DGME payments for residents training at a nonhospital setting(s). The commenters believe that the requirement that hospitals pay supervising physicians in nonhospital settings for the salary and fringe benefits that is attributable to the time spent teaching residents is severely detrimental to residency programs that depend on nonhospital training and runs counter to long-standing traditions prevalent in physician education.

Several commenters stated that there is inconsistency in the treatment of supervisory costs in nonhospital settings by CMS and fiscal intermediaries and requested clarification regarding CMS policy regarding compensation of supervisory physicians who “volunteer” their time to train residents in a nonhospital setting.

Several commenters proposed that CMS clarify in the final rule that where supervising physicians freely agree to volunteer their time and the hospital pays all other training costs (residents' salaries, benefits, and other training costs) that the hospital has incurred “all or substantially all” of the costs of the program.

Several commenters urged CMS to extend the MMA moratorium on disallowances of allopathic or osteopathic family practice residents training time in nonhospital settings (redesignated § 413.78) to cover all current, prior, and future nonhospital education. Another commenter believes that this moratorium should not be limited to Family Practice residents, but rather should cover any residents that train in nonhospital settings.

Response: While we sympathize with the commenter's concerns, the cost reporting period specified for the moratorium on disallowances of allopathic or osteopathic family practice residents training time in nonhospital settings is set by Section 713 of Public Law 108–173. Furthermore, we have no discretion to expand the moratorium to residency programs other than Family Practice. Many hospitals have claimed that the teaching physician is “volunteering” his or her time in the nonhospital site, and, therefore, the hospital is not providing any compensation to the teaching physician. The redesignated regulation at § 413.78 states that the hospital must incur all or substantially all of the direct GME costs. This requirement included those costs associated with the teaching physician, regardless of whether the written agreement states that the teaching physician is “volunteering.” The statute and our regulations require that the hospital must pay the costs of training residents at the nonhospital site in order to count FTE residents training at that site including teaching physician costs, as long as these teaching physician costs exist. We did not propose any regulation text changes that address these supervisory costs of training residents at nonhospital setting(s). Section 713(b) of Public Law 108–173 directs the Inspector General of the Department of Health and Human Services to conduct a study of the appropriateness of alternative methodologies for payment of residency training in nonhospital settings and to submit a report to the Congress on the results of the study, along with recommendations, as appropriate, by December 8, 2004. We will await the release of the Inspector General's report and may consider additional policy, regulation changes, and instructions to financial intermediaries at that time if they are warranted.

Comment: One commenter believes that there is unmeasured monetary value afforded to nonhospital sites that are training residents and that supervisory costs should be compared to what nonhospital sites gain as a result of training residents. For example, “off-site locations may also have reduced clinical staff hours, as some of the work delegated to residents is similar or identical to what might be * * * work normally performed by clinical staff in offices without residents.” The commenter believes compensation for supervising physicians that does not take into account these economic benefits would result in a “gross overpayment” to nonhospital sites.

Response: In order to count residents training at nonhospital sites, for purposes of direct and indirect GME payments, the statute requires a hospital to pay the nonhospital site for all or substantially all of the costs for the training program in that setting. Although we understand that a benefit does accrue to the nonhospital site because there is GME training being conducted at that site, a determination of the cost of the training must be made and the hospital must pay the nonhospital site for those costs. We are not proposing to make any changes regarding compensation for supervising physicians at nonhospital sites at this time. As stated above, section 713(b) of Public Law 108–173 directs the Inspector General of the Department of Health and Human Services to conduct a study of the appropriateness of alternative methodologies for payment of residency training in nonhospital settings and to submit a report to the Congress on the results of the study, along with recommendations, as appropriate, by December 8, 2004. We will await the release of the Inspector General's report and will consider the possibility of policy and regulation changes at that time if warranted.

Comment: Many commenters proposed that CMS “make very clear in regulation or intermediary instruction that if there are no payments made to the non-hospital site by the hospital, that is not an a priori reason to deny time spent by residents in that environment. If the hospital is paying the residents' salary and benefits, travel costs, lodging, etc., there may in fact be no costs (hence payments) to the non-hospital site. This would frequently be the case in situations where the preceptor is volunteering his/her teaching or supervisory time.”

Response: We did not propose any changes in policy concerning this issue. We note that Section 713(b) of Public Law 108–173 directs the Inspector General of the Department of Health and Human Services to conduct a study of the appropriateness of alternative methodologies for payment of residency training in nonhospital settings and to submit a report to the Congress on the results of the study, along with recommendations, as appropriate, by December 8, 2004. We will await the release of the Inspector General's report and will consider additional policy, regulation changes, and instructions to financial intermediaries at that time if warranted.

c. Requirements for Written Agreements for Residency Training in Nonhospital Settings (Redesignated § 413.78 (a) Redesignation of Existing § 413.86(f))

As mentioned above, under section 1886(h)(4)(E) of the Act, a hospital may count residents training in nonhospital settings for direct GME purposes (and under section 1886(d)(5)(B)(iv) of the Act, for IME purposes), if the residents spend their time in patient care activities and if “* * * the hospital incurs all, or substantially all, of the costs for the training program in that setting.” We believe the Congress intended to facilitate residency training in nonhospital settings by requiring hospitals to commit to incur, and actually incur, all or substantially all of the costs of the training programs in the nonhospital sites. Accordingly, in implementing section 1886(h)(4)(E) of the Act, first in the regulations at § 413.86(f)(3), effective July 1, 1987, and later at § 413.86(f)(4), effective January 1, 1999, we required that, in addition to incurring all or substantially all of the costs of the program at the nonhospital setting, there must be a written agreement between the hospital and the nonhospital site stating that the hospital will incur all or substantially all of the costs of training in the nonhospital setting. The later regulations further specify that the written agreement must indicate the amount of compensation provided by the hospital to the nonhospital site for supervisory teaching activities. (In the May 18, 2004 proposed rule, we noted that § 413.86(f)(3) was proposed to be redesignated as § 413.78(c), and § 413.86(f)(4) was proposed to be redesignated as § 413.78(d).)

We required the written agreements in regulations in order to provide an administrative tool for use by the fiscal intermediaries to assist in determining whether hospitals would incur all or substantially all of the costs of the training in the nonhospital setting in accordance with Congressional intent. Furthermore, our policy has required that the written agreement between the hospital and the nonhospital site be in place *prior* to the time that the hospital begins to count the FTE residents training in the nonhospital site. A written agreement signed before the time the residents begin training at the nonhospital site that states that the hospital will incur the costs of the training program at the nonhospital site indicates the hospital's ongoing commitment to incur the costs of training at that site.

In settling cost reports where hospitals have included residents

training at nonhospital sites in their FTE count, the fiscal intermediaries have encountered numerous situations where hospitals have complied with the requirement to incur all or substantially all of the costs of training in nonhospital settings. However, despite our longstanding regulations that state the requirement for a written agreement, these hospitals have not met the regulatory requirements related to written agreements. For example, some hospitals had no written agreement in place during the training in the nonhospital setting, or written agreements were not timely (that is, they were prepared after the residents began or, in some cases, finished training at the nonhospital site), or the agreements did not include a specific amount of compensation to be provided by the hospital to the nonhospital site for supervisory teaching activities. As a result, hospitals have faced disallowances of direct GME and IME payments relating to FTE residents training in nonhospital settings because the hospitals did not comply with the regulatory requirements concerning written agreements.

In retrospect, we believe the regulatory requirements concerning the written agreements may not have been the most efficient aid to fiscal intermediaries in determining whether hospitals would actually incur all or substantially all of the costs of the training programs in nonhospital settings. The fiscal intermediaries have been required to ensure that hospitals are complying with the regulations regarding written agreements, in addition to determining whether a hospital actually incurred the appropriate costs. We believe it would be more appropriate and less burdensome for both fiscal intermediaries and hospitals if we instead focus the fiscal intermediaries' reviews on the statutory requirement that hospitals must incur all or substantially all of the costs of the program in the nonhospital setting. Therefore, in the May 18, 2004 proposed rule (69 FR 28315), we proposed to revise the regulations under proposed new § 413.78 (a proposed redesignation of existing § 413.86(f)) to remove the requirement for a written agreement between the hospital and the nonhospital setting as a precondition for a hospital to count residents training in nonhospital settings for purposes of direct GME and IME payments. However, consistent with our belief that the Congress intended that hospitals commit to incur, and actually incur, all or substantially all of the costs of the

training programs in the nonhospital sites in order to facilitate training at nonhospital sites, we are also proposing that, in order for the hospital to count residents training in a nonhospital setting, the hospital must pay for the nonhospital site training costs concurrently with the training that occurs during the cost reporting period.

We understand that residents' rotations, including those to nonhospital settings, are generally in discrete blocks of time (for example, 4-week or 6-week rotations). Therefore, to account for various rotation lengths, we proposed under the new proposed § 413.78(e) that, in order to count residents training in a nonhospital setting, a hospital must pay all or substantially all of the costs of the training in a nonhospital setting(s) by the end of the month following a month in which the training in the nonhospital site occurred. If a hospital is counting residents training in a nonhospital setting for direct GME and IME purposes in any month of its cost reporting period, the hospital must make payment by the end of the following month to cover all or substantially all of the costs of training in that setting attributable to the preceding month. If the residents are employed by the hospital, and receive their salary payments (and fringe benefits) every 2 weeks, the hospital may continue to pay the residents' salaries every 2 weeks during the residents' rotation to the nonhospital setting. This should still result in payment being made for residents' time spent in nonhospital settings by the end of the following month. (We also note that the hospital must pay travel and lodging expenses, if applicable.) We proposed that the hospital would be required to pay the nonhospital site for the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct GME by the end of the month following the month in which the training in the nonhospital setting occurred. We proposed that if a hospital does not pay for all or substantially all of the costs of the program in the nonhospital setting by the end of the month following the month in which the training occurred, the hospital could not count those FTE residents in the month that the training occurred. Therefore, we proposed to determine if residents training in nonhospital sites should be counted on a month-to-month basis, depending on whether a hospital paid for the training costs of those residents by the end of the month following the month in which the training occurred.

The following are examples of how a hospital that sends residents to train in nonhospital sites would make payments concurrently with the nonhospital site training:

Example 1. • Hospital A, with a fiscal year end (FYE) of December 31, trains 10 internal medicine residents and 6 family practice residents. Each January, April, July, and October, Hospital A sends 5 internal medicine FTE residents to the Physicians' Clinic for 4 weeks. Each month, Hospital A sends 2 family practice FTE residents to the Family Clinic. The residents are employed by Hospital A, and the residents receive fringe benefits from and are paid every 2 weeks by Hospital A, regardless of whether they are training in Hospital A or at a nonhospital site. In order to make payments concurrently with the training that is occurring in the nonhospital sites, Hospital A must pay the Physicians' Clinic by the end of February, May, August, and November, respectively, of each cost reporting year, to cover the costs of teaching physician compensation and fringe benefits attributable to direct GME. Similarly, because residents are training at the Family clinic each month, Hospital A must pay the Family Clinic by the end of each month for the previous month's costs of teaching physician compensation and fringe benefits attributable to direct GME. There are no travel and lodging costs associated with these rotations to nonhospital sites.

Example 2. • University A will sponsor an ophthalmology program with eight residents beginning on July 1, 2005. The residents will be on the payroll of the University, but they will train at Hospital B and at the University's Eye Clinic, which is a nonhospital setting. Hospital B has a June 30 FYE. Four of the residents will train in the Eye Clinic from August 1 to October 15, and the other four residents will train in the Eye Clinic from February 15 to April 30. Thus, residents are training in the Eye Clinic during the months of August, September, October, February, March, and April. If Hospital B wishes to count these FTE residents for IME and direct GME purposes in its cost reporting year ending June 30, 2006, and onward, it must pay the Eye Clinic at the end of September, October, November, March, April, and May, respectively, for the previous month's cost of the residents' salaries and fringe benefits, and the teaching physician compensation and fringe benefits attributable to direct GME.

Example 3. • Hospital C sends a resident to train at a nonhospital site from January 28 to February 20. The resident was employed by the nonhospital site during this time. Hospital C paid the nonhospital site for the cost of the resident's salary and fringe benefits and the teaching physician compensation and fringe benefits attributable to direct GME by February 28 to account for the training that occurred from January 28 through January 31. However, Hospital C did not pay the nonhospital site by March 31 to account for the training that occurred in February. Therefore, Hospital C could not count the resident's time in the nonhospital setting from February 1 through February 20 for direct GME and IME purposes.

We note that our proposal to require hospitals to pay for the nonhospital site training costs concurrently with the training that occurs in the nonhospital site was a departure from our current policy concerning the timeframe in which a hospital must make payment for the training costs. Currently, we apply the existing regulations at § 413.100(c)(2)(i), which state that a short-term liability (such as the hospital's obligation to pay the nonhospital site for the residency training costs) must be liquidated within 1 year after the end of the cost reporting period in which the liability is incurred. However, because we are proposing to no longer require that a written agreement between the hospital and the nonhospital site be in place prior to the time that the hospital begins to count the FTE residents training in the nonhospital site, we believe that a reasonable alternative to ensure that a hospital is facilitating the training at the nonhospital site through its ongoing commitment to incur all or substantially all of the costs is to require the hospital to make payments concurrently with the training that occurs in the nonhospital site in order to count the FTE residents for purposes of direct GME and IME payments.

We are aware that there are situations where, rather than providing direct financial compensation to the nonhospital site for supervisory teaching activities, the hospital is incurring all or substantially all of the teaching physician costs through nonmonetary, in-kind arrangements. In the May 18, 2004 proposed rule, we proposed that, in order to be considered concurrent with the nonhospital site training, in-kind arrangements must be provided or made available to the teaching physician at least quarterly, to the extent that there are residents training in a nonhospital setting(s) in a quarter.

We proposed to revise § 413.86(f) (proposed to be redesignated as § 413.78 in this proposed rule) to add a new paragraph (§ 413.78(e)) to state that a hospital must incur all or substantially all of the costs of training in a nonhospital setting by the end of the month following a month in which the training in the nonhospital site occurred, to the extent that there are residents training in a nonhospital setting in a month. This proposed change would be effective for portions of cost reporting periods occurring on or after October 1, 2004. We proposed to revise paragraph (d) of the proposed redesignated § 413.78 to reflect the effective cost reporting periods of the provisions under the new paragraph (e).

Comment: Many commenters voiced strong opposition to the proposed regulation that requires hospitals to pay for all or substantially all of the costs of training residents at the nonhospital setting(s) by the end of the month following a month in which the training in the nonhospital setting(s) occurred. The commenters believe that this proposed regulation would not be less burdensome than the existing system and indeed would increase the administrative burdens to hospitals and intermediaries alike.

Response: As we stated in the May 18, 2004 proposed rule, we believe the Congress intended to facilitate residency training in nonhospital settings by requiring hospitals to commit to incur, and actually incur, all or substantially all of the costs of the training programs in the nonhospital sites. Accordingly, in implementing section 1886(h)(4)(E) of the Act, first in the regulations at § 413.86(f)(3), effective July 1, 1987, and later at § 413.86(f)(4), effective January 1, 1999, we required that, in addition to incurring all or substantially all of the costs of the program at the nonhospital setting, there must be a written agreement between the hospital and the nonhospital site stating that the hospital will incur all or substantially all of the costs of training in the nonhospital setting.

In the May 18, 2004 proposed rule, we indicated our belief that it would be more appropriate and less burdensome for both fiscal intermediaries and hospitals if, instead of focusing on the written agreement, we focus on the statutory requirement that hospitals must incur all or substantially all of the costs of the program in the nonhospital setting. Therefore, we proposed to remove the requirement for a written agreement between the hospital and the nonhospital setting as a precondition for a hospital to count residents training in nonhospital settings for purposes of direct GME and IME payments. Instead, we proposed that, in order to count residents training in a nonhospital setting, a hospital must pay all or substantially all of the costs of the training in a nonhospital setting(s) by the end of the month following a month in which the training in the nonhospital site occurred. Payment of these costs by the end of the month following a month in which the training occurs would show an ongoing commitment to incur the cost of training residents at the nonhospital site and is consistent with the Congress' intent.

In response to the commenter's concerns, we are revising the proposed finalized policy at § 413.78 (a redesignation of § 413.86(f)). We are

concerned that hospitals may not always be able to comply with the timeframe for payment of nonhospital supervisory costs as indicated by the commenters. Therefore, we will allow hospitals to demonstrate their ongoing commitment to incur the costs of the training program in the nonhospital setting, and to count the FTE residents training thereby meeting at least one of the following criteria: (1) There is a written agreement between the hospital and the nonhospital site stating that the hospital will incur all or substantially all of the costs of training in the nonhospital setting. If the hospital chooses the written agreement option, the existing requirements as specified in the regulations at § 413.100(c)(2)(i) and § 413.86(f)(4) would apply. Or, (2) the hospital pays the costs associated with the training program in the nonhospital setting(s) by the end of the third month following a month in which the training in the nonhospital setting(s) occurred. Allowing hospitals to choose between these two options and lengthening the required timeframe for concurrent payment of the costs of the training in a nonhospital site provides additional flexibility to hospitals and fiscal intermediaries while still ensuring compliance with the statutory requirement to demonstrate that hospitals will incur all or substantially all of the costs of the training program in the nonhospital setting.

Comment: Several commenters believe that our proposal to require hospitals to pay the costs of training residents at a nonhospital site by the end of the month following a month in which the training occurred is inconsistent with longstanding Medicare policy. They note that the regulations at § 413.100(c)(2)(i) allow a hospital to recognize an accrued cost for Medicare payment purposes if it is paid within one year after the end of the cost reporting period in which the liability was incurred. Several commenters proposed that a hospital be considered to have incurred the cost of training residents in a nonhospital setting, with or without a written agreement, if this cost is paid in accordance with § 413.100(c)(2)(i). One commenter proposed that a hospital be considered to have incurred the cost of training residents in a nonhospital setting, with or without a written agreement, if this cost is paid by the end of the month following the end of the cost reporting period.

Response: We agree that § 413.100(c)(2)(i) permits a hospital to recognize an accrued cost for Medicare payment purposes if it is paid within one year after the end of the cost

reporting period in which the liability was incurred. However, we have required a written agreement under our regulations in order to provide an administrative tool for use by the fiscal intermediaries to assist in determining whether hospitals would incur all or substantially all of the costs of the training in the nonhospital setting. As stated above, we are now allowing a hospital to choose how it will demonstrate that it will incur the nonhospital site training costs: either by executing a written agreement with the nonhospital site in accordance with existing regulations, or by concurrently paying the costs of training residents in the nonhospital setting (that is, by the end of the third month following the month in which the training occurred).

Comment: One commenter disagreed with CMS' policy requiring that the written agreement between a hospital and a nonhospital site be in place prior to residents commencing training at the nonhospital site. The commenter proposed that the written agreement be valid if in place at any time during the cost reporting year in which the training at the nonhospital site occurs.

Response: Regulations at 42 CFR 413.78 (previously § 413.86(f)(4)) specify that there must be a written agreement between the hospital and the non-hospital site stating that the hospital will incur specific costs of training in the non-hospital site, including costs for supervisory teaching activities. It is our policy under that regulation that the written agreement between the hospital and non-hospital site be in place prior to the time that the hospital begins to count the FTE residents training in the non-hospital site. As discussed earlier in this final notice, we are allowing a hospital to meet the requirement to pay all or substantially all of the costs of the program in the nonhospital setting, by either submitting a copy of the written agreement that was prepared *prior* to the residents' training or by documenting that payments were actually made within the required three month time period. We believe the new option for a hospital to demonstrate that it will incur the costs of a nonhospital site training program provides sufficient additional flexibility for providers. We are not adopting the commenter's proposal to allow hospitals to use a written agreement that is executed or submitted after the training has occurred. We do not believe allowing the written agreement to be put in place retrospectively, after resident training in the nonhospital site has commenced, would be consistent with our long-standing policy to demonstrate that the

hospital will incur all or substantially all of the costs of the training program in the nonhospital site.

Comment: One commenter representing a particular medical specialty recommended that CMS use proof of program accreditation as evidence of a written agreement between hospitals and nonhospital settings. The commenter pointed out that written agreements between hospitals and nonhospital sites are required by the specialty's accreditation process. Therefore, the commenter added, time spent in these nonhospital sites is eligible for reimbursement.

Response: Under our existing regulations, the written agreement between a hospital and a nonhospital site must include several specific elements as follows:

- The hospital will incur the cost of the resident's salary and fringe benefits while the resident is training in the nonhospital site.
- The hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities.
- The agreement must indicate the compensation the hospital is providing for supervisory teaching activities.

We must be able to verify that the written agreement conforms to these requirements of the regulation. Therefore, the actual written agreement must be used as proof rather than using proof of the program's accreditation as a proxy, because the proof of accreditation may not include all of the required information specified at redesignated § 413.78(d)(2).

Comment: One commenter requested that we place language in the regulations regarding the timing of nonmonetary compensation made available to supervising physicians that train residents in nonhospital settings. The commenter notes that while the preamble to the proposed rule addresses the timeframe for making in-kind compensation available to supervising physicians, the text of the regulations does not.

Response: The purpose of the preamble to a rule is to further explain, and often, to provide practical examples and guidance on the policy laid out in the regulation text. It would be highly impractical to address every specific circumstance to which our policies would apply in the text of our regulations. In this case, we believe the preamble to this final rule is sufficient to convey the policy regarding the timing of in-kind compensation made available to supervising physicians at nonhospital settings.

Comment: Several commenters asked for clarification regarding in-kind compensation for supervisory physicians in nonhospital settings. We proposed that in order to be considered concurrent with the nonhospital site training, in-kind arrangements must be provided or made available to the teaching physician at least quarterly. The commenters asked that we elaborate on in-kind arrangements and give examples. The commenters also asked for examples of in-kind arrangements between a hospital and a solo physician that is training residents at a nonhospital site.

Response: There are situations where rather than providing direct financial compensation to the nonhospital site for supervisory teaching activities, the hospital is providing compensation through non-monetary, in-kind arrangements. If the hospital is using the written agreement option to show that it will incur all or substantially all of the cost of training residents in the nonhospital setting(s), our regulations require that the written agreement describe the arrangements that are involved. For example, the hospital may provide continuing education and other professional and educational support for supervising physicians in the nonhospital site in lieu of financial support. Another example of in-kind compensation is office space provided by the hospital to the supervising physician. The value of this space may be substituted for monetary compensation for teaching activities. This type of support must be described in the written agreement in lieu of a monetary amount for the hospital. If the hospital is opting to pay all or substantially all of the cost of training in the nonhospital setting(s) concurrently with the training that occurs during the cost reporting period, we had proposed that the in-kind arrangements must be provided or made available to the teaching physician at least quarterly, to the extent that there are residents training in a nonhospital setting(s) in a quarter. However, in order to make the policy regarding monetary and in-kind compensation consistent, we are requiring in the final rule that in-kind compensation be provided or made available by the end of the third month following the month in which the training occurs.

We note further that, in the case of a solo practitioner, compensation at the practice is based solely and directly on the number of patients that the solo practitioner treats and for which the solo practitioner bills. Section 1886(h)(4)(E) of the Act requires that hospitals pay all or substantially all of

the cost of training at the nonhospital site in order to count the FTE residents at that site. In this instance, we recognize that there are no costs associated with the supervisory teaching physician's time because the physician is not receiving compensation in any form or from any source while conducting teaching activities. Under these circumstances, we acknowledge that no direct or in-kind payment needs to be made to the supervising physician in order for the hospital to incur all or substantially all of the costs of the training program in the nonhospital setting, and to count the FTE residents' training time in the nonhospital setting.

Out of scope comments relating to GME:

Comment: Several comments addressed miscellaneous IME and direct GME issues, including accreditation of dental programs, community education programs, community support, per resident amounts, the general application of affiliated groups, and redistribution of costs.

Response: We did not make any proposals relating to these issues in the May 18, 2004 proposed rule. Therefore, we decline to respond to these comments in this final rule. However, we will consider them for purposes of future rulemaking.

P. Rural Community Hospital Demonstration Program

Section 410A(a) of Public Law 108–173 requires the Secretary to establish a demonstration to test the feasibility and advisability of establishing “rural community hospitals” for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or treated as being so located under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH.

Sections 410A(a)(2) and (4) of Public Law 108–173 specify that the Secretary is to select for participation not more than 15 rural community hospitals in rural areas of States that the Secretary identifies as having low population densities. As we indicated in the May 18, 2004 IPPS proposed rule (69 FR 28317) and corrected in the June 25, 2004 correction notice (69 FR 39521),

using 2002 data from the U.S. Census Bureau, we identified 10 States with the lowest population density in which rural community hospitals must be located to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming. (Source: U.S. Census Bureau Statistical Abstract of the United States: 2003)

Under the demonstration, participating hospitals will be paid the reasonable costs of providing covered inpatient hospital services (other than services furnished by a psychiatric or rehabilitation unit of a hospital that is a distinct part), applicable for discharges occurring in the first cost reporting period beginning on or after implementation of the demonstration program. For discharges occurring in subsequent cost reporting periods, payment is the lesser of reasonable cost or a target amount, which is the prior year's cost or, after the second cost reporting period, the prior year's target amount, adjusted by the inpatient prospective payment update factor. Covered inpatient hospital services means inpatient hospital services (defined in section 1861(b) of the Act) and includes extended care services furnished under an agreement under section 1883 of the Act.

Sections 410A(a)(5) and (a)(6) require the demonstration to be implemented not later than January 1, 2005, but not before October 1, 2004. The demonstration is to operate for 5 years. The payment change for a participating hospital under this demonstration will be implemented with the hospital's first cost reporting period beginning on or after October 1, 2004.

Section 410A of Public Law 108-173 requires that "in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented."

Generally, when CMS implements a demonstration on a budget neutral basis, the demonstration is budget neutral in its own terms; in other words, aggregate payments to the participating providers do not exceed the amount that would be paid to those same providers in the absence of the demonstration. This form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration

participants. These reduced expenditures offset increased payments elsewhere under the demonstration, thus ensuring that the demonstration as a whole is budget neutral or yields savings. However, the small scale of this demonstration, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration could be viable under the usual form of budget neutrality. Specifically, cost-based payments to 15 small rural hospitals is likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these providers.

In order to achieve budget neutrality, as we proposed, we are adjusting national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are applying budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration. We believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. This is because the statutory language refers merely to ensuring that "aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration * * * was not implemented," and does not identify the range across which aggregate payments must be held equal. In the May 18, 2004 proposed rule, we invited public comment on this proposal. We discuss the payment rate adjustment that would be required to ensure the budget neutrality of this demonstration in the Addendum of this final rule.

Comment: One commenter requested that the demonstration be opened to a larger number of States. The commenter stated that arbitrarily designating a number of States does not serve Medicare beneficiaries and is contrary to the intent of legislation that was proposed prior to the enactment of Public Law 108-173.

Response: Because Public Law 108-173 allows no more than 15 demonstration sites, we targeted the program in the States with the lowest population densities, consistent with the legislative language. We recognize that there are many hospitals serving people in sparsely populated rural areas in other States. Given the limitations imposed by Public Law 108-173,

unfortunately we are unable to include many hospitals in additional States that could benefit from this provision. We have selected the demonstration areas to conform to the requirements of the law and to allow a reasonable process for determining the eligibility of applicants, given the legislative language of the statute.

Comment: One commenter stated that CMS has historically implemented demonstration projects on a budget neutral basis within the context of the given demonstration. The commenter opposed our proposal to fund the Rural Community Hospital Demonstration Program by reducing the payment rate to all hospitals paid on the basis of DRGs, and indicated that requiring nonparticipating hospitals to fund hospitals participating in a demonstration project is a bad policy precedent.

Response: The Rural Community Hospital Demonstration Program is mandated by section 410A of Public Law 108-173. It is aimed at testing the feasibility and advisability of reimbursement based on reasonable cost for covered inpatient services for rural hospitals as defined by the legislation. The commenter is correct in stating that CMS usually implements demonstrations in which savings occurring among participants guarantee budget neutrality. However, we believe that the statutory authority allows us to define budget neutrality across the payment system. In short, we believe that the method that we proposed to ensure budget neutrality, which is mandated by law, is permissible under the statute.

To participate in this demonstration, a hospital must be located in one of the identified States and meet the criteria for a rural community hospital. Eligible hospitals that desire to participate in the demonstration must submit an application to CMS. Information about the demonstration and details on how to apply can be found on the CMS Web site: <http://www.cms.hhs.gov/researchers/demos/rch.asp>.

The data collection instrument for the demonstration has been approved by OMB under the title "Medicare Waiver Demonstration Application," under OMB approval number 0938-0880, with a current expiration date of July 30, 2006.

Q. Special Circumstances of Hospitals Facing High Malpractice Insurance Rate Increases

In the May 18, 2004 proposed rule (69 FR 28318), we indicated that we had received comments from several hospitals about the effects of rapidly

escalating malpractice insurance premiums on hospital financial performance and continued access for Medicare beneficiaries to high quality inpatient hospital services. We are aware that malpractice insurance premiums have increased at a high rate in some areas of the country during the last few years. While we are not aware of any specific situations in which malpractice premiums have created issues of access to inpatient hospital services for Medicare beneficiaries, some hospitals have expressed concern that they may be compelled to curtail their current operations by the rate of increase in their malpractice premiums. Therefore, in the proposed rule, we invited comments on the effect of increases in malpractice insurance premiums on hospitals participating in the Medicare program, and whether increasing malpractice costs may pose access problems for Medicare beneficiaries.

Comment: Several commenters from individual hospitals and hospital associations commented on the trends in malpractice insurance premiums and the effects, or potential effects, of higher malpractice premiums on access to care. Several of these commenters provided detailed information about the specific experiences of individual hospitals or groups of hospitals.

Response: We appreciate the commenters' responses and especially the detailed information provided by several of the commenters. We will study this information carefully as we continue to consider whether increasing malpractice costs may pose access problems for Medicare beneficiaries.

V. Changes to the PPS for Capital-Related Costs

A. Background

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services "in accordance with a PPS established by the Secretary." Under the statute, the Secretary has broad authority in establishing and implementing the PPS for hospital inpatient capital-related costs. We initially implemented the PPS for capital-related costs in the August 30, 1991 IPPS final rule (56 FR 43358), in which we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

Federal fiscal year (FY) 2001 was the last year of the 10-year transition period established to phase in the PPS for

hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital PPS payments are based solely on the Federal rate for the acute care hospitals (other than certain new hospitals and hospitals receiving certain exception payments). The basic methodology for determining capital prospective payments using the Federal rate is set forth in § 412.312. For the purpose of calculating payments for each discharge, the standard Federal rate is adjusted as follows:

$$\text{(Standard Federal Rate)} \times \text{(DRG Weight)} \times \text{(Geographic Adjustment Factor (GAF))} \times \text{(Large Urban Add-on, if applicable)} \times \text{(COLA Adjustment for hospitals located in Alaska and Hawaii)} \times \text{(1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable)}$$

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year as specified in § 412.312(c) of the existing regulations.

The regulations at § 412.348(f) provide that a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of \$5 million due to extraordinary circumstances beyond the hospital's control. This policy was originally established for hospitals during the 10-year transition period, but as we discussed in the August 1, 2002 IPPS final rule (67 FR 50102), we revised the regulations at § 412.312 to specify that payments for extraordinary circumstances are also made for cost reporting periods after the transition period (that is, cost reporting periods beginning on or after October 1, 2001).

During the transition period, under §§ 412.348(b) through (e), eligible hospitals could receive regular exception payments. These exception payments guaranteed a hospital a minimum payment percentage of its Medicare allowable capital-related costs depending on the class of hospital (§ 412.348(c)), but were available only during the 10-year transition period. After the end of the transition period, eligible hospitals can no longer receive this exception payment. However, even after the transition period, eligible hospitals receive additional payments under the special exceptions provisions at § 412.348(g), which guarantees all eligible hospitals a minimum payment of 70 percent of its Medicare allowable capital-related costs provided that special exceptions payments do not exceed 10 percent of total capital IPPS payments. Special exceptions payments may be made only for the 10 years from the cost reporting year in which the hospital completes its qualifying

project, and the hospital must have completed the project no later than the hospital's cost reporting period beginning before October 1, 2001. Thus, an eligible hospital may receive special exceptions payments for up to 10 years beyond the end of the capital PPS transition period. Hospitals eligible for special exceptions payments were required to submit documentation to the intermediary indicating the completion date of their project. (For more detailed information regarding the special exceptions policy under § 412.348(g), refer to the August 1, 2001 IPPS final rule (66 FR 39911 through 39914) and the August 1, 2002 IPPS final rule (67 FR 50102).)

Under the PPS for capital-related costs, § 412.300(b) of the regulations defines a new hospital as a hospital that has operated (under current or previous ownership) for less than 2 years. (For more detailed information see the August 30, 1991 final rule (56 FR 43418).) During the 10-year transition period, a new hospital was exempt from the capital PPS for its first 2 years of operation and was paid 85 percent of its reasonable costs during that period. Originally, this provision was effective only through the transition period and, therefore, ended with cost reporting periods beginning in FY 2002. Because we believe that special protection to new hospitals is also appropriate even after the transition period, as discussed in the August 1, 2002 IPPS final rule (67 FR 50101), we revised the regulations at § 412.304(c)(2) to provide that, for cost reporting periods beginning on or after October 1, 2002, a new hospital (defined under § 412.300(b)) is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its first 2 years of operation, unless the new hospital elects to receive fully-prospective payment based on 100 percent of the Federal rate. (Refer to the August 1, 2001 IPPS final rule (66 FR 39910) for a detailed discussion of the statutory basis for the system, the development and evolution of the system, the methodology used to determine capital-related payments to hospitals both during and after the transition period, and the policy for providing exception payments.)

B. Payments to Hospitals Located in Puerto Rico

As explained in section III.G. of this preamble, operating PPS and capital PPS payments to hospitals located in Puerto Rico are currently paid based on a blend of the Federal rate and the Puerto Rico rate. The Puerto Rico capital rate is derived from the costs of Puerto Rico hospitals only, while the capital

Federal rate is derived from the costs of all acute care hospitals participating in the IPPS (including Puerto Rico). As also discussed in the section III.G. of this preamble, section 504 of Pub. L. 108-173 increases the national portion of the operating IPPS payment for Puerto Rico hospitals from 50 percent to 75 percent and decreases the Puerto Rico portion of the operating IPPS payments from 50 percent to 25 percent for discharges occurring on or after October 1, 2004. Under the broad authority of section 1886(g) of the Act, for the IPPS for capital-related costs, in the May 18, 2004 proposed rule, we proposed to revise the calculation of capital IPPS payments to hospitals located in Puerto Rico to parallel the change in operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after October 1, 2004. Therefore, we proposed to revise § 412.374 of the regulations to provide that, for discharges occurring on or after October 1, 2004, payments under the IPPS for capital-related costs to hospitals located in Puerto Rico would be based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the capital Federal rate.

We did not receive any comments on our proposal to increase the national portion of the capital IPPS payment for Puerto Rico hospitals from 50 percent to 75 percent and decrease the Puerto Rico portion of the capital IPPS payment from 50 percent to 25 percent beginning in FY 2005. Accordingly, as we proposed, we are revising § 412.374 of the regulations to provide that, for discharges occurring on or after October 1, 2004, payments under the IPPS for capital-related costs to hospitals located in Puerto Rico will be based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the capital Federal rate.

As we noted in the May 18, 2004 proposed rule, this change will increase capital IPPS payments to hospitals located in Puerto Rico because the Federal capital rate is higher than the Puerto Rico capital rate. In addition, we noted that this change is similar to the change in capital IPPS payments made to hospitals located in Puerto Rico beginning in FY 1998 that had paralleled the statutory change in the Puerto Rico blended payment amount required for operating IPPS payments to hospitals located in Puerto Rico as mandated by section 4406 of Public Law 105-33 (62 FR 46012 and 46048, August 29, 1997).

We did not receive any comments on our proposed blend change. Accordingly, we are adopting the

proposed revision of § 412.374 as final without change.

C. Exception Payment for Extraordinary Circumstances

During the transition period, hospitals were guaranteed a minimum payment of a percentage of their Medicare allowable capital-related costs, depending on the class of hospital; that is, the minimum payment level for sole community hospitals was no greater than 90 percent, for urban hospitals with at least 100 beds meeting particular disproportionate share criteria, the minimum payment level was 80 percent, and for all other hospitals, the minimum payment level was 70 percent (§§ 412.348(c)(i) through (iii)). Regular exception payments provided the means to ensure that hospitals received the minimum levels of capital payment. However, any amount by which a hospital's cumulative capital payments exceeded its cumulative minimum payment levels was deducted from the additional exception payment the hospital was eligible to receive (§ 412.348(e)). This type of exception payment ended with the end of the 10-year transition period.

In the August 1, 2002 IPPS final rule (67 FR 50102), we specified that payments to hospitals that incur capital expenditures in excess of \$5 million due to extraordinary circumstances beyond the hospital's control would be made for cost reporting periods after the transition period, that is, cost reporting periods beginning on or after October 1, 2001, as established at § 412.312(e). Generally, the exception payments for extraordinary circumstances are 85 percent of Medicare's share of allowable capital-related costs attributed to the extraordinary circumstances (100 percent for sole community hospitals). This amount is offset by any amount by which a hospital's cumulative payments exceed its cumulative minimum payment levels (adjusted for the extraordinary circumstances) under the PPS for capital-related costs. The minimum payment levels and the offsetting amounts were the same as those established for regular exceptions as indicated at § 412.348(f)(4). The regulation refers to the regular exception minimum payment levels at § 412.348(c)(1) and the offsetting amounts at § 412.348(e)(2).

Because the regulations governing the regular exception payments, which include the minimum payment levels regulations at § 412.348(c) and the offsetting amounts at § 412.348(e), were effective during the transition period only, we had not previously addressed whether or not the minimum payment

levels under § 412.348(c) and the offsetting amounts at § 412.348(e) remain applicable for extraordinary circumstances exceptions in the post-transition period. In the August 1, 2002 IPPS final rule (67 FR 50102), we clarified our policy at a new § 412.312(e) that exception payments for extraordinary circumstances continued to apply to periods beginning on or after October 1, 2001. When we added § 412.312(e), we did not believe it was necessary to explain in the preamble that the minimum payment levels in § 412.348(c) or the offsetting amounts in § 412.348(e) were incorporated into § 412.312(e). However, in order to avoid any confusion, in the May 18, 2004 IPPS proposed rule, we clarified our current policy that, although the minimum payment levels established at § 412.348(c)(1) are no longer in effect, they continue to be relevant in order to calculate the extraordinary circumstances exception payments after the end of the transition period. The extraordinary exception payment calculation incorporates the minimum payment levels as well as the offsetting deduction for cumulative payments. We further indicated that, although the regular exception payments themselves have expired, it has always been our policy that the minimum payment levels will continue to be part of the formula for calculating extraordinary circumstances exception payments after the end of the transition period. In the May 18, 2004 proposed rule, we proposed to amend § 412.312(e) to reflect our current policy that, for cost reporting periods beginning on or after October 1, 2001, the minimum payment levels established at § 412.348(c)(1) are part of the formula for calculating extraordinary circumstances exception payments.

Similarly, in the May 18, 2004 proposed rule, we clarified our current policy that the offsetting amounts established at § 412.348(e)(2) also are part of the formula for determining extraordinary circumstances exception payments after the end of the transition period, in spite of the fact that the regular exception payment provision that included the offsetting amounts at § 412.348(e)(2) expired at the end of the transition period. Accordingly, we proposed to revise § 412.348(e) to clarify that, for cost reporting periods beginning on or after October 1, 2001, the offsetting amounts established at § 412.348(e)(2) remain in effect for extraordinary circumstances exception payments.

In addition, we also proposed to revise the period of time used to determine the offsetting amounts in

§ 412.348(e)(2). Under existing regulations, the additional payment for extraordinary circumstances is offset by any amount by which a hospital's cumulative payments exceed its cumulative minimum payment levels under the IPPS for capital-related costs. In order to determine this offsetting amount, a hospital must keep a record of the difference between its cumulative capital payments and its cumulative minimum payment levels since it became subject to the PPS for capital-related costs. For instance, under existing regulations, if a hospital would be eligible for an additional payment for extraordinary circumstances in FY 2005 and the hospital had been subject to the IPPS for capital-related cost since that IPPS was implemented in FY 1992, the offsetting amount would be the difference in the hospital's cumulative capital payments and its cumulative minimum payment levels for the past 13 years. Similarly, under existing regulations, if a hospital would be eligible for an additional payment for extraordinary circumstances in FY 2012 and the hospital had been subject to the capital IPPS since it was implemented in FY 1992, the offsetting amount would be the difference in the hospital's cumulative capital payments and its cumulative minimum payment levels for the past 20 years.

We believe that when the provisions for exception payments were originally implemented with the start of capital IPPS in FY 1992, it was anticipated that the offsetting amounts at § 412.348(e)(2) would be determined based on a period of no longer than 10 years. However, under existing regulations, exception payments for extraordinary circumstances are offset by the difference in the hospital's cumulative payments and its cumulative minimum payment levels since it became subject to the IPPS for capital-related-costs, which for most hospitals is over 13 years. Therefore, in the May 18, 2004 proposed rule, for cost reporting periods beginning during FY 2005 and thereafter, we proposed to revise § 412.312(e) to specify that the offsetting amounts in § 412.348(e)(2) would be based on the hospital's capital payments and minimum payment levels from the most recent 10 years rather than from the entire period of time the hospital has been subject to the PPS for capital-related costs.

We did not receive any comments on our proposed changes to the provision for exceptions payments for extraordinary circumstances after the transition period. Accordingly, we are revising § 412.312(e) to clarify the minimum payment levels and offsetting

amounts that are applicable in determining exceptions payments for extraordinary circumstances after the transition period. Specifically, as proposed, we are amending § 412.312(e) to specify that the minimum payment levels established at § 412.348(c)(1) are part of the formula for calculating extraordinary circumstances exception payments for cost reporting periods beginning on or after October 1, 2001. In addition, as proposed, we are amending § 412.348(e) to specify that the offsetting amounts established at § 412.348(e)(2) remain in effect for extraordinary circumstances exception payments for cost reporting periods beginning on or after October 1, 2001. As we proposed, we are also amending § 412.312(e) to specify that for cost reporting periods beginning during FY 2005 and thereafter, the offsetting amounts in § 412.348(e)(2) will be based on the hospital's capital payments and minimum payment levels from the most recent 10 years rather than from the entire period of time the hospital has been subject to the PPS for capital-related costs.

Under this finalized policy, if a hospital has been paid under the IPPS for capital-related costs for less than 10 years, the offsetting amounts will be based on the hospital's capital payments and minimum payment levels beginning with the date the hospital became subject to the PPS for capital-related costs. For example, if a hospital is eligible for an additional payment for extraordinary circumstances in FY 2005 and the hospital had been subject to the IPPS for capital-related costs since FY 1992 (13 years), the offsetting amounts used in the calculation of the extraordinary circumstances exception payment will be based on the hospital's cumulative capital PPS payments and cumulative minimum payment levels for the hospital's cost reporting period beginning during FY 1995 through FY 2004. Similarly, if a hospital is eligible for an additional payment for extraordinary circumstances in FY 2005 and the hospital had only been subject to the PPS for capital-related costs since FY 2000 (5 years), the offsetting amounts used in the calculation of the extraordinary circumstances exception payment will be based on the hospital's cumulative capital IPPS payments and cumulative minimum payment levels for the hospital's cost reporting periods beginning during FY 2000 through FY 2004

D. Treatment of Hospitals Previously Reclassified for the Operating IPPS Standardized Amounts

As we discussed in section IV.C. of this preamble, prior to April 1, 2003, the standardized amounts varied under the operating IPPS based on a hospital's geographic location (large urban versus other urban and rural areas). Furthermore, previously, a hospital could be reclassified to a large urban area by the MGCRB for the purpose of the standardized amount if certain criteria were met (as described in Part 412, Subpart L of the Medicare regulations).

Similarly, the standard capital Federal rate under the PPS for capital-related costs is adjusted to reflect the higher costs incurred by hospitals located in large urban areas (large urban add-on at § 412.316), as well as for hospitals in urban areas with at least 100 beds serving low-income patients (capital disproportionate share (DSH) adjustment at § 412.320). In the past, if a rural or other urban hospital was reclassified to a large urban area for purposes of the operating IPPS standardized amount under § 412.63, the hospital also was then eligible for a large urban add-on payment, as well as a DSH payment, under the IPPS for capital-related costs.

Section 402(b) of the Consolidated Appropriations Resolution, 2003, Public Law 108-7, and section 402 of Public Law 108-89, (a Welfare Reform Act), provide that, for discharges occurring on or after April 1, 2003 and before March 31, 2004, under the operating IPPS, all hospitals are paid based on the large urban standardized amount, regardless of geographic location or MGCRB redesignation. Section 401(a) of Public Law 108-173 amended section 1886(d)(5)(A)(iv) by adding a subsection (II) that permanently equalizes the standardized amounts for large urban areas and for other urban and rural areas for discharges occurring on or after April 1, 2004.

In addition, under section 1886(d) of the Act, a hospital may reclassify under the operating IPPS only for the purpose of either its standardized amount or its wage index adjustment, or both. As further specified in regulations at § 412.230, a hospital may be reclassified for purposes of the standardized amount only if the area to which the hospital seeks redesignation has a higher standardized amount than the hospital currently receives. Because there are no longer differences in standardized amounts due to geographic classification as a result of the section 401 amendment, hospitals are no longer

eligible to reclassify solely for standardized amount purposes. Accordingly, as discussed in the May 18, 2004 proposed rule, the MGCRB denied all FY 2005 standardized amount reclassification requests. We note that although Public Law 108-7 and Public Law 108-89 also equalized the standardized amounts for all hospitals in FY 2004, because these laws were not enacted until after the MGCRB had already made its reclassification determinations for FY 2004, eligible hospitals received reclassification approval for the purposes of the standardized amount for FY 2004. However, in this case, Public Law 108-173 was enacted before the MGCRB issued its reclassification decisions for FY 2005. Therefore, we did not propose that any hospital would be reclassified for the purpose of the standardized amounts in FY 2005.

As we explained in the May 18, 2004 proposed rule, the changes to the operating IPPS described above have an effect on payments under the IPPS for capital-related costs. Rural and other urban hospitals that were previously eligible to receive the large urban add-on and DSH payments under the IPPS for capital-related costs if they reclassified to a large urban area for the purpose of the standardized amount under the operating IPPS, will no longer be reclassified, and therefore, will not be eligible to receive those additional payments under the IPPS for capital-related costs.

Our analysis indicates that rural and other urban hospitals will gain approximately \$0.5 billion in FY 2005 in operating IPPS payments due to the equalization of the standardized amounts compared to a relatively small adjustment to payments for capital-related costs under the IPPS. We understand that Congress was aware of the effect of the equalization of the standardized amounts on the rural and other urban hospitals' adjustments under the IPPS for capital-related costs. This approach is consistent with section 4203 of the BBA, which prevented hospitals from reclassifying to a different area to get an additional payment solely for DSH purposes under the operating IPPS. The restriction at section 4203 clearly indicates Congress' intent to maintain the principle that reclassifications under section 1886(d) of the Act are only intended to be made for purposes of either the standardized amount or the wage index adjustment.

Therefore, in the May 18, 2004 proposed rule, we clarified that, beginning in FY 2005, only hospitals geographically located in a large urban area (as defined in proposed revised

§ 412.63(c)(6)) would be eligible for large urban add-on payments under the PPS for capital-related costs under § 412.312(b)(2)(ii) and § 412.316(b). We proposed that, beginning in FY 2005, only hospitals serving low-income patients that are geographically located in an urban area (as defined in proposed new § 412.64 and discussed in section IV.D. of this preamble) with 100 or more beds (or that meet the criteria in § 412.106(c)(2)) would be eligible for DSH payments under the PPS for capital-related costs under § 412.320.

We did not receive any comments on the effect of the equalization of the operating IPPS standardized amounts on payments under the PPS for capital-related costs. Therefore, as we proposed, beginning in FY 2005 and thereafter, only hospitals geographically located in a large urban area (as defined in revised § 412.63(c)(6)) will be eligible for large urban add-on payments under the PPS for capital-related costs under § 412.312(b)(2)(ii) and § 412.316(b). Similarly, as we proposed, beginning in FY 2005 and thereafter, only hospitals serving low-income patients that are geographically located in an urban area (as defined in new § 412.64 and discussed in section IV.D. of this preamble) with 100 or more beds (or that meet the criteria in § 412.106(c)(2)) will be eligible for DSH payments under the PPS for capital-related costs under § 412.320.

E. Geographic Classification and Definition of Large Urban Area

1. Core-Based Statistical Areas

As we discuss in greater detail in section III.B. of this preamble, we are adopting changes to the MSA criteria used to define hospital labor market areas based on the new Core-Based Statistical Areas (CBSA) definitions announced by OMB on June 6, 2003, which are based on 2000 Census data. We currently define hospital labor market areas based on the definitions of Metropolitan Statistical Areas (MSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs) under standards issued by OMB in 1990. In addition, OMB designates Consolidated MSAs (CMSAs). A CMSA is a metropolitan area with a population of one million or more, comprised of two or more PMSAs (identified by their separate economic and social character). Under the operating PPS, the wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. For purposes of the hospital wage index, we use the PMSAs rather than CMSAs

because they allow a more precise breakdown of labor costs. However, if a metropolitan area is not designated as part of a PMSA, we use the applicable MSA.

As we discuss in sections III.B.3. and IV.C. of this preamble, in the May 18, 2004 proposed rule, we proposed to adopt OMB's new CBSA designations to define labor market areas for discharges occurring on or after October 1, 2004, which would be set forth in regulations under a proposed new § 412.64. Currently, the large urban location adjustment under § 412.316(b) and the DSH adjustment for certain urban hospitals under § 412.320 for payments for capital-related costs rely on the existing geographic classifications set forth at § 412.63. Because we proposed to adopt OMB's new CBSA designations for FY 2005 and thereafter, under proposed new § 412.64, we proposed to revise § 412.316(b) and § 412.320(a)(1) to specify that, for discharges on or after October 1, 2004, the payment adjustments under these sections, respectively, would be based on the geographic classifications at proposed new § 412.64.

Comment: One commenter expressed concern that the implementation of the new MSA definitions (proposed § 412.64) will result in some hospitals losing the 3-percent large urban add-on payment adjustment provided for at § 412.316(b) that they previously qualified for under the current MSA definitions (at existing § 412.63). The commenter recommended that we grandfather the large urban add-on payment adjustment for the affected hospitals or, alternatively, maintain the add-on for the affected hospitals for 5 years.

Response: The commenter is correct that as a result of the implementation of the new MSA definitions, hospitals that had previously been located in a large urban area under the current MSA definitions, but will now be located in another urban or rural area under the new MSA definitions will no longer qualify for certain payment adjustments that they previously qualified for under the prior MSA definitions, including the 3-percent large urban add-on payment adjustment at § 412.312(b)(2)(ii) and § 412.316(b). As discussed previously, in the May 18, 2004 proposed rule, we solicited comments on the effect of the equalization of the operating IPPS standardized amount. Specifically, we discussed that rural and other urban hospitals that were previously eligible to receive the large urban add-on payment adjustment (and DSH payment adjustment) under the IPPS for capital-related costs if they reclassified to a

large urban area for the purpose of the standardized amount under the operating IPPS, will no longer be reclassified and, therefore, will not be eligible to receive those additional payments under the IPPS for capital-related costs beginning in FY 2005. As we noted previously, we received no comments on that clarification.

One of the results of the decennial census is that changes in population data may affect a hospital's geographic classification under OMB's standards. We explain in further detail in section III.B. of this preamble the reason for adopting OMB's revised definitions for geographical statistical areas. The OMB announced the new MSAs based on Census 2000 data over a year ago (a copy of the June 6, 2003 announcement may be obtained at the following Internet address: <http://www.whitehouse.gov/omb/bulletins/fy04/b04-03.html>). Although OMB's revised definitions were available early last summer, we did not propose to adopt the changes until FY 2005 so that we could thoroughly assess the impact of adopting these revised geographical criteria.

In section III.B.3.d. of the preamble, we also discuss the establishment of a transition period for the wage index to help mitigate the change from the current MSAs to the new MSAs based on the OMB's revised CBSA definitions. However, as we note below in section III. of the Addendum to this final rule, total payments to hospitals under the IPPS are relatively unaffected by changes in the capital PPS payments since capital IPPS payments constitute about 10 percent of hospital's total (operating and capital) PPS payments and in addition, the changes we proposed are only a small percentage of total capital IPPS payments. The large urban add-on payment adjustment under section § 412.312(b)(2)(ii) and § 412.316(b) provides for an additional payment equal to 3 percent of the amount otherwise payable to the hospital based on the capital Federal rate. Because the large urban add-on payment adjustment is a very small percentage of a hospital's total IPPS payments, we do not estimate a "significant payment implication" to those hospitals that will no longer be eligible for the large urban add-on payment adjustment under the new MSA definitions. Therefore, we do not believe that it is necessary to grandfather or maintain the large urban add-on for the hospitals that previously qualified for that adjustment under the current MSA definitions. As previously discussed, we proposed and adopted as final our policy that, beginning in FY

2005 and thereafter, only those hospitals geographically located in a large urban area (as defined in revised § 412.63(c)(6)) will be eligible for the large urban add-on payment adjustment provided under § 412.312(b)(2)(ii) and § 412.316(b). Similarly, beginning in FY 2005 and thereafter, to receive capital IPPS DSH payments under § 412.320, a hospital will need to be geographically located in an urban area (as defined in new § 412.64) and meet all other requirements of § 412.320. Accordingly, we are adopting our proposed revisions as final without change.

2. Metropolitan Divisions

Under the revised MSA criteria based on CBSAs, a Metropolitan Division is a county or group of counties located within an MSA with a core population of at least 2.5 million, representing an employment center, plus adjacent counties associated with the main county or counties through commuting ties (see section III.B.3.b. of this preamble for further details). In the May 18, 2004 proposed rule, to conform to the proposed changes to the MSA criteria discussed in section III.B. of this preamble, we proposed to use the Metropolitan Divisions where applicable under the CBSA definitions. Thus, similar to our treatment of PMSAs as labor market areas where applicable, we proposed to use the Metropolitan Divisions rather than MSAs to define labor market areas.

Currently, under the existing MSA criteria, a large urban area is defined at existing § 412.63(c)(6) as an MSA with a population of more than 1,000,000 or a NECMA with a population of more than 970,000 based on the most recent available population data published by the Bureau of the Census. As noted above, we currently use the PMSAs rather than CMSAs to define labor market areas. Accordingly, we currently determine large urban areas under existing § 412.63(c)(6) based on the most recent available population data for each PMSA rather than the CMSA. Similarly, because we proposed to treat Metropolitan Divisions of MSAs as labor market areas under the proposed changes based on CBSA designations, we proposed to designate large urban areas based on the most recent available population data for each Metropolitan Division, rather than the MSA.

As discussed in section III.B.3.b. of the proposed rule and this final rule under the CBSA definitions, there are 11 MSAs containing Metropolitan Divisions: Boston; Chicago; Dallas; Detroit; Los Angeles; Miami; New York; Philadelphia; San Francisco; Seattle; and Washington, DC. Within these 11

areas are a total of 29 Metropolitan Divisions, which would be treated as MSAs. Of those 29 MSAs, 23 meet the definition of large urban area under § 412.63(c)(6) (as denoted in Tables 4A and 4B in the Addendum to this final rule). Under the proposed and final changes to the MSA criteria, there are a total of 62 large urban areas, including those 23 Metropolitan Divisions, as denoted in Tables 4A and 4B in the Addendum to this final rule.

In the May 18, 2004 proposed rule, we proposed to clarify that the current definition of large urban area at existing § 412.63(c)(6) would remain in effect for the purpose of the large urban add-on adjustment to the Federal rate under the PPS for capital-related costs under §§ 412.312(b)(2)(ii) and 412.316(b). With the equalization of the operating standardized amounts (as discussed in section IV.D. of this preamble), we proposed to revise the regulations under § 412.63(c), and make them effective for FYs 1984 through 2004, and to add a new § 412.64 that would be applicable for FYs 2005 and thereafter. We indicated that because we would compute a single standardized amount for hospitals located in all areas beginning in FY 2005, the term "large urban area" is no longer applicable under the operating PPS and therefore, a definition of large urban area would not be included under the proposed new § 412.64. However, the term "large urban area" continues to be applicable under the capital IPPS for the large urban add-on adjustment at §§ 412.312(b)(2)(ii) and 412.316(b). Therefore, we proposed to revise §§ 412.312(b)(2)(ii) and 412.316(b) to state that the definition of large urban area set forth at § 412.63(c)(6) would continue to be in effect under the capital PPS for discharges occurring on or after October 1, 2004. In addition, since under the new definitions, NECMAs no longer exist, we clarify as an interpretive matter that the reference in § 412.63(c)(6) to NECMAs will be interpreted as referring to New England MSAs.

We did not receive any comments on our proposed clarification that the current definition of large urban area at existing § 412.63(c)(6) would remain in effect for the purpose of the large urban add-on adjustment to the capital IPPS Federal rate under §§ 412.312(b)(2)(ii) and 412.316(b). Accordingly, as we proposed, we are revising §§ 412.312(b)(2)(ii) and 412.316(b) to state that the definition of large urban area set forth at § 412.63(c)(6) will continue to be in effect under the capital IPPS for discharges occurring on or after October 1, 2004.

VI. Changes for Hospitals and Hospital Units Excluded from the IPPS

A. Payments to Excluded Hospitals and Hospital Units (§§ 413.40(c), (d), and (f))

1. Payments to Existing Excluded Hospitals and Hospital Units

Section 1886(b)(3)(H) of the Act (as amended by section 4414 of Public Law 105–33) established caps on the target amounts for certain existing hospitals and hospital units excluded from the IPPS for cost reporting periods beginning on or after October 1, 1997 through September 30, 2002. For this period, the caps on the target amounts (as defined at § 413.40(c)(4)(iii)(B)) applied to the following three classes of excluded hospitals or units: psychiatric hospitals and units, rehabilitation hospitals and units, and LTCHs. In accordance with section 1886(b)(3)(H)(i) of the Act and effective for cost reporting periods beginning on or after October 1, 2002, payments to these classes of existing excluded hospitals or hospital units are no longer subject to caps on the target amounts.

In accordance with existing §§ 413.40(c)(4)(ii) and (d)(1)(i) and (ii), where applicable, excluded psychiatric hospitals and units continue to be paid on a reasonable cost basis, and payments are based on their Medicare inpatient operating costs, not to exceed the ceiling, up to the date that an inpatient psychiatric facility PPS discussed in section VII.A. of this preamble becomes effective. The ceiling is computed using the hospital's or unit's target amount from the previous cost reporting period, updated by the rate-of-increase specified in § 413.40(c)(3)(viii) of the regulations, and then multiplying this figure by the number of Medicare discharges.

Effective for cost reporting periods beginning on or after October 1, 2002, rehabilitation hospitals and units are paid in accordance with the IRF PPS at 100 percent of the Federal rate. In addition, effective for cost reporting periods beginning on or after October 1,

2002, LTCHs are no longer paid on a reasonable cost basis, but are paid under a DRG-based PPS. However, as part of the PPS for LTCHs, we established a 5-year transition period from reasonable cost-based reimbursement to a fully Federal PPS. Under the LTCH PPS, a LTCH that is subject to the blend methodology may elect to be paid 100 percent of the Federal prospective rate. We have proposed, but not finalized, an inpatient psychiatric facility (IPF) prospective payment system under which psychiatric hospitals and psychiatric units would no longer be paid on a reasonable cost basis but would be paid on a prospective per diem basis. (Sections VI.A.3, 4, and 5 of this preamble contain a more detailed discussion of the IRF PPS, the LTCH PPS and the proposed IPF PPS.)

2. Updated Caps for New Excluded Hospitals and Units

Section 1886(b)(7) of the Act established a payment limitation for new psychiatric hospitals and units, rehabilitation hospitals and units, and long-term care hospitals that first receive payment as a hospital or unit excluded from the IPPS on or after October 1, 1997. A discussion of how the payment limitation was calculated can be found in the August 29, 1997 final rule with comment period (62 FR 46019); the May 12, 1998 final rule (63 FR 26344); the July 31, 1998 final rule (63 FR 41000); and the July 30, 1999 final rule (64 FR 41529).

The amount of payment for a "new" psychiatric hospital or unit (as defined at 42 CFR 413.40(f)(2)(ii)) will be determined as follows:

- Under existing § 413.40(f)(2)(ii), for the first two 12-month cost reporting periods, the amount of payment is the lesser of: (1) The operating costs per case; or (2) 110 percent of the national median (as estimated by the Secretary) of the target amounts for the same class of hospital or unit for cost reporting periods ending during FY 1996, updated by the hospital market basket increase

percentage to the fiscal year in which the hospital or unit first receives payments under section 1886 of the Act, as adjusted for differences in area wage levels. The amount of payment, as determined above, is also referred to as a payment limitation or target amount since the payment for the first 2 years of a hospital or unit cannot exceed the amount determined under § 413.40(f)(2)(ii).

- Under existing § 413.40(c)(4)(v), for cost reporting periods following the hospital's or unit's first two 12-month cost reporting periods, the target amount is equal to the amount determined under § 413.40(f)(2)(ii) for the preceding cost reporting period, updated by the applicable hospital market basket increase percentage to the third cost reporting period.

The amounts included in the following table are the payment amounts (or payment limitations) reflecting the updated 110 percent of the national median target amounts of new excluded psychiatric hospitals and units. The payment amount is for cost reporting periods beginning during FY 2005. These figures have been updated with the most recent data available to reflect the projected market basket increase percentage of 3.3 percent. This projected percentage change in the market basket reflects the average change in the price of goods and services purchased by hospitals to furnish inpatient hospital services (as projected by the Office of the Actuary of CMS based on its historical experience with the IPPS). For a new provider, the labor-related share of the target amount is multiplied by the appropriate geographic area wage index, without regard to IPPS reclassifications, and added to the nonlabor-related share in order to determine the per case payment limitation on payment under the statutory payment methodology for new providers (section 1886(b)(7)(A)(i) of the Act and § 413.40(f)(2)(ii) of the regulations).

Class of Excluded Hospital or Unit	FY 2005 Labor-Related Share	FY 2005 Nonlabor-Related Share
Psychiatric	\$7,535	\$2,995

Effective for cost reporting periods beginning on or after October 1, 2002, this payment limitation was no longer applicable to new LTCHs as defined under § 412.23(e)(4), since LTCHs with

a first cost reporting period beginning on or after October 1, 2002, are paid 100 percent of the Federal rate for LTCH PPS. However, new LTCHs, as defined under § 413.40(f)(2)(ii), which were paid

as LTCHs before the effective date of the LTCH PPS, were eligible for a blended payment for up to 5 years under the LTCH PPS for cost reporting periods beginning on or after October 1, 2002.

Those hospitals would have had their payments determined using the payment limitation for use in determining the TEFRA portion of this blend. However, an update of this payment limitation is no longer necessary after FY 2002 because the same payment limitation published for FY 2002 was effective for 2 years for "new" LTCHs as defined under § 413.40(f)(2)(ii), including those "new" LTCHs with a first cost reporting period beginning in FY 2002. A target amount would be determined for any subsequent years that those "new" LTCHs were eligible for a blended payment under the LTCH PPS.

Thereafter, the LTCH is paid under the LTCH PPS. Accordingly, since a new hospital established on or after October 1, 2002 is no longer subject to this payment limitation and any new hospital as defined at § 413.40(f)(2)(ii) would also not have its FY 2002 payment limitation for new LTCHs as defined under § 413.40(f)(2)(ii).

A freestanding inpatient rehabilitation hospital, an inpatient rehabilitation unit of an acute care hospital, and an inpatient rehabilitation unit of a CAH are collectively referred to as an IRF.

Effective for cost reporting periods beginning on or after October 1, 2002, this payment limitation is also no longer applicable to new rehabilitation hospitals and units because they are paid 100 percent of the Federal prospective rate under the IRF PPS. Therefore, it is also no longer necessary to update the payment limitation for new rehabilitation hospitals or units.

3. Implementation of a PPS for IRFs

Section 1886(j) of the Act, as added by section 4421(a) of Public Law 105-33, provided for the phase-in of a case-mix adjusted PPS for inpatient hospital services furnished by a rehabilitation hospital or a rehabilitation hospital unit (referred to in the statute as rehabilitation facilities) for cost reporting periods beginning on or after October 1, 2000, and before October 1, 2002, with a fully implemented PPS for cost reporting periods beginning on or after October 1, 2002. Section 1886(j) of the Act was amended by section 125 of Public Law 106-113 to require the Secretary to use a discharge as the payment unit under the PPS for inpatient hospital services furnished by rehabilitation facilities and to establish classes of patient discharges by functional-related groups. Section 305 of Public Law 106-554 further amended section 1886(j) of the Act to allow rehabilitation facilities, subject to the blend methodology, to elect to be paid the full Federal prospective payment

rather than the transitional period payments specified in the Act.

On August 7, 2001, we issued a final rule in the **Federal Register** (66 FR 41316) establishing the PPS for inpatient rehabilitation facilities, effective for cost reporting periods beginning on or after January 1, 2002. There was a transition period for cost reporting periods beginning on or after January 1, 2002 and ending before October 1, 2002. For cost reporting periods beginning on or after October 1, 2002, payments are based entirely on the Federal prospective payment rate determined under the IRF PPS.

4. Implementation of a PPS for LTCHs

In accordance with the requirements of section 123 of Public Law 106-113, as modified by section 307(b) of Public Law 106-554, we established a per discharge, DRG-based PPS for LTCHs as described in section 1886(d)(1)(B)(iv) of the Act for cost reporting periods beginning on or after October 1, 2002, in a final rule issued on August 30, 2002 (67 FR 55954). The LTCH PPS uses information from LTCH hospital patient records to classify patients into distinct LTC-DRGs based on clinical characteristics and expected resource needs. Separate payments are calculated for each LTC-DRG with additional adjustments applied.

We published in the **Federal Register** on May 7, 2004, a final rule (69 FR 25673) that updated the payment rates for the LTCH PPS and made policy changes effective for a new LTCH PPS rate year of July 1, 2004, through June 30, 2005. The 5-year transition period from reasonable cost-based reimbursement to the fully Federal prospective rate will end with cost reporting periods beginning on or after October 1, 2005 and before October 1, 2006.

5. Development of a PPS for IPFs

Section 124 of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) requires the development of a per diem prospective payment system (PPS) for payment of inpatient hospital services furnished in psychiatric hospitals and psychiatric units of acute care hospitals (inpatient psychiatric facilities (IPFs)). We published a proposed rule to implement the IPF PPS on November 28, 2003 (68 FR 66920). We published a proposed rule to implement the IPF PPS on November 28, 2003 (68 FR 66920). On January 30, 2004, we published a notice to extend the comment period for 30 additional days (69 FR 4464). The comment period closed on March 26, 2004.

Under the proposed rule, we would compute a Federal per diem base rate to be paid to all IPFs based on the sum of the average routine operating, ancillary, and capital costs for each patient day of psychiatric care in an IPF adjusted for budget neutrality. The Federal per diem base rate would be adjusted to reflect certain characteristics such as age, specified DRGs, and selected high-cost comorbidities, and certain facility characteristics such as wage index adjustment, rural location, and indirect teaching costs.

The November 28, 2003 proposed rule assumed an April 1, 2004 effective date for the purpose of ratesetting and calculating impacts. However, we are still in the process of analyzing public comments and developing a final rule for publication. The effective date of the IPF PPS would occur 5 months following publication of the final rule.

6. Technical Changes and Corrections

a. Change Related to Establishment of Payments for Excluded Hospitals

We have become aware of a number of technical errors in the existing regulations governing how we determine payments to hospitals that are excluded from the IPPS. The existing regulations under § 413.40 set forth requirements for establishing the ceiling on the rate of increase in operating costs per case for hospital inpatient services furnished to Medicare beneficiaries that will be recognized as reasonable for purposes of determining the amount of Medicare payments. The rate-of-increase ceiling applicable to cost reporting periods has been adjusted a number of times since it was first applied for hospital cost reporting periods beginning on or after October 1, 1982. In revising the regulations over the years to reflect the different applicable adjustments for cost reporting periods for specific providers, we have inadvertently overlooked updating or conforming § 413.40 to reflect various statutory changes. We note that, although we erroneously omitted the technical changes in the regulation text, we did, in fact, comply with the changes required by the statute when determining the rate-of-increase ceiling. Therefore, in the May 18, 2004 proposed rule (69 FR 28323), we proposed to make several changes to § 413.40(c)(4)(iii) in order to conform it to section 1886(b)(3)(J) of the Act. These changes are as follows: (1) In § 413.40(c)(4)(iii)(A)(1) and (c)(4)(iii)(B)(4)(i), the phrase "on or after October 1, 2001", should read "during FY 2001"; and in § 413.40(c)(4)(iii)(A)(2), the phrase "on

or after October 1, 2000" should read "during FY 2001". In order to include pertinent changes that were erroneously omitted from the regulatory text and to conform the text to section 1886(b)(2)(A) of the Act, we proposed to delete the phrase "and ending before October 1, 2000" in § 413.40(d)(4)(i) because, in section 1886(b)(2)(A) of the Act, there is no ending date for the continuous improvement bonus payment. In addition, at § 413.40(d)(4)(ii), we proposed to delete the word "ending" from the introductory phrase so that the phrase would read, "For cost reporting periods beginning on or after October 1, 2000 and before September 30, 2001." The word "ending" in the existing language at best limits the provision to cost reporting periods beginning on October 1, 2000. The provision was intended to apply to cost reporting periods beginning during all of FY 2001.

We did not receive any public comments on this proposal and, therefore, are adopting it as final without modification.

b. Technical Correction Related to Long-Term Care Hospitals

In the June 6, 2003 **Federal Register** (68 FR 34122), we published a final rule establishing the annual update of the payment rates for the Medicare prospective payment system for inpatient hospital services provided by LTCHs. In that final rule, we added a new paragraph (h)(6) to §§ 412.22. This paragraph eliminated the bed size

limitation for pre-1997 LTCHs with satellite facilities once the LTCH is paid at 100 percent of the Federal rate.

In the August 1, 2003 **Federal Register** (68 FR 45674), we published a final rule that established the annual update for payment rates for the Medicare prospective payment system for inpatient hospital services provided by IRFs. The IRF PPS final rule added a new paragraph (h)(7) to §§ 412.22. Through an inadvertent error, in the August 1, 2003 IRF PPS final rule, we removed and reserved §§ 412.22(h)(6) that was added by the June 6, 2003 LTCH PPS final rule. Therefore, we are correcting this error by adding a new paragraph §§ 412.22(h)(6) to reinstate the regulatory language from the June 6, 2003 LTCH PPS final rule.

7. Report of Adjustment (Exception) Payments

Section 4419(b) of Public Law 105-33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment (exception) payments made to excluded hospitals and units, by reason of section 1886(b)(4) of the Act, during the previous fiscal year.

The process of requesting, adjudicating, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, an excluded hospital or unit must file its cost report for a fiscal year with its intermediary within 5 months after the close of its cost reporting period. The fiscal intermediary then reviews the cost

report and issues a Notice of Program Reimbursement (NPR) within approximately 2 months after the filing of the cost report. If the hospital's operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment within 6 months from the date of the NPR. The intermediary, or CMS, depending on the type of adjustment requested, then reviews the request and determines if an adjustment payment is warranted. This determination is often not made until more than 6 months after the date the request is filed. Therefore, it is not possible to provide data in this final rule. However, in an attempt to provide interested parties with data on the most recent adjustments for which we do have data, we are publishing data on adjustments that were processed by the fiscal intermediary or CMS during FY 2003.

The table below includes the most recent data available from the fiscal intermediaries and CMS on adjustment payments that were adjudicated during FY 2003. As indicated above, the adjustments made during FY 2003 only pertain to cost reporting periods ending in years prior to FY 2002. Total adjustment payments awarded to excluded hospitals and units during FY 2003 are \$11,931,305. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating cost over ceiling, and the amount of the adjustment payment.

Class of Hospital	Number	Excess cost over ceiling	Adjustment payments
Rehabilitation	15	\$10,020,001	\$4,320,038
Psychiatric	18	9,853,039	5,233,873
Long-Term Care	1	2,052,853	1,545,245
Children's	--	--	--
Cancer	1	9,014,031	832,149
Christian Science	--	--	--

B. Criteria for Classification of Hospitals-Within-Hospitals

Existing regulations at § 412.22(e) define a hospital-within-a-hospital as a hospital that occupies space in a building also used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital. Moreover, existing § 412.22(f) provides for the grandfathering of hospitals-within-a-hospitals that were in existence on or before September 30, 1995.

One of the goals of our hospital-within-a-hospital regulations at § 412.22(e) has been to prevent a LTCH co-located with an acute care hospital to function as a unit of that hospital, a situation precluded under section 1886(d)(1)(B) of the Act. This policy protects the integrity of the IPPS by ensuring that costly, long-stay patients who could reasonably continue treatment in that setting would not be unnecessarily discharged to an onsite LTCH, a behavior that would skew and undermine the Medicare IPPS DRG system. Further, there is concern that

the hospital-within-hospital configuration could result in patient admission, treatment, and discharge patterns that are guided more by attempts to maximize Medicare payments than by patient welfare. We believe that the unregulated linking of an IPPS hospital and a hospital excluded from the IPPS could lead to two Medicare payments for what was essentially one episode of patient care.

In the September 1, 1994 IPPS final rule (59 FR 45389), we first discussed hospitals-within-hospitals, describing them as entities that were manipulating

the conditions of participation (COPs) for hospitals under Medicare, set forth in regulations at 42 CFR Part 482, to permit them to receive exclusion from the prospective payment systems. Specifically, these hospitals have begun to organize what they themselves refer to as the 'hospital-within-a-hospital' model. Under this model, an entity may operate in space leased from a hospital, and have most or all services furnished under arrangements by employees of the lessor hospital. The newly organized entity may be operated by a corporation formed and controlled by the lessor hospital, or by a third entity that controls both. In either case, the new entity seeks State licensure and Medicare participation as a hospital, demonstrates that it has an average length of stay of over 25 days, and obtains an exclusion from the IPPS. The effect of this process is to extend the long-term care hospital exclusion to what is, for all practical purposes, a "long-term care unit." We noted that the averaging concept that underlies the IPPS recognizes that some patients will stay longer and consume more resources than expected, while others will have shorter, less costly stays. We envisioned that abuse of the PPSs could result if an acute care hospital under the IPPS "diverted all long-stay cases to the excluded unit, leaving only shorter, less costly cases to be paid for under the IPPS. In such cases, hospitals would profit inappropriately from prospective payments." Further, we stated that we believed that the "exclusion of long-term care 'units' was inconsistent with the statutory scheme." Section 1886(d)(1)(B) of the Act clearly provides for an exclusion of LTCHs from the acute care IPPS. While the statute also provides for an exclusion for psychiatric units and rehabilitation units, it does not provide for an exclusion of long-term care units. (59 FR 45389)

In addition, in that September 1, 1994 final rule, we proceeded to establish "separateness and control" regulations at (then) § 412.23(e) that required the two hospitals to have separate medical and administrative governance and decision-making and also ensured that each hospital operated as a separate facility. We believed at that time that such rules were sufficient solutions to our concerns about these new entities and, therefore, we did not preclude common ownership of the host and the LTCH at that time.

In the ensuing decade, we have revisited the issue of hospitals-within-hospitals several times (for example, 60 FR 45836, September 1, 1995; 62 FR 46012, August 29, 1997; 67 FR 56010, August 30, 2002; 68-7 FR 45462, August

1, 2003) during which we clarified and amplified the separateness and control requirements. In the August 29, 1997 IPPS final rule, we extended the application of these rules beyond LTCHs to include other classes of facilities that might seek exclusion from the IPPS as hospitals-within-hospitals, such as IRFs. In addition, in the August 29, 1997 final rule, we also established a "grandfathering" provision for hospitals-within-hospitals in existence prior to September 30, 1995, at § 412.22(f), and in the August 1, 2003 IPPS final rule, we clarified and codified the requirements for "grandfathered" hospitals-within-hospitals (68 FR 45463).

As stated earlier, presently, a hospital-within-a-hospital must meet the separateness and control criteria set forth at § 412.22(e). In order to be excluded from the IPPS, the hospital-within-a-hospital must have a separate governing body, a separate chief medical officer, a separate medical staff, and a separate chief executive officer. Regarding the performance of basic hospital functions (§ 412.22(e)(5)), currently, the hospital must meet at least one of the following criteria: (i) The hospital performs the basic functions through the use of employees or under contracts or other agreements with entities other than the hospital occupying space in the same building or on the same campus, or a third entity that controls both hospitals; (ii) for the same period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the cost of the services that the hospital obtained under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals, is no more than 15 percent of the hospital's total inpatient operating costs, as defined in § 412.2(c) (that is, inpatient operating costs include operating costs for routine services, such as costs of room, board, and routine nursing services; operating costs for ancillary services such as laboratory or radiology; special care unit operating costs; malpractice insurance costs related to serving inpatients; and preadmission services); or (iii) for the same period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the hospital has an inpatient population of whom at least 75 percent were referred to the hospital from a source other than another hospital occupying space in the same building or on the same campus or with

a third entity that controls both hospitals.

It is our experience that the vast majority of hospitals-within-hospitals have elected to meet the second of the three criteria at § 412.22(e)(5), that is, the cost of the services that the hospital obtained from the co-located hospital or with a third entity that controls both hospitals is no more than 15 percent of its total inpatient operating costs. In establishing the 15-percent rule, we originally believed that we would be able to detect a true corporate identity and actual function and to guard against an arrangement that could undermine the statutory preclusion of long-term care units. We sought to distinguish admissions to independently operating facilities from what were, in effect, transfers of patients from one unit of the corporation to another unit of the corporation without a truly distinct and separate corporate identity. Our underlying policy rationale was that, if an entity could not be separately identified, it effectively would be functioning as a mere unit of the parent entity in violation of the statutory prohibition on long-term care units. We explained in the September 1, 1994 rule (59 FR 45390) that "if an entity is effectively part of another hospital and the principles of the prospective payment system do apply well to the organization as a whole, then it would not be appropriate to exclude part of that organization from the prospective payment system."

Although we have periodically revisited the phenomenon of hospitals-within-hospitals in our rules and we have revised or clarified some related issues, we have not proposed significant changes in our policies in this area for some time. This is despite the significant changes that have been made in the payment systems for Medicare-certified, excluded hospitals and units. Medicare payments to two types of IPPS-excluded hospitals, LTCHs and IRFs, are now made on a prospective basis. We believe that, in part, the new LTCH PPS is one of the reasons for the rapidly increasing number of LTCH hospitals-within-hospitals. In its June 2003 Report to the Congress, MedPAC identified hospitals-within-hospitals as the fastest growing type of LTCHs, and specified that the number had grown from 10 in 1993 to 114 in 2002, an average annual increase of approximately 30 percent (p. 85). In the August 30, 2002 final rule that implemented the PPS for LTCHs, we noted that " * * * we remain extremely concerned about rapid growth in LTCH hospitals-within-hospitals and will be collecting data on the relationship

among host hospitals, hospitals-within-hospitals, and parent corporations in order to determine the need for additional regulation” (67 FR 56010). We indicated that if, as a consequence of these monitoring activities, we determine the need to revisit existing regulations dealing with ownership and control of hospitals-within-hospitals, we would follow the notice and comment rulemaking process (67 FR 56011).

The LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002. We have gathered considerable anecdotal information from inquiries from the provider community, fiscal intermediaries, and, particularly, from the survey and certification divisions of our CMS Regional Offices.

As we had indicated in the May 18, 2004 proposed rule (69 FR 28323 through 28327), we believe that existing policies regarding hospitals-within-hospitals do not sufficiently protect the Medicare program from the problems that we envisioned in the September 1, 1994 final rule. We also questioned the effectiveness of the “separateness and control” requirements alone because entities have used complex arrangements among corporate affiliates, and obtained services from those affiliates, thereby impairing or diluting the separateness of the corporate entity. While technically remaining within the parameters of the rule, these arrangements have intermingled corporate interests so that the corporate distinctness has been lost.

In corporate law, several standards are used to determine how much separateness is sufficient for corporate autonomy to be recognized. The courts have applied a number of tests and considered a number of factors in determining when a parent corporation is liable for the acts of its subsidiary, including the parent corporation’s exercise of control over the decision making of the subsidiary; the subsidiary’s actions as an alter ego of the parent corporation such that recognition of a distinct corporate entity would lead to fraud or an injustice or would defeat public policy and the interrelatedness of operations. While we do not believe that it is necessary to apply any single test that might be used in the context of assigning liability, we believe that some of the same considerations apply when trying to determine whether there is functional separateness among related or affiliated organizations.

The requirement for separate governing bodies, separate medical boards, separate medical officers, and separate chief executive officers in co-

located hospitals under the same ownership does not prevent, on a practical level, the establishment of admission, treatment, and discharge policies that maximize payments. Some of these co-located facilities are under common ownership, either nonprofit or for profit, and, therefore, the payments generated from care delivered at both settings affect their mutual interests. Even when the hospital-within-a-hospital and the host hospital are separately owned, we believe that there may have been incentives to prematurely discharge patients to a post-acute care setting in spite of the fact that the acute care hospital could continue to provide the appropriate level of care. We found this situation even more troubling regarding LTCHs, in particular, because LTCHs are certified as acute care hospitals and the statutory and regulatory distinction between LTCHs and acute care hospitals is generally the greater than 25-day average length of stay criterion at § 412.23(e)(2). In many parts of the country, there are no LTCHs and appropriate care for patients who could otherwise be treated in LTCHs is being delivered in acute care hospitals, often followed by post-acute care at SNFs. Because a similar level of care is often available in either an acute care hospital or a LTCH, we believe that, when an acute care hospital and a LTCH are co-located, there are significant inducements for patients to be moved to the provider setting that generates the highest Medicare payments.

This movement of patients is facilitated by the fact of co-location because, rather than arranging for the patient to be admitted to another offsite facility and transporting the patient by ambulance to another hospital, all that may actually be required to “discharge” the patient from one hospital and admit the patient to another is wheeling the patient down the hall or on and off an elevator.

Although co-location of Medicare providers, at best, may embody the positive economic benefits of sharing expensive medical equipment and provide a measure of convenience for patient families, at worst, co-location and patient-shifting can serve to undermine the basic premise of the IPPS DRG classification system and generate inappropriate Medicare payments. This is the case because payment for specific diagnoses is determined by setting DRG weights that represent a national averaging of hospital costs for each diagnosis. In addition, the Federal standardized payment amount was based on the average cost of a patient across all hospitals. This assumes that,

on average, both high-cost and low-cost patients are treated at a hospital. Although Medicare might pay a hospital less than was expended for a particular case, over a period of time, the hospital would also receive more than was expended for other cases. However, an acute care hospital that consistently discharges a higher cost patient to a post-acute care setting for the purpose of lowering its costs undercuts the foundation of the IPPS DRG system, which is based on averages. In this circumstance, the hospital would recoup larger payments from the Medicare system than is intended under the DRG system because the course of acute treatment has not been completed. At the same time, the patient, still under active treatment for an acute illness, will be admitted to a LTCH, thereby generating a second admission and Medicare payment that would not have taken place but for the fact of co-location.

In the May 18, 2004 proposed rule, we indicated that we believe the 15-percent policy is being sidestepped through creative corporate reconfigurations. Therefore, if the LTCH is nominally complying with the 15-percent requirement, it has not been required to meet the basic hospital function requirements at existing § 412.22(e)(5)(iii). Thus, it is free to accept even 100 percent of patients from the onsite host, and share the same basic hospital functions as the host. Reliance on meeting the 15-percent criterion has enabled the creation of LTCH hospitals-within-hospitals that rely upon affiliated entities both for their operations and for their patient referrals. This results in a situation very similar to the hospital-within-hospital serving as a LTCH unit of the acute care hospital, which is precluded by the statute.

One of the reasons we proposed revisions to the existing criteria for hospitals-within-hospitals in the May 18, 2004 proposed rule was because we believe that determining whether a hospital has complied with the 15-percent criterion is burdensome for a fiscal intermediary on an ongoing basis. Presently, review of corporate arrangements represents a snapshot in time that may assess a particular set of business transactions but does not provide relevant details to reveal the extent of the unity of interests between the parties over time. Further, the widespread existence of such complex configurations, as well as the ongoing creation of new business arrangements, convinced us that a hospital-within-a-hospital’s compliance with § 412.22(e)(5)(ii) may be fluid,

unreliable, or, in some cases, nonexistent.

Another reason we proposed revisions to the existing criteria for hospitals-within-hospitals in the May 18, 2004 proposed rule is because the concerns that we expressed in 1994 and 1995, when excluded hospitals were paid under the reasonable cost-based TEFRA system, are even more compelling with the implementation of PPSs for LTCHs and IRFs, because now one episode of care for a beneficiary could generate two full Medicare prospective payments, one under the IPPS, and another under the applicable excluded hospital PPS. In addition, the substantial increase in the number of hospitals-within-hospitals adds further urgency to reevaluation of the existing hospital-within-a-hospital policies. Therefore, it is incumbent upon us to revise our regulations in order to offer the greatest possible protection against potential abuses.

Accordingly, for qualification purposes, we proposed to delete the 15-percent criterion at § 412.22(e)(5)(ii) and the rarely elected criterion at § 412.22(e)(5)(i) that required the hospital-within-a-hospital to perform basic hospital functions, which include nursing services, medical records, pharmacy services, radiology, laboratory services, infection control, and discharge planning, through the use of employees or under contracts or other agreements with entities other than the host hospital or a third entity that controls them both. Because we believe that efficient use of excess space at a hospital and the sharing of medical facilities and services may represent the strongest argument for the existence of hospitals-within-hospitals, from the standpoint of efficiency and cost reduction, we do not believe that these criteria should be maintained.

We proposed that all hospitals-within-hospitals would be required to comply only with the criterion set forth at the existing § 412.22(e)(5)(iii), which requires that at least 75 percent of the admissions to the hospital-within-a-hospital be referred from a source other than the host hospital. We believe that this "functional separateness" test (62 FR 46014, August 29, 1997) directly addresses our concern that the excluded hospital not function either as a vehicle to generate more favorable Medicare reimbursement for each provider or as a de facto unit. Compliance with the 75-percent criterion is a requirement that we can verify without the involvement of corporate attorneys and a yearly reevaluation of corporate documents and transactions. The goal of the proposed provisions was to diminish the possibility that a hospital-within-a-

hospital could actually be functioning as a unit of an acute care hospital and generating unwarranted payments under the much more costly LTCH PPS.

Therefore, under the proposed policy in the May 18, 2004 proposed rule, a hospital must demonstrate that it has a separate governing body, a separate chief medical officer, and a separate chief executive officer, and that at least 75 percent of its admissions originate from a source other than its host hospital, in order to be totally excluded from the IPPS. Fiscal intermediaries would reevaluate compliance with these regulations annually. In implementing our belief that separation and control can best be objectively determined by limiting compliance to the 75-percent criterion as the single "performance of hospital functions" test, we proposed several policy options that are detailed below that, if not met, notwithstanding compliance with the separate governance and control requirements under existing § 412.22(e)(1) through (4), could result in the either total discontinuance of IPPS-exclusion payment status or Medicare payment adjustments for hospital-within-a-hospital patients from the host hospitals.

As noted above, DRG weights and hence payments under the IPPS are established annually based on the average concept that recognizes that, for patients with a particular diagnosis, some will stay longer and consume more hospital resources than expected, while others will have shorter, less costly stays. Under the IPPS, a full DRG payment is triggered on the first day of admission to the acute care hospital. Medicare adopted an IPPS transfer policy at § 412.4(b) in order to pay appropriately for cases that were discharged to other IPPS hospitals prior to the hospitals delivering full treatment to a beneficiary. We also promulgated the post-acute care transfer policy at §§ 412.4(c) and (d) to discourage premature transfers or discharges from IPPS hospitals for particular DRGs to post-acute care settings, including LTCHs (63 FR 40977, July 31, 1998, 68 FR 45469, August 1, 2003). The issues that we addressed in formulating the acute and post-acute care transfer policies are similar to those we are raising as our present concerns: that the incentives of the IPPS could result in acute care hospitals shifting a portion of the cost of services that should reasonably be treated in that setting to other providers; that the acute care hospitals would still collect a full DRG payment under the IPPS for less than a full course of treatment; and that an additional and unnecessary Medicare

payment would be made to the second provider. We believe that the potential for linking clinical decisions to the highest Medicare payments is even stronger when the acute care hospital and a postacute care provider are collocated and, even more so, if they are also under common ownership.

Therefore, in the May 18, 2004 proposed rule, we also proposed to revise § 412.22(e), effective October 1, 2004, to preclude common ownership (wholly or in part) of hospitals-within-hospitals and host hospitals (proposed new § 412.22(e)(2)(ii)). However, we also proposed to "grandfather" those hospitals-within-hospitals that were under common ownership with their host hospitals prior to June 30, 2004, and to continue to pay them as hospitals excluded from the IPPS, as long as they comply with the existing control criteria at § 412.22(e)(1) through (4) (as set forth in proposed new § 412.22(e)(2)(i)) and with the proposed mandatory 75-percent criterion (as set forth in proposed new § 412.22(e)(2)(iii)).

In addition, in the May 18, 2004 proposed rule, we presented, for public comment, three payment options that we believe would diminish the possibility of a hospital-within-a-hospital actually functioning as a unit of an acute care hospital and at the same time generating unwarranted payments under the more costly LTCH PPS.

Option 1. Under the first option, as discussed earlier, in order for a hospital-within-a-hospital to receive payment as an IPPS-excluded hospital, we proposed to retain as the only qualifying criterion that the hospital-within-a-hospital have at least 75 percent of its admissions from a source other than the host hospital (existing § 412.22(e)(5)(iii)). The hospital-within-a-hospital would still be required to demonstrate that it meets the separateness and control criteria at § 412.22(e-). Under this option, a hospital-within-hospital that admitted more than 25 percent of its patients from the host hospital would not be paid as an IPPS-excluded hospital for any of its patients. The hospital or unit that does not meet the criteria under this option would receive payment as an acute care hospital for all of its patients.

As stated earlier, we believe that compliance with the 75-percent criterion under this option is a requirement that fiscal intermediaries would be able to evaluate annually in an efficient manner without the involvement of corporate attorneys and a yearly reevaluation of corporate documents and transactions. Further, we believe that this option would ensure increased protections to the

Medicare program and greatly diminish opportunities for maximizing Medicare payments under the PPS.

Option 2. Under the second option, as we had proposed earlier, we would require the hospital to meet the existing qualifying 75-percent criterion under § 412.22(e)(5)(iii). However, under this option, we would allow a hospital-within-a-hospital that failed to meet the 75-percent criterion to be paid as a PPS-excluded hospital only for the patients admitted to the hospital-within-a-hospital from providers other than the host hospital. For example, no payments would be made to a LTCH for those patients that had been transferred to the LTCH from the host hospital because it failed to meet this criterion. Payments for patients referred from the host hospitals would only be paid to the host under the IPPS. We would treat services provided by the hospital-within-a-hospital as services furnished "under arrangement." Therefore, in keeping with our existing policy at § 411.15(m) that restricts separate Medicare payment to hospital services furnished under arrangements, we would make payment only to the acute care hospital from which the patients were referred for "under arrangements" furnished by the hospital-within-a-hospital.

Option 3. Under the third option, as we proposed earlier, we would require that the hospital-within-a-hospital must meet the existing qualifying 75-percent criterion under § 412.22(e)(iii). However, under this option, we would pay the hospital-within-a-hospital directly for services, even for services provided to patients admitted to the hospital-within-a-hospital from the co-located acute care hospital. However, the payment to the hospital-within-a-hospital for those patients would be the lesser of what would be paid under the IPPS for that DRG, or what would be paid to the hospital-within-a-hospital under the applicable excluded hospital payment system. Payments to the hospital-within-a-hospital for patients admitted to the hospital-within-a-hospital from another hospital that was not the co-located hospital would be made under the hospital-within-a-hospital payment system with no adjustment. Therefore, for example, a LTCH that was a hospital-within-a-hospital and failed to meet the 75-percent criterion would be paid the lesser of the IPPS payment or the LTCH PPS payment for its patients that were admitted from its host hospital. However, for patients admitted from other hospitals, the LTCH hospital-within-a-hospital would be paid under the LTCH PPS with no adjustment.

In the May 18, 2004 proposed rule, we indicated that we believe that adoption of any of these three options is within the broad discretion conferred on the Secretary by section 123 of Public Law 106-113 (BBRA) and by section 307 of Public Law 106-554 (BIPA), which grant the Secretary the authority to develop a per discharge PPS for payment of inpatient hospital services by LTCHs and to provide for appropriate adjustments to the LTCH PPS.

We proposed to revise the existing separateness and control regulations at § 412.22(e) for hospitals-within-hospitals and to require that in order to be excluded from the IPPS, all hospitals-within-hospitals must admit no more than 25 percent of their patients from the onsite host hospital. (See section § 412.534.) We also proposed to preclude common ownership of host hospitals and excluded hospitals, while grandfathering existing hospitals-within-hospitals and hosts that are under common ownership, as long as they comply with the proposed mandatory 75-percent criterion. We further sought comments on the options presented if the hospital-within-a-hospital fails to meet the 75-percent criterion that would either require that all of the hospital's Medicare payment would be made under the IPPS or, alternatively, to allow a hospital-within-a-hospital to still be paid as an excluded hospital for its admissions from onsite providers while applying specific payment adjustments for patients admitted from the host hospital.

In the proposed rule, we solicited comments on the three options presented and whether they provide sufficient protection against the phenomenon of inadequate separateness and control as described in the proposed rule. We want to emphasize that, under any of the options, nowhere is a change in physician clinical decisionmaking or a change in the manner in which a physician or hospital practices medicine intended. The policy options outlined in the proposed rule simply addressed the appropriate level of payments once those decisions have been made.

Comment: One commenter expressed the opinion that the increase in the number of LTCHs is in part due to the conversion of IRFs to LTCHs that is due to the enforcement of the criterion for exclusion from the IPPS as a rehabilitation hospital or unit which is set forth in §§ 412.23(b)(2) and 412.30, and relates to the inpatient population treated by a hospital or unit. This criterion is frequently referred to as the "IRF 75-percent rule." In addition, the

same commenter recommended that those IRFs and IPFs that are converting to LTCHs should first have to meet the length of stay requirements for exclusion as a LTCH by operating and being paid under the IPPS for 1 year. The commenter believed that such a requirement would be consistent with the LTCH PPS final rule published on May 7, 2004 (69 FR 25674), which the commenter described as requiring a satellite facility to qualify under the IPPS for 1 year.

Response: Our primary reason for disagreeing with the comment on this point is that the 75 percent rule as described in prior regulation is not currently being enforced. Until recently, as explained further below, our regulations at 42 CFR 412.23(b)(2) stated that, except in the case of a newly participating rehabilitation hospital seeking exclusion for its first 12-month cost reporting period, a hospital could qualify for exclusion from the IPPS and payment under the IRF PPS only if at least 75 percent of the inpatient population of the hospital required intensive rehabilitative services for one or more of 10 specified medical conditions. On June 7, 2002, CMS issued a memorandum to fiscal intermediaries instructing them to suspend enforcement of the 75 percent rule. After further review of this issue, and notice and comment rulemaking on it, on May 7, 2004, CMS issued revised regulations, effective for cost reporting periods starting on or after July 1, 2004, which changed the list of qualifying medical conditions and, for a hospital's first cost reporting period beginning on or after July 1, 2004, require only a 50 percent compliance level. These regulations are set forth, and explained in detail, in the final rule published at 69 FR 25752.

Although we have heard anecdotally that some of IRFs have converted to LTCHs or are in the process of evaluating such a conversion, we have no objective evidence to support the view that such conversions are occurring in large enough numbers to be a significant factor in causing the recent increase in the number of LTCHs. Thus, while there may be many reasons for the growth in the number of LTCHs, we continue to believe that it is likely that this increase may have been induced to a significant extent by the establishment and implementation of a LTCH PPS.

We also considered, but do not agree with, the commenter's recommendation that IRFs and IPFs wishing to convert to LTCHs should first have to operate and be paid under the IPPS for a specified time period, described by the commenter as 1 year, in order to make

the policies applicable to IRFs and IPFs consistent with 42 CFR

§ 412.23(e)(4)(ii), as revised by the May 7, 2004 LTCH PPS final rule (69 FR 25706–25708) regarding a satellite facility (as defined in § 412.22(h)) or a remote location of a hospital (as defined in § 413.65(a)(2)) that voluntarily reorganizes as a separate Medicare-participating hospital. The regulations in § 412(e)(4) are clear that the applicable average length of stay requirement for exclusion from the IPPS as an LTCH can be satisfied only based on discharges that occur on or after the effective date of its Medicare participation as a separate hospital and not based on operating experience obtained when the facility was not itself a separate Medicare participating hospital but instead was a part of a larger institution which participated in Medicare as a hospital. However, a facility excluded from the IPPS as a rehabilitation hospital under 42 CFR 412.23(b)(2) is already a hospital as required by § 412.23(e)(4), and its discharges can be used to determine whether it satisfies the applicable length of stay requirement. Thus, because the Medicare participation status of a separate rehabilitation hospital is different from that of a satellite or a remote location, consistency with § 412.23(e)(4)(ii) does not require the change suggested by this commenter, and we have therefore not adopted that change in this final rule.

Comment: One commenter shared CMS' concerns regarding the potential for manipulation of the intent of the separateness and common ownership regulations, and was also in agreement that hospitals-within-hospitals should be prevented from functioning as units of acute care hospitals.

Response: We appreciate the commenter's support of our concerns regarding the current hospital-within-hospital policy and took the comment into account in developing this final rule. We are finalizing revisions to separateness and control regulations at § 412.22(e) and adding a new regulation at § 412.534, Special payment provisions for long-term care hospitals-within-hospitals.

We are limiting the finalized policy revisions addressing host hospitals and LTCH HwHs and also to satellites of LTCHs that is, of LTCH HwHs, or free-standing LTCHs and not to other co-located PPS excluded hospitals). These policies, as were the existing policies, are also applicable to any type of host hospital, including IRFs.

We are finalizing policy to eliminate the existing three "Performance of basic hospital functions" options under

existing § 412.22(e)(5) for qualifying as a LTCH HwH or a LTCH satellite (the 15 percent rule and the basic functions test, and the 75/25 test). If a LTCH HwH meets existing separateness and control of administrative and medical governance provisions at § 412.22(e)(1) through (e)(4), payment will be made under the LTCH PPS as specified in § 412.534. Under § 412.534, if a LTCH HwH or LTCH satellite's admissions from its host hospital exceed 25 percent (or the applicable percentage) of its discharges for the LTCH HwH or LTCH satellite's cost reporting period, an adjusted payment will be made at the lesser of the otherwise payable amount under the LTCH PPS or the amount that would be equivalent to what Medicare would otherwise pay under the IPPS. In determining whether a hospital meets the 25 percent criterion, patients transferred from the host hospital that have already qualified for outlier payments at the host would not count as part of the host's 25 percent (or the applicable percentage) and therefore the payment would not be subject to the adjustment. Those patients would be eligible for full payment under the LTCH PPS. (Cases admitted from the host before the LTCH crosses the 25 percent threshold would be paid an otherwise unadjusted payment under the LTCH PPS.)

We are finalizing additional adjustments to the 25 percent policy for specific circumstances. For rural host hospitals with LTCH HwHs or LTCH satellites, instead of the 25 percent criterion, the majority (that is, more than 50 percent) of the patients would have to be from hospitals other than the host. In addition, in determining the percentage of patients admitted from the host, any patients that had been Medicare outliers at the host and then discharged to the LTCH HwH or LTCH satellite would be considered as if they were admitted from a non-host hospital. For urban single or MSA dominant hospitals, we would allow the LTCH HwH or LTCH satellite to admit from the host up to the host's percentage of total Medicare discharges for like hospitals in the MSA. We would apply a floor of 25 percent and a ceiling of 50 percent to this variation. In addition, in determining the percentage of patients admitted from the host, any patients that had been Medicare outliers at the host and then transferred to the LTCH HwH or LTCH satellite would be considered as if they were admitted from a non-host hospital.

In this final rule, after further analysis and consideration of the commenter's concerns, we have made various changes in the proposed policy as

detailed later in this section. We have provided a 4-year transition for existing LTCH HwHs or LTCH satellites that will provide a reasonable period during which the host and the LTCH HwH or LTCH satellite will be able to adapt to the requirements of the new policy. Also included in this policy are LTCHs-under-formation that satisfy the following two-prong requirement: the hospital was certified as an acute care hospital on or before October 1, 2004, under Part 489; and was designated as a LTCH before October 1, 2005. For cost reporting periods beginning on or after October 1, 2004 through September 30, 2005, these hospitals will be grandfathered, with the first year as a "hold harmless." Therefore, grandfathered LTCH HwH or LTCH satellites will only need to continue to meet the existing separateness criteria at § 412.22(e) which includes compliance with either paragraphs (e)(5)(i)(ii), or (iii) for that first cost reporting period. However, we are requiring that even for grandfathered facilities, in the first cost reporting period, the percentage of discharges admitted from the host hospital may not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period. Therefore, while we are grandfathering existing LTCH HwHs and allowing for a 4-year transition, beginning on or after October 1, 2004 and before October 1, 2005 (FY 2005), those hospitals may not increase the percentage of discharges admitted from the host in excess of the percentage that they had admitted in FY 2004. After the first grandfathered cost reporting period, these LTCH HwHs will be required to meet a percentage transition over the 3 years beginning in FY2006. For the second year (cost reporting periods beginning on or after October 1, 2005 but before October 1, 2006), the applicable percentage from the host will be the lesser of the percentage of their discharges admitted from their host for their FY 2004 cost reporting period or 75 percent. For the third year (cost reporting periods beginning on or after October 1, 2006 but before October 1, 2007), the applicable percentage from the host will be the lesser of the percentage of their discharges admitted from their host for their FY 2004 cost reporting period beginning or 50 percent, and finally 25 percent (or other applicable percentage) beginning with the third year (cost reporting periods beginning on or after October 1, 2008).

Comment: Several commenters believed that hospitals-within-hospitals have grown in numbers because they are a more efficient and less expensive

model. The commenters further stated that these providers are cost-effective and convenient for physicians associated with both the hospital with a hospital and the host hospital, and state that the location and ability to work closely with the acute care hospital leads to efficient usage of space and sharing of medical facilities and services. Another commenter noted that many hospitals-within-hospitals have strict admission standards; this is to ensure that a patient requires hospital-level care. One commenter pointed to a report compiled over a 6-month period across all provider types that asserted that the Medicare program saved money for all LTCHs regardless of their designation as freestanding or hospital-within-hospital. Under the circumstances, the commenter believed that CMS should not place restrictions on patient access to beneficial care through the application of a cap on the percentage of host hospital admissions.

Response: As we discussed in the proposed regulation, even though the co-location of Medicare providers may possibly have some positive economic benefits to both hospitals, such as the sharing of expensive medical equipment as well as provide a measure of convenience for patient families, at its worst, co-location and patient shifting can serve to undermine a basic premise of both the IPPS and the LTCH PPS, “which is that a single discharge-based PPS payment is adequate and appropriate reimbursement for the entire bundle of services that a hospital provides during the course of a patient’s stay.” (69 FR 28275). That is, with the implementation of PPS for LTCHs, now one episode of care for a beneficiary who is transferred from an acute care hospital to a co-located LTCH could generate two full Medicare prospective payments, one under the IPPS, and another under the applicable excluded hospital PPS.

As we had discussed previously in the September 1, 1994 final rule implementing the original hospital-within-hospital criteria, we believe a long term care hospital-within-a-hospital that is not adequately separated from the facility with which it is co-located is “essentially a long term care hospital unit that accounts for only a part of the larger hospital’s patient load. Exclusion of long-term care units [from the IPPS] could inadvertently encourage hospitals to try to abuse the prospective payment systems, by diverting all long-stay cases to the excluded unit, leaving only the shorter, less costly cases to be paid for under the prospective payment systems. In such cases, hospitals would

profit inappropriately from prospective payments.” (59 FR 45389).

Moreover, exclusion of long term care “units” is inconsistent with the statutory scheme. Section 1886(d)(1)(B) of the Act clearly provides for exclusions from the prospective payment system for psychiatric and rehabilitation units, but the statute does not provide for exclusion of long-term care units. Because we believe such exclusions are contrary to the purpose and scheme of section 1886(d)(1)(B) of the Act, we proposed to revise the regulations to prevent inappropriate exclusions.” (56 FR 45389). Notwithstanding the commenter’s concerns, we continue to believe that a revision to the current hospital-within-a-hospital policy is necessary in order to prevent potential abuses to the Medicare program.

Comment: Several commenters that noted that, although existing separateness and control regulations at § 412.22(e) govern all hospitals excluded from the IPPS and our proposed changes would apply to all types of hospitals-within-hospitals, the concerns underlying our proposed revisions actually focus on the particular relationship between a host acute care hospital and a co-located LTCH. The commenters requested that we limit any revisions in the hospitals-within-hospitals regulations to address that particular configuration. Two other commenters recommended the exclusion of children’s hospitals because this policy could impose a significant potential barrier to children’s hospitals’ ability to respond to the growing demand for their services for the children of their regions, as well as to receive adequate payment from other payers.

Response: As we noted above, in the September 1, 1994 IPPS final rule (59 FR 45389), our concern with the “new” phenomenon of hospitals-within-hospitals and the ensuing separateness and control regulations that we established were originally directed at the relationship between a host acute care hospital and a co-located entity that was seeking State licensure and Medicare participation as a hospital, and then after demonstrating that it has an average length of stay of over 25 days, would obtain an exclusion from the IPPS and designation as a LTCH. We believed that the effect of this process would be an extension of the long-term care hospital exclusion to what was, for all practical purposes, a “long-term care unit.” Only in the August 29, 1997 IPPS final rule did we extend the application of § 412.22(e) beyond LTCHs to include other classes of facilities that might seek

exclusion from the IPPS as hospitals-within-hospitals, including IRFs (62 FR 46012, August 29, 1997).

Notwithstanding this extension of our hospital-within-a-hospital policy, our data reveal that the vast majority of hospitals-within-hospitals are LTCHs and the considerable growth, discussed above, is in the number of new LTCH hospitals-within-hospitals. Thus, because we believe this to be a significant issue with regard to LTCH HwHs or LTCH satellites (as seen by the increase in the number of LTCH HwHs or LTCH satellites), at this time, we will be limiting the scope of this policy only to LTCH HwHs (and also to satellites of LTCHs, as noted elsewhere in these responses). Although we will continue to monitor the establishment of other excluded hospital groups as well as LTCH HwHs or LTCH satellites, we are presently finalizing revised regulations targeted to the unique relationship between LTCH HwHs or LTCH satellites and host hospitals. We believe that this is necessary and appropriate because we are concerned about the potential for LTCH HwHs or LTCH satellites to, in effect, function as units of the host, and there is no statutory authority for LTCH “units” excluded from the IPPS under section 1886(d)(1)(B) of the Act but there is for the establishment of IRFs and psychiatric units of acute care hospitals. Therefore, historically, it has been less likely that an acute care hospital will be co-located with a free-standing IRF or psychiatric hospital as a HwH or satellite since the acute care hospital can establish its own rehabilitation or psychiatric unit. However, the fact that an acute care hospital is precluded from establishing its own LTCH “unit” may account for an increase in the number of separately certified co-located LTCHs at acute care hospitals.

In addition to this statutory basis, our concern with LTCHs existing as LTCH HwHs or LTCH satellites continues to be that an on-site LTCH can easily be utilized “seamlessly” as a step-down unit of the host hospital. A LTCH, in fact, is certified by Medicare and licensed by its State as an acute care hospital. (This is not the case where a patient is transferred from an acute care hospital to an IRF or psychiatric unit since the transfer of an acute care patient to an IRF or an IPF unit of the acute care hospital would typically indicate a determination that there would be a clinical advantage to that patient’s receiving highly specialized rehabilitation or psychiatric services otherwise unavailable at the acute care hospital.)

As we noted above, for an on-site LTCH, configured as a LTCH HwH or LTCH satellite, to actually function as a unit of the acute care hospital, despite the statutory preclusion, would undermine payments under the IPPS DRG classification system and generate inappropriate Medicare payments. This is the case because payments for specific diagnoses under the IPPS were determined by setting DRG weights that represent a national averaging of hospital costs for each diagnosis and assumes that, generally, both high-cost and low-cost patients are treated at a hospital. In addition, the Federal standardized payment amount was also based on the average cost of all patients across all hospitals.

Presently, because of the particular concerns that we have expressed, we believe that our policy revisions may relate more directly to LTCHs that exist as LTCH HwHs or LTCH satellites than to other excluded hospital designations. Therefore, although we will continue to monitor increases and changes in the HwH or the satellite "universe" and may revisit this issue in the future, the policy revisions for HwHs or satellites that we are finalizing in this notice will apply only to a situation where the HwH or satellite is a LTCH or a satellite of a LTCH.

Comment: Two commenters questioned whether a LTCH HwH or satellite or satellite that is co-located with an IRF would be subject to the separateness and control policies that we proposed.

Response: When we first addressed the existence of LTCH HwHs in the September 1, 1994 final rule for the IPPS (59 FR 45389), we were responding to the proliferation of a particular entity: a LTCH hosted by an acute care hospital. We expanded our definition of LTCH HwH to include all excluded hospitals in the September 1, 1995 final rule for the IPPS (60 FR 45836) because we recognized that co-location of other hospital types could give rise to payment concerns similar to those that we believed were likely to occur between a host hospital and a LTCH HwH. Therefore, although the vast majority of host/LTCH HwH arrangements are between acute care hospitals and LTCH HwHs, in § 412.22(e), we addressed circumstances under which a "hospital that occupies space in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital" will be excluded from the IPPS, but we do not specify a particular designation of excluded hospital.

Similarly, existing regulations at § 412.22(e) do not specify what type of hospital the host hospital must be. Section 1886(d)(1)(B) of the Act, which establishes the distinction between a "subsection (d) hospital" and hospitals excluded from the IPPS, also includes a provision on grandfathering for certain HwHs and specifies that "[A] hospital that was classified by the Secretary on or before September 30, 1995, as a hospital described in clause (iv) [not a "subsection (d) hospital"] shall continue to be so classified notwithstanding that it is located in the same building as, or on the same campus as, another hospital." Although the statute establishes that certain HwHs will continue to be paid as an excluded hospital, the designation of the host is not limited. (We did not receive any comments suggesting that we restrict the proposed regulations to only one type of host.)

We are presently limiting the finalized revisions to the separateness and control policy to LTCH HwHs, as noted in the previous response. Our concerns, as discussed earlier, about the relationship between a host hospital and a LTCH HwH or LTCH satellite would apply equally to situations where the LTCH HwH or LTCH satellite is co-located with either an acute care hospital or an IRF, and the existing statutory preclusion against the existence of LTCH units would also apply if the host hospital was an excluded hospital.

Therefore, we are clarifying that a LTCH HwH or LTCH satellite that is co-located with any hospital is subject to the revised regulations. We also want to note that even under existing LTCH HwH regulations at § 412.22(e) or LTCH satellite regulations at § 412.22(h), regardless of the designation of the host hospital, a LTCH that existed as a LTCH HwH that failed to meet requirements of (e)(1) through (e)(4) or one of the three performance of basic hospital functions tests at (e)(5)(i), (ii) or (iii) would have been paid under the IPPS. Similarly, if a satellite failed to meet the separateness criteria under § 412.22(h), the satellite would also be paid as an acute care hospital under IPPS.

We have established in this final rule, under § 412.534, that if a LTCH HwH or LTCH satellite admits more than 25 percent (or the applicable percentage) of its patients during a cost reporting period from its host, Medicare will pay an adjusted LTCH PPS payment based on the lesser of the otherwise unadjusted LTCH PPS rate or an amount equivalent to what would have otherwise been payable under the IPPS for each discharge. (Since LTCHs are

certified as acute care hospitals, we believe that this is an appropriate policy determination.) Furthermore, this payment policy is applicable in all situations where a LTCH HwH or a LTCH satellite is co-located with another hospital.

Comment: One commenter noted that the proposed revision of the separateness and control policy at § 412.22(e)(v)(2)(iii) calculates the 75 percent of patients that must be "referred to the hospital from a source other than hospital occupying space in the same building or on the same campus" based on the "inpatient population" of the HwH. The commenter questions whether this limitation was intended to apply solely to Medicare beneficiaries. Two other commenters express concern that the proposed 25 percent rule, will affect admissions to the HwH directly from the host acute care hospital of even non-Medicare patients.

Response: When we first established the requirements at § 412.22(e) to determine separateness between host hospitals and LTCHs in the September 1, 1994 final rule for the IPPS (59 FR 45389), the average length of stay calculation for purposes of designation as a LTCH was based on an average inpatient length of stay of greater than 25 days as calculated under paragraph § 412.23(e)(3)(i) implementing section 1886(d)(1)(B)(iv)(I) of the Act. Under (then) § 412.23(e)(3)(i), the calculation was determined by "dividing the number of total inpatient days (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period." With the implementation of the LTCH PPS, we revised the regulations at § 412.23(e)(2)(i) and (e)(3)(i) to calculate the average length of stay based solely on Medicare patients, a change which we believed was more in keeping with the establishment of a specialized PPS for Medicare patients who required long-stay hospitalizations at LTCHs. (See 67 FR 55970, August 30, 2002.) (We did not change the formula for calculating the average length of stay for an LTCH governed by section 1886(d)(1)(B)(iv)(II) of the Act, implemented at § 412.23(e)(2)(ii), for a "subclause (II)" LTCH because we believed that in establishing a "subclause (II)" LTCH the Congress provided an exception to the general definition of LTCHs under subclause (I), and we had no reason to believe that the change in methodology for determining the average inpatient length of stay would better identify the hospitals that the Congress intended to excluded

under subclause (II)). See 67 FR 55974, August 30, 2002.)

When we proposed the recent revision to existing regulations at § 412.22(e)(5)(iii), we intended to apply the revision to the existing regulations and calculate the percentage of patients admitted to the LTCH from the host based solely on Medicare inpatients in conformity with § 412.23(e)(2)(i) and (e)(3)(i). We appreciate the commenter's bringing this to our attention, and we will revise the regulation text to reflect that the 25 percent or other applicable percentage test will only apply to Medicare patients. (Since qualification of LTCHs under § 412.23(e)(2)(ii) is not based only on Medicare patients, the LTCH HwH provisions at § 412.534 would not apply to these hospitals.) We would also note that by restricting the calculation of the percentage of patients so it will be based solely on Medicare patients for the purposes of complying with payment under the 25 percent or other applicable percentage test (new § 412.534), we have, in effect, assumed that payment to the LTCH may be affected by the number of Medicare patients that a LTCH HwH or LTCH satellite admits from the host hospital but will not be impacted by the LTCH HwH or LTCH satellite admitting any number of non-Medicare patients from the host hospital because the number of non-Medicare patients will have no effect on a LTCH HwH or LTCH satellite's meeting the 25 percent or other applicable percentage requirement.

In addition, as discussed later in this preamble, we are finalizing a policy to count discharges from the host that had achieved outlier status at the host prior to being admitted to the LTCH HwH or LTCH satellite, as if they were LTCH patients from other than the host. Because that determination is not possible for non-Medicare patients, we are only applying the 25 percent test to Medicare patients.

Comment: One commenter challenged our concern that inappropriate patient shifting from a host acute care hospital to a LTCH hospital-within-a-hospital could result in undermining the IPPS by noting that even if such behavior is taking place, the annual reweighting of DRGs is a self-correcting mechanism for the IPPS that works to adjust payments to approximate costs.

Response: The "self-correcting" remedy noted by the commenter could in theory provide considerable protection to the integrity of the IPPS-DRG system, if all acute care hospitals hosted LTCH HwHs because charge data gathered for purposes of recalibrating DRG weights would be based on

equivalent or at least similar circumstances throughout the nation. However, according to our most recent data, there are less than 130 LTCH HwHs as of June 2004 and approximately 4000 acute care hospitals. The charge data gathered from the acute care hospitals that are used to recalibrate the DRG weights is data for the full range of patients within each DRG across all acute care hospitals in the nation. Because in the vast majority of these hospitals, the acute care hospital does not have a co-located LTCH hospital-within-a-hospital, the DRG weight for a specific DRG is reflective of the higher cost of hospital-level care for the types of patients that in relatively few hospitals may be treated at LTCHs. Therefore, Medicare payments to the overwhelming majority of acute care hospitals without LTCH HwHs that will continue to treat a patient for the entire episode of care and which may ultimately become a high-cost outlier discharge would be the same for a particular DRG as it would be to one of the relatively few acute care hospitals that hosts a LTCH hospital-within-a-hospital and has the option of discharging a patient to the hospital-within-a-hospital prior to the full provision of clinical services to that same patient. In that situation, Medicare would have overpaid the acute care hospital under the IPPS (and the admission to the LTCH HwH would generate an additional payment under the LTCH PPS) for the same episode of care that in most parts of the country would have been delivered solely at the acute care hospital. Therefore, although the IPPS relies on the "self-correcting" nature of the DRG system for annual recalibration, we continue to believe that since there are so few acute care hospitals that have co-located LTCHs, this mechanism is not an effective remedy for such situations.

Comment: Several commenters suggested that the existing post-acute transfer policy already address many of the concerns with inappropriate payments under the IPPS in situations where a patient is discharged to a LTCH hospital-within-a-hospital while the patient is still under active treatment at the co-located acute care hospital. Further, the commenters suggested an expansion of the existing post-acute transfer policy to include DRGs of patients frequently discharged from acute care hospitals to LTCHs as an alternative remedy to our proposed policies revising separateness and control policies for hosts and hospitals-within-hospitals. The commenter noted that this policy was mandated by statute

and is the "primary vehicle" that Congress has chosen to deal with "substitution of service questions."

Response: The post-acute transfer policy at § 412.4(c) which implemented section 1886(d)(5)(J) of the Act, stipulates that if an acute care hospital discharges a case assigned one of a specified groups of DRGs to a post-acute setting, such as a LTCH, prior to reaching the geometric means length of stay for that particular DRG, the discharge is considered to be a "transfer" and the Medicare payment to the acute care hospital under the IPPS is adjusted reflecting that less than a full course of treatment had been delivered.

In developing the revised separateness policy, we have looked at data from our 1996 through 2003 MedPAR files, focusing our data analyses on changes in lengths of stay that exceed the geometric mean length of stay for various DRGs at acute care hospitals with hospitals-within-hospitals as compared to those without hospitals-within-hospitals.

Our concern is that rather than just transferring patients before the geometric mean length of stay, which could be subject to a transfer policy adjustment if the case was assigned to one of the specified 29 DRGs, in general, we believe that these acute care hospitals are often discharging their patients to the onsite LTCH so as to reduce the length of stay of outlier patients. If the patient is discharged after the geometric mean ALOS, the payment for that patient would no longer be adjusted under the transfer policy. Accordingly, we do not believe that possible expansion of the existing post-acute transfer policy to other DRGs, which we discuss elsewhere in this final rule, would necessarily address the problem we are attempting to address with the 25 percent or other applicable percentage provision.

Comment: Four commenters asserted that our concerns about inappropriate payments to LTCHs under Medicare are already being addressed through several policies which are already in place: The post acute transfer policy under the IPPS which limits reimbursement to host hospitals when a patient is transferred to a LTCH; both the 3-days or less and the greater than 3-day interruption of stay policies under the LTCH PPS, the onsite discharge and readmission policy under the LTCH PPS; the greater than 25-day average length of stay policy for LTCHs; the short-stay outlier policy under the LTCH PPS; and requirements for medical necessity review. Finally, another commenter recommended a reduced payment methodology for host

acute care hospitals discharging patients early to LTCH HwHs. That is, the early discharge could be addressed with the geometric mean length of stay; an edit could monitor the length of stay; and if early discharge occurs, the commenter suggested converting the PPS per discharge payment to a per diem payment.

Response: The existence of the policies noted by the commenters confirms the fact that, as PPS policies have evolved, we have continually been concerned about the issue of inappropriate Medicare payments, particularly at points of intersection between various payment systems. Although each policy establishes certain safeguards, none effectively address the concern that we are dealing with in this revision of hospitals-within-hospitals regulations: That of inappropriate patient movement from a host hospital to a co-located LTCH. As discussed above, the post-acute transfer policy at § 412.4 ensures that a full DRG is not paid to the admitting IPPS hospital if a patient, whose diagnosis falls into one of a very limited number of categories, is transferred to an alternative provider after an extremely short stay at the acute care hospital. Both the 3-day or less and the greater than 3-day interruption of stay policies at § 412.531, as well as the onsite discharge and readmission policies at § 412.532, are only triggered if a LTCH patient is discharged from the LTCH and is then subsequently readmitted to the LTCH after an interruption. These policies do not address our concern with inappropriate discharges from host hospitals to LTCH HwHs or LTCH satellites because they are focused on the site of care during the LTCH stay rather than on shifting care from the host to the LTCH HwH.

In response to the commenter's statement that the requirement that for LTCH designation, an acute care hospital must demonstrate that it has an average patient length of stay of greater than 25 days is another existing policy that protects against inappropriate payments to LTCHs, we would note that section 1886(d)(1)(B)(IV)(I) of the Act (implemented at § 412.23(e)(2)(i)), is the specific statutory basis for of a LTCH as a type of acute care hospital that is excluded from the IPPS. This statutory definition only defines how long patients must stay on average at the LTCH, once they are admitted for the LTCH to maintain its IPPS exemption. It has no impact on the movement of patients from a host hospital to a LTCH HwH or LTCH satellite or the length of stay of that patient at the host before that patient is admitted to the LTCH. With this length of stay mandate in

mind, however, at the outset of the LTCH PPS for FY 2003, we established the short stay outlier policy under the LTCH PPS at § 412.529 to provide proportionately appropriate payments to LTCHs when patients receive treatment for considerably less than the statistically-defined average length of stay for a particular LTC-DRG. This policy established a payment policy under the LTCH PPS for short-stays at the LTCH and does not address truncated stays at a host hospital (since this policy does not look to see if the stay at the host was truncated). The commenters mentioned medical review requirements at § 412.508, a process that, at least presently, actually consists of a QIO reviewing a statistical sample of hospital records or is prompted by a specific incident-review request or appeal. Although the option of a retrospective QIO evaluation of medical appropriateness of a hospital discharge is always an option available to beneficiaries, we do not believe that such a specific situation provides significant protection for purposes of establishing payment policy under Medicare since so few discharges are actually subjected to QIO review.

Thus, as noted above, we do not believe that the results of any of these existing policies can effectively speak to the issues that we are addressing in the revised hospital-within-hospital policy. While we appreciate the commenter's recommendation concerning a reduced payment methodology for early discharges from the host acute care hospital, we do have an existing policy, the post-acute transfer policy discussed in the previous comment and response, that appears to be similar to what was described by the commenter. As we state above, we do not believe that even an extension of that policy addresses the issues we have identified here as the basis for the new separateness policy.

Comment: Two commenters stated that because the LTCH PPS was just implemented in October 2002, there has not been enough time to review the impact of this payment system on the industry. The commenters urged us to adopt the recommendations promulgated by MedPAC in its June 2004 Report to the Congress as well as to conduct a serious study of the LTCH industry and to continue to monitor growth and payment issues prior to implementing additional regulations. Two other commenters supported a time-limited moratorium (3 years) on new LTCHs to allow QIO reviews to become well established and CMS research to be completed.

Response: Although we agree with much of what the commenter stated

regarding the fact that the LTCH PPS is relatively new and the impact of the payment system on the industry is not yet certain, we do not believe that our regulations are premature. While we continue to monitor and evaluate the impact of the LTCH PPS on the LTCH industry, we believe that the policy revisions that we are finalizing in this rule arise from concerns with the host/hospital-within-a-hospital relationship that have been present since our September 1, 1994 final rule (59 FR 45390) and, thus, predate the implementation of the LTCH PPS. These concerns have achieved new urgency with the considerable and continuing growth in the number of LTCH hospitals-within-hospitals. Although one method of dealing with our concerns is a time-limited moratorium on the establishment of new LTCHs, and hospitals-within-hospitals in particular, we believe that such a step is best left to the Congress. Even if this occurred, however, it would not address any problems occurring in existing hospital-within-hospital LTCHs. In addition to finalizing this separateness policy, however, we plan to continue our monitoring efforts and to publish a detailed evaluation of MedPAC's recommendations in **Federal Register** documents updating the LTCH PPS for rate year 2006.

Comment: Several commenters expressed concern that the policies that we proposed were based upon assumptions that were not supported by data. Three commenters, in particular, included reports that were commissioned by industry groups, two of which evaluated data from specific LTCH chains that have hospitals-within-hospitals and one which analyzed MedPAR data for acute care hospitals from FY 2000. The data from one LTCH chain indicate that a large percentage of hospitals-within-hospitals admit considerably more than 25 percent of their patients from their host acute care hospitals. Another chain provided data indicating that, at least for its hospitals-within-hospitals, patients are generally reaching outlier status at the host acute care hospital prior to being discharged to the hospital-within-a-hospital. Data were also provided indicating that as a percentage of all of the host's discharges, the number of patients of the host that are discharged to LTCH hospitals-within-hospitals is extremely low (in the low single digits).

Response: We disagree with the commenters' statement that our policy revisions are not supported by data. Although we noted in the proposed rule that given the relatively recent implementation of the LTCH PPS, our

data sources are relatively limited, the policies that we are finalizing for LTCH HwHs or LTCH satellites are the result of policy evaluations, anecdotal information, as well as data analyses. We also note, elsewhere in this preamble, that our concerns about the potential for inappropriate Medicare payments under the IPPS arising from the co-location of an acute care hospital and a LTCH, were first stated in the September 1, 1994 final rule for the IPPS (59 FR 45389).

When we proposed the regulations that we are finalizing in this document regarding LTCH HwHs, we noted that we were proposing to revise payment policies for LTCH HwHs because we had become aware that, along with the considerable growth in their numbers, there was a trend indicating widespread corporate reconfigurations affecting the host/LTCH HwH relationship, particularly with regard to LTCH HwH. The existence of Web sites sponsored by industry consultants urging underutilized acute care hospitals to increase profits by renting space to LTCH HwHs in order to reduce the number of long-stay patients, further added to our concern.

Since we first became aware of the existence of LTCH HwHs in 1994, we have been aware of the strong resemblance that they bore to LTCH units of acute care hospitals, a configuration precluded by statute. We believe that it is incumbent upon us to continually refine our payment systems in light of concerns about the continued viability of the Medicare Trust Fund. In finalizing the revised LTCH HwH policy, therefore, as discussed previously in this preamble, we believe that this policy will help to protect the integrity of the IPPS DRG system as well as discouraging inappropriate payments under the LTCH PPS, the system that provides for the highest per discharge payment to a provider in the Medicare program. These policy goals typically require both proactive as well as reactive decisions on our part. We are aware that the majority of LTCH HwHs presently admit considerably more than 25 percent (or the applicable percentage) of patients from their host hospitals and have taken that fact into account when we designed the transition policy for existing LTCH HwHs or LTCH satellites described elsewhere in these responses.

Nothing in our data analyses was contradicted by the above-mentioned studies sponsored by the LTCH industry. In finalizing the separateness policy in this regulation, we are aware that not all hosts with LTCH HwHs or LTCH satellites are manipulating their

discharge patterns in order to avoid reaching outlier status. In response to the commenter that suggests we use, as a qualifying criteria, the percent of the host's patients that are admitted to the LTCH HwH, our data verifies that as a percentage of the total number of patients the host discharges, the percentage that are discharged to LTCH HwHs or LTCH satellites, is low. But this is logical and to be expected since most LTCH HwHs or LTCH satellites consist of approximately 25 beds in contrast to significantly larger host hospitals. However, we are focusing on the percentage of patients admitted to the LTCH HwH or LTCH satellite from the host and since data from the LTCH HwH indicates that even the relatively small percentage of the host's patients (as a fraction of all the host's patients) is sufficient to assure that most if not all of the relatively smaller LTCH beds are occupied, we are concerned with the appropriateness of payments to the LTCH based on our existing policy for those patients, and we believe that our new policy is warranted.

In analyzing the discharge data, we have looked at data from 1996 through 2003 from our MedPAR files, focusing our data analyses on changes in lengths of stay that exceed the geometric mean cases at host hospitals that are co-located with LTCH HwHs or LTCH satellites as opposed to those without LTCH HwHs or LTCH satellites. Our concern is that, in general, a significant volume of these cases are being discharged to the onsite LTCH prior to reaching outlier status. We compared the number of Medicare covered days for specific DRGs with data from hospitals before and after they became a host hospital. We selected DRGs that MedPAC had identified as being more likely to lead to cases in which a host hospital would transfer the patient from the acute care hospital to their co-located long-term acute care facility.

Acute hospitals were grouped into cohorts for each year from 1996 through 2003: those that were freestanding as distinct from those that currently were hosting a long-term care hospital. For all but one DRG (482), the mean amount of covered days across all years for hospitals that were currently hosting a LTCH was lower in comparison to when they were not hosting a LTCH. Four DRGs (263, 265, 266 and 483) experienced decreases over ten percent. We also looked at covered days for DRGs 483, 126, 264, and 475 for the year 1999 (since all the acute care hospitals in the analysis were not hosting LTCH HwHs or LTCH satellites that year) in comparison to 2002 and 2003 (because all the acute care hospitals in the

analysis were hosting LTCH HwHs or LTCH satellites in those years). For most of these DRGs (particularly DRG 483), the number of discharges with a very high number of Medicare days decreases quite significantly at the acute care hospital after it became a host. We believe that this data indicates a correlation between the presence of a LTCH as a LTCH HwH or a LTCH satellite within an acute care hospital and a shorter length of stay for Medicare beneficiaries at the acute care hospital.

We, therefore, believe that the regulations that we are finalizing represent a reasonable response to our continuing policy concerns, industry monitoring, anecdotal information, as well as an evaluation of our available data. As additional data is gathered, we will continue our monitoring and analytic activities and determine whether additional policy revisions or refinements may be warranted.

Comment: One commenter asks whether satellites of HwHs will be required to meet the 25 percent test regarding their relationship with their host hospital.

Response: Although we did not explicitly discuss the impact of the proposed change on satellites, we believe that since satellites are also parts of a hospital that is within another hospital, it is appropriate to require that satellites of LTCHs meet the 25 percent or other applicable percentage test regarding discharges admitted from their host hospitals. These satellites may be linked either to LTCHs that are also co-located with a host hospital, that is, a LTCH HwH or LTCH satellite, or they may be a satellite of a free-standing LTCH. Under the current regulations, we have developed requirements for satellites of excluded hospitals at § 412.22(h) that have generally mirrored those we have required for LTCH HwHs at § 412.22(e) (64 FR 41532, July 30, 1999; 67 FR 50105, August 1, 2002) except for the application of the 15 percent requirement, discussed in detail above, because attempting to apply this 15 percent test could actually serve to undermine separateness and control rules already in effect for a satellite and a host. In the August 1, 2002 final rule for the IPPS, we stated, that "[S]ince the costs for the entire excluded hospital (at both the main hospital and the satellite facility) are reported on one cost report by looking at the costs that are shared between the satellite facility and the acute care hospital, the costs of services that the satellite facility receives from its 'host' hospital will invariably be less than 15 percent of the costs of the entire hospital, even if all the costs of the

satellite facility were incurred by the host hospital.” (67 FR 50106).

As we are finalizing regulations that abandon reliance on the 15 percent test as an indicator of separateness and control for LTCHs, and rather establishing the 25 percent or other applicable percentage test as the determinant of “functional separateness” between a LTCH HwH or LTCH satellite and its host hospital for determining the appropriate payment level for LTCH patients admitted from the host, we are also establishing this same requirement for satellites of LTCHs under new regulations at § 412.534. There is a considerable similarity between a LTCH HwH and a LTCH satellite, notwithstanding that satellites are “parts of a hospital” and HwHs are distinct facilities. We believe that the same concerns that we have expressed throughout this preamble regarding the potential for medically-unwarranted patient shifting between a host hospital and a LTCH HwH or LTCH satellite resulting in inappropriate Medicare payments are also present when an acute hospital is co-located with a satellite of a LTCH. In the July 30, 1999 IPPS final rule, when we stipulated that satellites of excluded hospitals would be required to meet the PPS exclusion requirements applicable to a hospital or unit, we noted that requirements for separate identification of the beds, patients, and costs of the satellite “closely parallel similar requirements applicable to all excluded units under § 412.25(a)(3) and (a)(7) through (a)(12).” Therefore we believe that there are both administrative and procedural precedents for the application of separateness requirements to satellites. Accordingly, we have revised the regulations to clarify that the separateness policy applies to LTCH satellites under new § 412.534, as well. In order for a LTCH satellite to be included in the grandfathering provision and payment policy phase-in, under § 412.534, which we have established for certain LTCH HwHs, discussed in detail below, the LTCH satellite will have had to be in existence by October 1, 2004. (**Note:** Satellites do not have a 6-month qualifying period.) If a LTCH satellite does not meet that requirement, (that is, if it is established after October 1, 2004) Medicare payments will be governed by § 412.534 (a) through (e). In determining whether the satellite meets the 25 percent (or other applicable percentages, discussed earlier) threshold, we would compare the total number of patients treated at the satellite location to the number of those patients that were

admitted from the co-located host (subject to the outlier adjustment discussed earlier.)

Throughout this preamble, when we refer to this policy applying to LTCH HwHs, we intend this to apply as well to LTCH satellites that are co-located with a host hospital. In fact, a satellite location of a hospital is also co-located within another hospital.

Comment: Regarding our proposed policy precluding common ownership of an acute care hospital and a HwH, we received three comments in favor of the preclusion and ten comments urging us not to finalize this proposed policy. One commenter noted that where the LTCH is co-located but not commonly owned, the LTCH has no incentive to accept inappropriate patients from the host hospital. Two other commenters noted that that the financial incentive to accept inappropriate patients from a host hospital only exists when the acute care hospital and the LTCH are commonly owned, a situation that can exist even without co-location, that is, a freestanding LTCH, exempt from the requirements of § 412.22(e) may be owned and governed by the hospital from which it receives the majority of its referrals. Three commenters expressed concern that in prohibiting common ownership of a host and a LTCH, we were unintentionally creating a regulatory preference for for-profit LTCHs. Another commenter stated that not-for-profit hospitals would particularly suffer from any preclusion of common ownership and since LTCH “start-ups” already sustain financial loss because of the 6-month qualification period during which they are paid under the IPPS and, therefore, only if a community-based non-profit organization senses a real need in the community for LTCH services would it invest, develop and open a LTCH either as a HwH or free-standing. Two other commenters emphasized the distinction between ownership and control, noting that advantageous arrangements between entities that are not under common ownership could produce more “control” than would be present in a common ownership situation that is being administered in compliance with present regulations.

Several commenters requested that if we finalized the preclusions against common ownership, that we include in our proposed grandfathering provision, those HwHs that were “under development” to the extent that they were already operating as acute care hospitals within a host while collecting data that would enable them to qualify as LTCHs. Two of the commenters responded to our proposal to

grandfather existing commonly owned hosts and HwHs while prohibiting the establishment of any new such arrangements by stating that grandfathering “any form of ownership or control by a related entity” would create inequity among providers as well as perpetuate any potential or existing abuses of Medicare policy. Two other commenters focused on the particular situation facing rural referral centers and sole community hospitals, two distinct categories of acute care hospitals that serve in unique markets and requested that even if our proposed policy prohibiting common ownership was finalized, that an exception be granted in these situations where there may be no other alternatives than for these isolated facilities to develop their own LTCHs. Another commenter further asserted that our present policies for separateness and control, which also governs commonly owned hosts and LTCH HwHs are sufficient and effective.

Response: We thank the commenters that endorsed our proposed policy to prospectively preclude common ownership of a host hospital and a LTCH HwH. Our goal in proposing this policy was based on our concern that common ownership of a host hospital as well as a HwH (in particular, a LTCH) could result in revenue-driven rather than medically necessary discharge and admission determinations between the commonly-owned facilities that were also co-located since the benefits would accrue to one corporate entity. In response to another commenter, we are also aware that even in the absence of common ownership, or if a commonly-owned host and a HwH were being administered in strict compliance with existing policies, the host/LTCH HwH configuration where each component is separately owned could provide inappropriate benefits to each facility. (For example, as noted elsewhere in this preamble, we are familiar with Internet advertisements sponsored by certain consultants and hospital corporations that specialize in LTCH HwH that urge underutilized acute care hospitals to decrease or eliminate their high cost outliers by leasing space to a LTCH HwH, a result which would lead to inappropriate Medicare payments to both the host as well as the LTCH HwH.) We also acknowledge the commenters that noted that common ownership, even between hospitals that did not share a location, could result in incentives for patient discharges and admissions more related to reimbursement than for clinical purposes. From the initial implementation of the LTCH PPS in

2002, we established on-going monitoring as an essential component of the LTCH PPS (67 FR 56014, August 30, 2002) and we will continue to review data from varieties of LTCHs that reflect discharge and admission patterns from other Medicare providers: LTCH HwHs that are under common ownership with hosts and LTCH HwHs that are independently owned, as well as free-standing LTCHs, in order to evaluate whether further regulation may be necessary in order to address inappropriate Medicare payments. In response to the commenter who noted that a common-ownership preclusion is a requirement for all LTCHs, under § 412.23(e)(3), both not-for-profit and for profit. After reviewing all of the comments, in this final rule, we are not finalizing the proposed policy precluding common ownership. In the proposed notice, we had offered a number of alternative policies to address the situation of a HwH that admitted more than 25 percent of its patients from its co-located host hospital. As an additional policy response to address this problem, we had proposed to regulate common ownership. However, we believe that because we are addressing our major concerns with commonly owned hosts and LTCH HwHs or satellites with the finalized 25 percent test which we believe will impact in the number and type of patients discharged from the host and admitted to the LTCH HwH, we do not need to also regulate against common ownership at this time. We will continue to monitor the common ownership issue and, if appropriate, revisit it at a later date. Therefore, one of the commenters that expressed concern regarding an "inequity" of competition between those LTCH HwH that would be subject to new regulation as opposed to those LTCH HwHs under common ownership with their host that would be grandfathered, is no longer an issue. We have revisited the issue of common ownership, first discussed in the September 1, 1994, final rule for the IPPS (59 FR 45392) because, we did not agree with the commenter that asserted that our existing policies were "sufficient and effective "to address our concerns with the circumstance of common ownership. However, we do believe that our new revision of the entire separateness policy, set forth in the next response, is presently an

adequate response to our significant policy concerns in the area of LTCH HwHs including commonly owned host/LTCH HwH arrangements. Since we are not finalizing the policy that precludes common ownership of a host and its LTCH HwH it is unnecessary to respond to those commenters that requested an extension of the proposed grandfathering provision and also to those commenters who believe that grandfathering of common ownership arrangements would perpetuate unnecessary abuses of the Medicare system. We will address other comments on grandfathering of existing LTCH HwHs unrelated to the common ownership issue elsewhere in these comments.

Comment: Several commenters urged us to retain the 15 percent criterion at existing § 412.22(e)(5)(ii) and to strengthen both its enforceability as well as associated sanctions. One commenter objected to the change in policy and stated that if the 15 percent policy was enforced then "bad players" could be sanctioned. One of the commenters, a corporate officer of a LTCH HwH scheduled to open in August 2004 stated that complying even with the existing 15 percent rule would require turning away from "otherwise sound business practices." Two of the commenters further suggested that we extend separateness and control policies to limit specific business arrangements such as loans or financial arrangements, whereby the host funds or contributes to the working capital of the LTCH HwH or reimburses operating expenses or losses; that the 15 percent rule be reframed as a preclusion with civil and/or criminal penalties attached in the event of violation; and that executive officers be required to file an annual attestations of compliance with separateness and control as part of the cost reporting procedure. Two commenters specifically suggest that we consider adopting provisions of the Sarbanes-Oxley Act of 2002 for the purposes of policing corporate financial reporting which includes requirements that CEOs and CFOs of public corporations certify via an attestation to the veracity of financial statements and disclosures with severe penalties for willful and knowing violations. The commenters believed that the attestation procedure, as well as the potential for civil or criminal liability, would shift the burden of enforcement of the 15 percent criterion from the fiscal intermediary to the providers. One commenter characterized our proposed policy as one that removes the 15 percent criteria, which can be

monitored and replaces it with a test that is directly related to and acts to limit the admission and treatment of patients in need of hospitalization. On the other hand, there was one commenter who supported our proposal to strengthen separateness requirements and encouraged enforcement of existing requirements. The same commenter indicated an awareness of hospital systems setting up a co-located LTCH HwH that "on paper" appeared to meet our requirements but in effect was controlled by the host, leading to the on-site LTCH functioning as a unit. This commenter suggested that we require a written certification and supporting documentation verifying that the separation requirements have been met.

Response: When we established the regulations governing payment policy for hospitals within hospitals at § 412.22(e) in the September 1, 1994 final rule for the IPPS (59 FR 45389) our goal was to create "a firewall" between the acute care host hospital and a new entity that we feared would actually function as a LTCH unit of that hospital, a statutorily precluded configuration.

As stated above in this preamble, in the May 18, 2004 proposed rule, we proposed to eliminate the 15 percent rule because we were aware that the vast majority of LTCH HwHs were choosing to comply with that option as opposed to the more rigorous separation of basic functions (for example, medical records, pharmaceutical services, radiological services, laboratory services (§ 482.21 through §§ 482.27, 482.301 482.42, 482.43, and 482.45) or the "functional separateness" test of the 25 percent referral requirement (62 FR 46014, August 29, 1997) and we did not believe that allowing a LTCH HwH to choose that the 15 percent rule among the existing policies regarding hospitals-within-hospitals had, in fact, sufficiently protected the Medicare program from the problems that we first envisioned in the September 1, 1994 final rule.

Moreover, queries from providers and consultants as well as information from fiscal intermediaries, and our regional offices, concerns expressed by MedPAC in its June 2003 Report to the Congress and at meetings held at outset of the implementation of the LTCH PPS (which was implemented for cost reporting periods beginning on or after October 1, 2002), and the recent growth in the LTCH universe, particularly LTCH HwHs, convinced us that it was incumbent upon us to revisit separateness and control policies. Furthermore, we were recently given the opportunity to review a number of corporate documents, including Articles

of Incorporation of existing host/LTCH HwH arrangements as well as pending arrangements for the establishment of LTCH HwHs. These reviews made us aware of the development of a new generation of complex and creative corporate reconfigurations that would make it difficult and burdensome, if not impossible, for our fiscal intermediaries to ascertain compliance with § 412.22(e) based on the 15-percent policy. We want to note that we understand that many LTCH HwHs made every possible effort to comply with the 15 percent provision.

However, in response to commenters suggesting a range of options which preserve the 15 percent criterion, such as toughening the policies to prohibit specific business arrangements; the attachment of civil and/or criminal penalties in the event of violations; a requirement for annual attestations be required by corporate officers; adoption of particular corporate policing provisions of the Sarbanes-Oxley Act of 2002, we would note that retaining the 15 percent criterion, even under any of the proffered circumstances would be an administrative burden on CMS and its contractors since they would require extensive reviews, audits, and monitoring to ferret out the "bad players." We also want to note, in response to the commenter who expressed concern about having to depart from "sound business practice" in order to comply with the 15 percent rule, that it is our statutory responsibility under sections 1102 and 1871 of the Act to establish regulations as may be necessary to effectively administer the Medicare program. A hospital retains the ability to conduct its corporate affairs as it sees fit and to the extent that the hospital's behavior does not conform to Medicare payment requirements, the hospital has made a choice, since it has been put on notice that it will not be paid under the regulations governing the Medicare program. The participation of a business in the Medicare program generally indicates that the provider has decided that the advantages of participation outweigh any adaptations in business practices required by our rules.

We now believe that allowing LTCH HwHs to qualify by complying with the 15 percent test did not operate to prevent the creation of LTCH HwH that were actually functioning as units of hosts. Further, even if at their creation, there was effective compliance with the 15 percent test, monitoring continued compliance was nearly impossible. But even if it were possible to accurately monitor a LTCH HwH or satellite's compliance with the 15 percent test, we

now believe that meeting this particular test, would not sufficiently ensure that Medicare payments otherwise payable under the LTCH PPS, for LTCH patients admitted from the host (that exceed 25 percent (or the applicable percentage of the HwH's discharges)) are appropriate. Moreover, we consider that for Medicare payment purposes, the significant movement of patients between the host hospital and the LTCH HwH or satellite continues to be the most effective indication of whether they are functioning as distinct hospitals or whether, in violation of statutory intent, in fact, the configuration is resulting in these facilities behaving as acute care hospitals with sub-acute units.

As we previously stated, we want to reiterate that we are not substituting a criterion that will limit admission and/or treatment of Medicare beneficiaries by eliminating the 15 percent policy. We agree with the commenter who stated that our goal in establishing this policy revision was to prevent a co-located LTCH HwH or satellite from appearing to comply with our requirements "on paper," but actually to be controlled by and functioning as a unit of the host. In response to the same commenter, we would also note that under the finalized policy, submission of documentation to fiscal intermediaries regarding compliance with existing separateness and control policies under § 412.22(e)(1) through (e)(4) is required to be paid as an IPPS excluded LTCH HwH or satellite under § 412.22(h)(2)(D) and we will continue to require such documentation to demonstrate compliance with those requirements. As noted elsewhere in these responses, detailed instructions will be sent to fiscal intermediaries regarding implementation procedures for payment adjustments under new § 412.534.

In this final notice, therefore, effective for cost reporting periods beginning on or after October 1, 2004, for LTCH HwHs we are eliminating the 15 percent test under existing § 412.22(e)(5)(ii), and the performance of basic hospital functions test under subsection § 412.22(e)(5)(i) and the 75 percent of admissions from other than the host criteria at § 412.22(e)(5)(iii). If a LTCH demonstrates compliance with the medical and administrative separateness and control policies at § 412.22(e)(1) through (e)(4), under our finalized policy, it will satisfy LTCH HwH requirements. The 25-percent or other applicable percentage test, described in the next response, will be the threshold criteria for a new payment adjustment for LTCH HwHs or satellites in new regulations at § 412.534.

Comment: We received numerous comments from LTCHs, industry groups, Congressional representatives, and individual medical professionals expressing great concern with respect to our various payment proposals, which are based on utilizing the 25 percent test. As proposed in the proposed rule, the 25 percent test would have been the sole determinant for a LTCH HwH or satellite to receive payment as a hospital excluded from the IPPS. We received several comments urging us not to adopt any of the proposed payment policies; that they were arbitrary and unprecedented and would result in lesser payments to the LTCH HwH or satellite based upon the source of patients. The commenters argued that reducing payments to the LTCH HwH or satellite for patients admitted from the host hospital beyond 25 percent of the LTCH HwH or satellite's total annual discharges would have two highly negative effects. First, this policy would result in the denial of necessary and appropriate care to patients who could benefit from treatment at the LTCH HwH or satellite. Additionally, a lower level of reimbursement would lead to the closing of LTCHs with all the attendant consequences of such closures such as shortage of hospital beds, industry insecurity leading to the inability to retain and attract professional staff, and loss of jobs for employees of the LTCH HwH or satellite. The policy that we are suggesting, several commenters assert, sets a "maximum limitation" on the admission of patients from the host, arbitrarily diverting patients away from LTCHs that share buildings with other hospitals.

A number of commenters stated that our proposed policy constitutes discrimination against certain LTCHs solely because of their location, and if finalized, will disrupt health care service delivery and also exert a destabilizing effect on patient care programs and capital projects. One commenter asserts that the location of a duly licensed hospital may not be utilized as a basis for excluding it from participation in the Medicare program as a LTCH. Several other commenters assert that there would also be an impact on the availability of intensive care unit beds in the acute care hospitals, creating shortages which could threaten the availability of care for trauma patients in certain communities, if patients no longer needing these services were not discharged to onsite LTCHs.

Response: We do not agree with the commenters who interpret our regulations as establishing arbitrary and

unprecedented limits on the right of a LTCH HwH to receive payment under the LTCH PPS. We are providing an adjustment to the payment under the LTCH PPS in accordance with the broad authority conferred on the Secretary by the Congress in section 307(b) of Public Law 106-554 to include "appropriate adjustments" in the establishment of a PPS for LTCHs. The finalized payment policies described below and the concerns that they represent echo concerns first expressed in the September 1, 1994 final rule for the IPPS, when we began to regulate new entities that we named "hospitals within hospitals." As noted elsewhere in these responses, the reason why we proposed the changes in the May 18, 2004 proposed rule at this time is the nexus between these decade-old concerns and the recent explosive growth in the numbers of LTCH HwHs. Furthermore, these regulations are grounded in a thorough review of the available data as well as exhaustive policy evaluations and are rationally related to the analyses of such information. In addition, we would emphasize most strongly that these regulations do not establish either arbitrary or unprecedented limits on the rights of a LTCH HwH or LTCH satellite to be paid under the LTCH PPS. Although we have made significant revisions to the policies in the May 18, 2004 proposed rule, our basic premise is unchanged.

As we first stated in that September 1, 1994 final rule, "we agree that the extent to which a facility accepts patients from outside sources can be an important indicator of its function as a separate facility, not merely a unit of another hospital. In general, a facility's functional separateness should be reflected in its ability to attract patients from sources other than the hospital that it serves. For example, if a facility receives all (or nearly all) of its admissions independently (that is, from outside sources), it can reasonably be assumed to be functioning separately from the host hospital. (59 FR 45391).

Having reevaluated the first two options that we presented in the May 18, 2004 proposed rule (69 FR 28326 through 28327) in light of comments that we received, we believe that the policy that we are finalizing is reasonable, and more directly addresses the relationship between movement of patients between the host hospital and the LTCH HwH or satellite and inappropriate or unnecessary Medicare payments, our central concern. Under the above policy, a LTCH must continue to demonstrate compliance with the medical and administrative separateness

and control policies at § 412.22(e)(1) through (e)(4). In the proposed rule, we stated that we would eliminate the two alternative qualifications for LTCH HwH (the 15 percent rule and the basic functions test) and instead rely solely on the 25 percent or other applicable percentage threshold for qualification purposes. We have refined this policy, in this final notice, and for purposes of qualifying as a LTCH HwH, we will eliminate all three performance of basic hospital functions options in § 412.22(e)(5) if a LTCH HwH complies with § 412.22(e)(1) through (e)(4) which addresses separateness and control of administrative and medical governance, the LTCH will qualify as a LTCH HwH. Instead, the 25 percent or other applicable percentage test will be the threshold for a new payment adjustment for LTCH HwH in new regulations at § 412.534, where Medicare payment policy under the LTCH PPS is promulgated and will apply to LTCH satellites as well. We are establishing a distinction in this new payment adjustment between patients admitted from the host and from sources other than the host because we believe that even if a facility satisfies the requirements of § 412.23(e)(1) and (e)(2) and is eligible for payment as a LTCH and also satisfies revised § 412.22(e)(1) through (e)(4) for purposes of being considered a LTCH HwH it may still appear to be functioning like a unit because of the number of patients that it admits from its host hospital. Payments will be made to the LTCH HwH or satellite for all Medicare patients under the otherwise unadjusted LTCH PPS only until the 25 percent or other applicable percentage threshold is reached after which point unadjusted (that is, not limited by a LTCH PPS payment amount that is equivalent to the amount otherwise payable under IPPS) payments will be made under the LTCH PPS for all Medicare patients admitted to the LTCH from sources other than the host. Once a LTCH HwH or satellite exceeds the 25 percent or other applicable percentage threshold, Medicare LTCH PPS payments for patients admitted to the LTCH from the host will be adjusted. This per discharge payment adjustment for patients from the host exceeding the threshold, will be based on the lesser of payments otherwise paid under the LTCH PPS or an adjusted payment under the LTCH PPS that is equivalent to the applicable payment that would otherwise be made under the IPPS. Payments for a non-host patients would continue to be made under the otherwise unadjusted LTCH PPS.

The policy that we will be finalizing is a variation of option III in the May 18, 2004 proposed rule and is applicable only to LTCHs governed under section 1886(d)(1)(B)(iv)(I) of the Act because the policy addresses payment policy related to the percentage of Medicare patients that are admitted to the LTCH HwH or satellite and as noted in a previous response, for a "subclause (II)" LTCH, the 25 percent test will not be applied because their certification as a LTCH is not tied to Medicare patients.

We believe that this policy captures the intent of section 1886(d)(1)(B)(iv)(I) of the Act which established LTCHs as a separate category of acute care hospitals for patients with average stays of greater than 25 days but precluded the establishment of LTCH units. To the extent that the source of its admissions reveal that the LTCH HwH or satellite is behaving like a unit of its host hospital, in contravention of both the statute and implementing regulations, Medicare will make adjusted per discharge payments under the LTCH PPS. When the facility appears to be functioning in compliance with the intent of the statute and implementing regulations, however, Medicare will make otherwise unadjusted payments under the LTCH PPS. In determining whether a hospital meets the 25 percent or other applicable percentage criterion, patients transferred from the host hospital that have already qualified for outlier payments at the acute host would not count as part of the host percentage. We believe that this is appropriate because as we discuss earlier in these responses, a patient reaching outlier status at a host hospital may be presumed to have received a full course of treatment in that setting. Further, in such a case, our policy presumes that a discharge to a LTCH HwH or satellite for post-acute care treatment may be clinically appropriate and therefore should reasonably be eligible for otherwise unadjusted payment under the LTCH PPS. In addition, if a LTCH HwH or satellite exceeds the 25 percent or other applicable percentage threshold (with host outlier patients paid as non-host patients), Medicare will pay the lesser of the LTCH PPS payment or a reduced LTCH PPS payment based on an amount equivalent to what would otherwise be paid under the IPPS. (The adjustment would only be applied to discharged patients admitted from the host hospital that exceed the 25 percent (or the applicable percentage) threshold. Cases transferred from the host up to the LTCH applicable percentage threshold would be paid the unadjusted LTCH PPS rate.)

In this final rule, we have revised our use of the 25 percent test as a determinant of LTCH HwH satellite status that was originally set forth in the proposed policy and rather established it as a payment threshold under new § 412.534. We have provided a 4-year transition for existing LTCH HwHs or satellites to allow for a reasonable period during which the host and the LTCH HwH or satellite will be able to adapt to the requirements of the new policy. Also included in this transition policy are LTCHs-under-formation that satisfy the following two-prong requirement: the hospital was certified as an acute care hospital on or before October 1, 2004, under Part 489; and was designated as a LTCH before October 1, 2005. We believe that these LTCH HwHs, since they have undergone significant efforts which could be adversely affected by these final rules, should be allowed a 4-year transition as well. For cost reporting periods beginning on or after October 1, 2004 through September 30, 2005, these hospitals will be grandfathered, with the first year as a "hold harmless." Therefore, grandfathered LTCH HwHs will only need to continue to meet the existing separateness criteria at § 412.22(e) which includes compliance with either paragraphs (e)(5)(i), (ii), or (iii) for that first cost reporting period. Grandfathered LTCH HwHs and LTCH satellites would not need to meet the 25 percent or other applicable threshold for the cost reporting periods beginning on or after October 1, 2004 through September 20, 2005. However, we are requiring that even for grandfathered facilities, in the first cost reporting period, the percentage of discharges admitted from the host hospital may not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period. Therefore, we are grandfathering existing LTCH HwH and those LTCHs under-development that meet the 2 prong test and LTCH satellites that were in existence by October 1, 2004. Grandfathered HwHs and satellites may not increase the percentage of discharges admitted from the host in excess of the percentage they had in FY 2004. After the first grandfathered cost reporting period, these LTCH HwH will be required to meet a percentage transition over the 3 years beginning in FY2006. For the second year (cost reporting periods beginning on or after October 1, 2005, but before October 1, 2006), the applicable percentage from the host will be the lesser of the percentage of their discharges admitted from their host for their FY 2004 cost

reporting period or 75 percent. For the third year (cost reporting periods beginning on or after October 1, 2006, but before October 1, 2007), the applicable percentage from the host will be the lesser of the percentage of their discharges admitted from their host for their FY 2004 cost reporting period or 50 percent, and finally 25 percent (or the applicable percentage) threshold will apply beginning with the fourth year (cost reporting periods beginning on or after October 1, 2007). We have adopted a transition of 75 percent, 50 percent, and then 25 percent since we felt it was reasonable to allow existing LTCH HwHs and HwHs under-development, as defined using the two-prong test above, 3 years to gradually meet our regulatory threshold.

Transitions are a frequently incorporated feature of new Medicare payment policies. Examples are the 4-year phase-in of the IPPS, the 5-year phase-in of the LTCH PPS, and the 3-year phase-in of the IRF PPS. In establishing a 1-year grandfathering as well as 3 additional years during which an existing LTCH HwH or satellite or "pipeline" LTCH HwH will be able to discharge the lesser of a proportionally-declining percentage or the hospital-specific percentage of Medicare patients that it admitted from its host during its final cost-reporting year prior to the implementation of this new 25 percent or other applicable threshold for the LTCH PPS payment adjustment, we are providing a reasonable and equitable methodology by which LTCH HwHs or satellites will be able to adapt to our new requirements.

Comment: Several commenters expressed concern about the impact of the proposed 25 percent test on rural hospitals. In particular, a commenter pointed out a situation where a single tertiary acute care hospital is the only provider for a multi-county area, capable of treating medically complex patients in the entire region and which hosts a LTCH HwH or satellite. In a rural county, for example, commenters assert that there would not be sufficient patient volume to support any other LTCH. In such markets, small or medium sized communities, the commenters maintain that our proposed 25 percent test would deprive communities of LTCH services or force construction of free-standing LTCHs.

Response: After considering the commenters' concerns and after further analysis, we are further revising the 25 percent criterion to provide for a payment adjustment for rural hospitals (§ 412.62(f)) or urban single or MSA-dominant hospitals (that is a hospital in an MSA that discharges more than 25

percent of all Medicare inpatient acute care hospital discharges in that MSA for like hospitals.) The Congress has authorized special treatment for rural areas under the Medicare program because of the particular geographic and demographic challenges in those locations as well as the differences between the provision and availability of medical services in rural as compared to urban areas. Further, in establishing this adjustment the Secretary is exercising the broad discretion granted by the Congress under section 307(b) of Public Law 106-554 to provide for appropriate payment adjustments in the LTCH PPS. Therefore, for rural acute care hospitals with LTCH HwHs or satellites, following the phase-in period, instead of the 25 percent criterion, we have provided that the majority, (that is, of at least 50 percent) of the patients would have to be from the hospitals other than the host. Where the majority of the patients are admitted from hospitals other than the host in this instance, since there are few other hospitals from which the LTCH HwH or satellite can admit inpatients, we believe the majority is a reasonable criterion to establish that the LTCH HwH or satellite is not acting as a unit of the acute hospital. As with other hospitals, any Medicare patient that had been at the rural host in outlier status and then transferred to the LTCH HwH or satellite would be treated as if the patient had been admitted from a non-host hospital in determining the percentage of patients admitted from the rural host hospital.

Additionally, for urban single or MSA dominant hospitals, which would generally be providing services under similar circumstances as rural hospitals, that is, being the only hospital in the area, we would allow the LTCH HwH or satellite to discharge Medicare patients admitted from the host up to the host's percentage of total Medicare discharges in the MSA for the most recent fiscal year that data is available for a hospital similarly certified as the host. We would apply a floor of 25 percent and a ceiling of 50 percent (representing a numerical majority of patients) to this group. We believe the maximum threshold of a majority of its patients admitted from the host indicates that the HwH is a separate hospital and is not operating as a unit of the host. For example, if there are only two acute care hospitals in the MSA and based upon the most recent data available, hospital A had 500 Medicare discharges in its fiscal year while hospital B had 1500 Medicare discharges, the total number of Medicare discharges for that MSA is

2000 discharges. If hospital B has a co-located LTCH HwH or satellite we would calculate its separateness percentage (that is, the percentage of Medicare patients that it could admit from the host for otherwise unadjusted LTCH PPS payments) based on its percentage of total Medicare discharges in the MSA. In this instance, hospital B has discharged 75 percent (1500/2000) of the discharges in the MSA.

Accordingly, we would require that following the phase-in of the policy, the LTCH HwH or satellite be held to a determination that a ceiling of 50 percent (that is, less than a majority) of its discharges were admissions from the host hospital. Again, as previously noted, in determining the percentage of Medicare patients admitted from the host, as with all LTCH HwHs or satellites, any patient that had been in outlier status at the host and then transferred to the LTCH HwH or satellite would be treated as if they were admitted from a non-host hospital.

As the above description of our revised payment policy for LTCH HwH or satellite demonstrates, we are not setting a "maximum limitation" on the admission of patients from the host. We are not establishing policies to prevent these facilities from delivering necessary and appropriate medical care and compliance with the policy need not result in hospital closures, industry insecurity, and a loss of professional and support staff. Instead, if the LTCH or satellite does not meet the applicable variation of the 25 percent test, rather than losing its ability to be paid as a hospital excluded from the IPPS in its entirety we will reduce Medicare payments under this policy only for those patients whose discharges exceed the threshold. Because hospitals will still be paid an appropriate amount for the care they deliver, we do not believe that those hospitals will close nor should there be industry insecurity or loss of professional or support staff. This reduction is to account for the fact that the LTCH is not functioning as a separate hospital but rather is effectively behaving as a unit. We would emphasize again that LTCH HwHs or satellites are free to admit any patient from any source without limit or restriction. In this policy revision, we merely address how Medicare will pay for patients in LTCH HwHs or satellites and establish the applicable thresholds that are the basis for such payment.

We disagree with the comment that suggests that we are "discriminating" against a hospital because of its location (within another hospital), we would respond that there are a significant number of Medicare payment policies

that address certain hospitals for "special treatment" because of their locations such as sole community hospitals (§ 412.92), rural referral centers (§ 412.96), and critical access hospitals (§ 413.70). Therefore, we believe it is appropriate to consider a hospital's location in determining payments. Similarly, it has been a long-standing practice to anticipate potential opportunities for "gaming" or to encourage behavioral change on the part of providers by establishing payment policies, often related to physical location, such as the onsite discharge and admission policy, under the TEFRA system for excluded hospitals at § 413.40 (a)(3)(B) and under a similar policy in the LTCH PPS at § 412.532. Further, in response to comments that suggest that the impact of our policy will be a disruption to health care delivery, patient care programs, and capital projects, we would state that we do not agree with these predictions. Rather, we believe that a reasoned analysis of the policies that we are finalizing, described in detail above, will reveal that they are neither destructive nor onerous to the effective functioning of either a host or a LTCH HwH or satellite.

Finally, with regard to the potential shortage of intensive care beds in the host and the possible consequential harm to the treatment of local trauma victims that commenters threaten will result from a limitation of admissions to the LTCH or satellite, we would once again respond that our policy does not limit patient admissions, it sets appropriate payment for patient categories. Moreover, while we understand the concerns about the availability of intensive care unit beds in an acute care hospital, we believe that this is a problem that may occur due to other unexpected circumstances, for example, issues related to the need to appropriately staff those ICU beds. We do not believe that the policy that we are finalizing would increase the possibility of this problem arising, particularly since it is generally clinically appropriate to move a patient no longer in need of ICU treatment to a "step-down" unit of the host acute care hospital and not to maintain the patient needlessly in an ICU bed.

In addition, as we explained earlier, for some patients in the acute care hospital, Medicare payment under the IPPS would include high-cost outlier payments. Under the policy described above, if an ICU patient had been moved to a "step-down" unit at the host hospital and the costs of treatment resulted in the case qualifying as a high cost outlier, Medicare payment for an

admission of such a patient to the LTCH or satellite from the host acute care hospital would not be included as an admission from the host and would be paid based at the higher LTCH PPS rate. Accordingly, we believe with this policy we have addressed some of the concerns raised by the commenters as to the effect of the separateness percentage policy on access to services. We would also remind the commenters that we have established adjustments to the 25 percent test for rural hospitals or urban single or MSA dominant hospitals in response to situations where communities have a scarcity of inpatient options, thus further tailoring the revised policy to the unique needs of these communities.

Comment: Several commenters expressed concern with the impact of the proposed 25 percent test on rural hospitals.

Response: The Congress has authorized special treatment for rural areas under the Medicare program in a number of areas. In addition, we agree with the commenter that in rural areas it often will be difficult for a LTCH HwH or satellite not to exceed the 25 percent threshold since the co-located acute care hospital may be the only one in the area. To address this issue, as noted in the previous response, we are finalizing a modification of our 25 percent test for rural hospitals (and also for urban single or MSA-dominant hospitals). We would also note, however, that while we have addressed the commenters' concerns with LTCH HwHs in rural areas, in fact, there are very few rural LTCHs, even including free-standing LTCHs. With approximately 320 LTCHs in existence, the vast majority of rural areas throughout the country do not have either free-standing LTCHs or LTCH HwHs or satellites. Therefore, currently almost all patients in need of hospital-level long-stay care are being treated as high-cost outliers in rural acute care hospitals and are not treated in LTCHs.

Comment: Several commenters questioned CMS' authority to impose new criteria for exclusion of long-term care hospitals and contend that existing separateness and control rules already enables us to distinguish between hospitals and units. The commenters state that the sole reliance on the 25 percent test establishes "admissions criteria," and the Secretary does not have the right to disqualify a LTCH HwH or satellite meeting other exclusion criteria from payment under the LTCH PPS based on a failure to meet admissions criteria. The commenters stated that the term "hospital" is defined in section 1861(a) of the Act

and that section 1886(d)(1)(B)(iv) of the Act provides an exclusion from the prospective payment systems for a hospital having an average length of stay greater than 25 days. These commenters therefore maintain that if a LTCH qualifies for Medicare participation by meeting the applicable participation requirements in 42 CFR Part 489 and also meets the statutory "greater than 25 day length of stay criterion", CMS has no right to "remove" this status because of where the LTCH is located or because of the source of its admissions. Several commenters claim that the proposed policy is "arbitrary and capricious" and one commenter maintains that the regulations fail the "Chevron test."

Response: We do not agree that we have imposed additional criteria for the exclusion of LTCHs. Rather we are imposing new criteria for adjusting payments under the LTCH PPS for LTCH HwHs or satellites.

The commenters are correct in noting that the term "hospital" is defined in section 1861(e) of the Act and that a statutory definition of a LTCH is the one set forth in section 1886(d)(1)(B)(iv)(I) of the Act. However, this fact does not mean that the Secretary is precluded from acting, under the general rule-making authorization in sections 1102 and 1871 of the Act, to establish further rules and regulations as necessary to administer the Medicare program and to prevent exclusions or excessive payments that are contrary to the purpose of the statutory scheme. Section 123 of BBRA of 1999 as amended by section 307 (b) of BIPA of 2000 confers upon the Secretary tremendous discretion in creating the LTCH PPS. As explained in the preamble to the proposed rule published on May 18, 2004, we continue to be concerned that only qualified facilities be excluded from the IPPS and paid under the existing LTCH PPS and that payments under each system (IPPS and LTCH PPS) be made appropriately.

When we first established regulations for LTCH HwH, in the September 1, 1994 final rule for the IPPS, in § 412.22(e), we stated that a LTCH HwH or satellite must "meet the following criteria in order to be excluded from the prospective payment systems specified in § 412.1(a)(1)." At that time, we explained in the preamble as follows: "[A]s discussed above and in the proposed rule, we are adding new criteria to prevent an inappropriate exclusion from the prospective payment system. The purpose of excluding entities from the prospective payment system is to address situations in which the principles of prospective payment do not apply well. The considerations

underlying exclusions may not apply to situations involving a "hospital within a hospital." If an entity is effectively part of another hospital and the principles of prospective payment do apply well to the organization as a whole, then it would not be appropriate to exclude part of that organization from the prospective payment system.

Moreover, we believe that granting an exclusion to a LTCH HwH or satellite may be contrary to the statutory scheme. The statute provides for exclusion of certain types of hospitals and certain types of hospital units. Significantly, the statute does not provide for exclusion of LTC units. A LTCH HwH or satellite may essentially be a long-term care unit of another hospital. We believe these distinctions are meaningful and that it would undermine the distinctions if we allowed exclusion of entities that are essentially long-term care units (59 FR 45390, September 1, 1994). "Thus, in order to prevent exclusions that are contrary to the purpose of the statutory scheme [section 1886(d)(1)(B) of the Act] we proposed additional criteria for entities seeking exclusion. Sections 1102 and 1871 of the Act confer authority on the Secretary to establish rules and regulations as may be necessary to administer the Medicare program." (59 FR 45390, September 1, 1994). Existing regulations, therefore, finalized in 1994 established the regulatory principle that in order to be paid as a hospital excluded from the IPPS, separateness and control requirements would have to be met.

The 25 percent or other applicable percentage threshold test that we are finalizing in this document in new § 412.534 does not remove LTCH status from a hospital that otherwise meets these separateness and control requirements, as the commenter suggests. In fact, we are defining a level of payment distinction based upon an adjustment that, following the 4-year phase-in, will enable an existing hospital or satellite or new HwHs effective with cost reporting periods beginning on or after October 1, 2004, to retain its excluded status but to be paid under an otherwise unadjusted LTCH PPS payment for up to 25 percent (or the adjusted threshold established for rural, urban single, or MSA dominant hospitals) of its discharged patients that are admitted to the LTCH HwHs or satellites from the host hospital. If the LTCH or satellite exceeds this 25 percent (or the applicable percentage) threshold, Medicare payments under the LTCH PPS will be based on the lesser of an otherwise unadjusted LTCH PPS payment for the case or an amount

equivalent to what would have otherwise been paid for that case under the IPPS. We would note that this policy merely represents a new adjustment in the evolution of the LTCH PPS. We believe that LTCH HwHs that discharge greater than the appropriate percentage of patients admitted from their hosts may be understood to be functioning as units and therefore, we believe that it is appropriate to adjust the payment to be made to the LTCH under the LTCH PPS. The payment adjustment we are implementing is not the equivalent to setting "admissions criteria" for treatment at a LTCH. As noted elsewhere in these responses, a LTCH is free to admit as many patients as it can safely treat and from whatever source(s) it chooses. The policy revision that we are finalizing in this document establishes a payment formula that will enable the LTCH to be paid under the LTCH PPS appropriately for patients admitted to the LTCH from other than the host and appropriately for patients admitted to the LTCH HwH or satellite from the host where the LTCH has exceeded the applicable threshold, albeit at different LTCH PPS rates. We want to emphasize that the medical and administrative governance component of the separateness and control criteria at § 412.22(e)(1) through (e)(4) will continue to apply to LTCH HwH or satellite but, as explained in detail above, we are deleting paragraph (e)(5), the performance of basic hospital functions test to LTCHs as a basis for determining whether they may be paid as an IPPS-exempt hospital. Rather the 25 percent or other applicable percentage criterion will be used as a basis for a payment adjustment under the LTCH PPS.

We believe that the regulations that we are finalizing represent a permissible construction of the statute precluding the establishment of LTCH units at section 1886(d)(1)(B) of the Act, and are consistent with sections 1102 and 1871 of the Act which confer authority on the Secretary to establish rules and regulations as may be necessary to administer the Medicare program. It is also consistent with our statutory authority under section 123 of BBRA as amended by section 307(b) of BIPA. Moreover, they are consistent with the statute and the statutory scheme. The finalized payment policies described below and the concerns that they represent echo concerns first expressed in the September 1, 1994 final rule for the IPPS, when we began to regulate new entities that we named 'hospitals within hospitals' and after ten years,

represent a reasonable extension of existing regulatory policies.

Comment: We received several comments that asserted that in establishing the category of hospitals excluded from the IPPS, the Congress recognized that the DRG payment system did not accurately reflect the patient census and types of treatment found in those hospitals. These commenters also quoted the requirements of the BBRA and BIPA for the establishment of a specific PPS for LTCHs "reflecting differences in patient resource use" and that therefore paying a LTCH under the IPPS, as we described in our third payment option in the proposed rule, would constitute a statutory violation.

Response: In the proposed rule, we expressed this payment scheme incorrectly when we described payment as "the lesser of the IPPS payment or the LTCH PPS payment." The payment formula, as we described in a previous response, is not, in fact, an IPPS payment at all but instead is an adjusted payment under the LTCH PPS. In section 307(b) of Public Law 106-554, the Congress conferred broad authority on the Secretary to include "appropriate adjustments" in the establishment of a PPS for LTCHs. As stated in previous responses, we are providing an adjustment to Medicare payments under the LTCH PPS in the event that a LTCH HwH or satellite LTCH admits a greater number of patients from its host above the 25 percent or other applicable percentage threshold. This adjustment to the LTCH PPS would allow, for each additional case that the LTCH admitted that were discharges from the host, beyond 25 percent (or the applicable percentage), a payment that would be based on the lesser of an amount payable under this subpart that is equivalent to what would have otherwise been paid under the IPPS or the otherwise payable LTCH PPS payment amount. We believe that this specific adjustment to payments under the LTCH PPS is comparable to other adjustments that we established under the LTCH PPS, such as the short-stay outlier policy (§ 412.529) and both the 3-day or less and the greater than 3-day interruption of stay policy (§ 412.531), in that we have attempted to adjust the otherwise payable LTCH PPS payment rate to more accurately pay for a specific type of patient stay. If a patient stay is governed under any one of these policies, payment under the LTCH PPS will be computed differently than it would for a typical LTCH stay where the patient remains in the LTCH for greater than 5% of the average length of stay for the applicable LTC-DRG to which the

episode is grouped. We believe that paying the LTCH an LTCH PPS adjusted payment that is the lesser of the LTCH PPS payment amount or a payment equivalent to the amount that would have otherwise been made under the IPPS, when a particular LTCH exceeds the percentage of admissions established under the formula set forth above, is entirely compatible with the broad statutory authority conferred on the Secretary, in section 307 of the BIPA, to establish a LTCH PPS and provide for "appropriate payment adjustments" under that system.

Comment: We received six comments on the grandfathering of existing host/LTCH HwH arrangements where the LTCH HwH had in the past met the 15 percent test for purposes of demonstrating compliance with the performance of basic hospital functions requirements. Four commenters urged us not to finalize the proposed revisions to the separateness and control policies but, as an alternative, to grandfather all existing LTCH HwHs and hence exempt them from prospective compliance with new finalized regulations until "an in-depth study of the industry has been completed or until alternative qualifying criteria are implemented." One commenter opposed any grandfathering provision, absent a statutory approval, stating that such a policy provided no benefit for Medicare patients or the Medicare program and could serve to institutionalize behavior that we had already determined was in contravention of the intent of LTCH HwH regulations. Two commenters specifically suggested that we permit entities to unwind abusive practices within a specific period of time rather than legitimize abuses through grandfathering. Two commenters expressed concern about including providers that are in the formative stages any grandfathering protection. One commenter specifically urged us to include hospitals that were in their 6-month qualification period for LTCH classification and would be in compliance by January 1, 2005 and to deem them to meet existing governance, separateness and control policies and therefore to be eligible for any grandfathering provision that we would finalize. These commenters suggest that we establish a provision similar to that in section 507 of Public Law 108-173 that established a moratorium on physician-referrals to specialty hospitals in which they have an ownership or investment interest but grandfathered in those facilities under development. Without such a provision, the commenters believe that the financial

backers (the host hospital in partnership with a venture capital group) would lose a considerable investment of time and resources.

Response: As noted in a previous response, the LTCH HwH or satellite policy that we are finalizing to ease the transition to the new policy for existing LTCH HwHs and satellites, we specify a 1-year grandfathering for LTCH HwHs or satellites that had been paid under the LTCH PPS as of October 1, 2004 and also for LTCH HwHs-in-information that qualify under the following two-pronged test: they were certified as acute care hospitals, under Part 489, on or before October 1, 2004; and they achieved LTCH designation prior to October 1, 2005. This two-pronged test identifies hospitals that by the effective date of this regulation, have been operating in anticipation of becoming a HwH under the existing rules.

The finalized policy provides for an adjusted payment for LTCH HwHs and satellites that admit more than 25 percent of their patients (with an adjusted percentage for rural and urban single or dominant hospitals) effective for cost reporting periods beginning on or after October 1, 2004. Further, for both existing LTCH HwH and LTCH satellites and those LTCHs-in-information that meet the above tests, following the 1-year hold-harmless provision, we have provided a 3-year transition, in order to allow LTCH HwHs or satellites and their hosts what we believe is sufficient time to adapt to the new requirements and enable them to ultimately meet the 25 percent or other applicable percentage test. We believe that establishing this provision is a fair and equitable response to concerns expressed by providers, members of the Congress who have written on behalf of their constituent LTCHs, and LTCH trade groups.

The LTCH PPS, from its inception, has included an evaluation and monitoring component which focuses on the LTCH industry and in light of policy recommendations made by MedPAC in its June 2004 Report to the Congress, we plan to expand these initiatives. However, we do not believe that it would be appropriate to delay implementing these payment policies affecting LTCH HwHs or satellites pending the results of such on-going analysis. We also see no need to adopt a policy that would allow time for entities to correct prohibited practices prior to the imposition of sanctions since we are eliminating the necessity to comply with the performance of basic hospital functions requirements under § 412.22(e)(5) and rather relying on changes to the payment policy to

address situations where a LTCH HwH or satellite exceeds the percentage threshold of patients admitted from the host, effective with cost reporting periods beginning on or after October 1, 2004. With the October 1, 2004 implementation of this final rule, for LTCHs that are not grandfathered, we will rely on the 25 percent test as a basis for a payment adjustment under the LTCH PPS at new § 412.534, if a LTCH HwH complies with the medical and administrative separateness and control requirements of § 412.22(e)(1) through (e)(4) or the LTCH-in-formation meets the LTCH HwH requirements prior to October 1, 2005 and the satellite meets the requirements at § 412.22(h). We also do not believe the statutory protection for those facilities under development promulgated by in the moratorium on physician-owned specialty hospitals established under section 507 of the Public Law 108–173 is applicable to this provision.

Comment: We received numerous comments urging us not to finalize the proposed policies that would prevent admissions to LTCH HwHs or satellites from being based on determinations of medical necessity, clinical assessment, and treatment practices, but rather, based on a restrictive numerical admission standard. Comments from industry groups, members of the Congress, host hospitals, LTCH HwHs or satellites, and physicians practicing at these providers, and in communities where they are located, objected to the proposed elimination of other options for qualification as a LTCH and instead, requiring LTCH HwHs or satellites to comply with the 25 percent test. The commenters believe this change in policy will have a significant impact on physician decision-making and admission policies at LTCH HwH or satellite. Several physicians accused us of being disingenuous in drawing a sharp distinction between payment policy and its impact on medical decision-making.

Response: We disagree with the commenters' assertion that finalizing our 25 percent or other applicable percentage test for determining payments to LTCH HwH or satellite will interfere with a physician's efforts to procure the highest level of medical care for Medicare beneficiaries. Once again, we must state that we are not preventing the admission of patients to the LTCH HwH or satellite; rather we are establishing a methodology for determining what are fair and reasonable payments based on the type of patient being treated at the LTCH HwH or satellite. We continue to believe that there is a clear distinction between

medical decision-making and payment policy, particularly on the physician level, when the patient is a Medicare beneficiary and the medically necessary services are covered by Medicare.

There has always been a range of payments under Medicare for services that, from a medical standpoint, could appear to be identical. Since its inception, the LTCH PPS has included patient-level adjustments to the per discharge Federal payment rate, whereby Medicare would adjust payments depending upon the patient's length of stay, or whether the patient was being readmitted to the LTCH following a brief stay for treatment in another setting, or from a co-located provider. Similarly, in general, under Medicare's PPSs for inpatient services there have always been facility-level adjustments for variables including size and location of the hospital, presence of training programs, or the nature of the population served. Thus, payment for a patient at one facility could differ considerably from payment for a patient with similar clinical needs at another facility. Additionally, acute care hospitals, rehabilitation hospitals, and LTCHs can often be a legitimate site of care provided to a specific patient. However, Medicare's distinct PPSs for each of these provider types would provide for different payments to the specific hospital that treated the patient based upon the provider category. This is another example that demonstrates that under Medicare, payments for the same diagnosis, even for the same patient, could vary depending upon where the patient was admitted. Even within the same facility, a different Medicare payment would be made under the acute hospital IPPS for a rehabilitation or a psychiatric DRG than would be made for the same diagnosis if the patient is admitted to the IPPS-excluded rehabilitation or psychiatric unit at that hospital. We do not agree that in setting payment policy we are restraining physicians from utilizing their best clinical judgment on behalf of their patients. We continue to believe that payments made under the policy that we are finalizing in this document simply represent another patient-level adjustment under the LTCH PPS.

Comment: We received numerous comments from LTCHs, industry groups, Congressional representatives, and individual medical professionals expressing great concern that the proposed policy, which required compliance with the 25 percent test, would have very deleterious consequences for Medicare beneficiaries. The commenters asserted that the policy would establish new

admissions criteria and, in effect, act as a quota or cap on patient admissions to LTCH HwHs eliminating beneficiary and family choice as to treatment settings, produce needless trauma for beneficiaries, and reduce beneficiary access to the level of quality care that such settings could provide. Several commenters state that our proposed policies would violate section 1801 which, among other matters, preclude any Federal officer or employee from interfering in the practice of medicine or the provision of services; and section 1802 of the Act, which they interpret to mean that Medicare beneficiaries cannot be denied health services. The commenters believe that LTCHs forced to monitor admissions from the host will have a strong incentive to deny patients medically necessary inpatient service as the percentage of admissions from the host approaches 25 percent. Three commenters emphasized that there would be less likelihood of medical errors if a patient discharged from an acute care hospital could be admitted to an onsite co-located facility because of consistency in care and "fewer handoffs" would decrease the possibility of errors occurring. The costs of care would also be reduced because it would be unnecessary to repeat tests and other ordered procedures. Furthermore, the commenters felt that proposing such a policy indicated a lack of appreciation for the specialized care provided by LTCH HwHs and LTCHs in general.

Response: We disagree with the commenters who assert that through finalizing the 25 percent (or the applicable percentage) criterion, as a basis for adjusting payments to LTCH HwHs or satellites for patients admitted to the LTCH from the host acute care hospital, we are restricting patient care. As stated in the previous responses, we have established a payment policy, not a patient care policy. We would remind commenters who express disapproval of a LTCH monitoring its admission numbers as it approaches its threshold, that even before the October 1, 2002 implementation of the LTCH PPS, LTCHs under the TEFRA system had to monitor their admissions as well as their lengths of stay lest they fall below the greater than 25 day average length of stay qualification threshold for designation as a LTCH. From our research in designing the short-stay outlier policy during the development of the LTCH PPS, we became distinctly aware of admission choices made by LTCHs, particularly as the cost reporting period was drawing to a close, if the length of stay averages were below the

greater than the 25 day threshold required by the statute. Thus, this phenomenon is neither unique nor new. The establishment of a payment policy that may result in payment adjustments for certain admissions is well within the existing regulatory framework. We fail to see the relationship between the payment policy we are finalizing and an increase in the likelihood of medical errors, unnecessary tests, or other ordered procedures, patient trauma, or disruption in the consistency of care. Nor do we see compliance with the policy as leading to increased costs. We are finalizing this policy because we are concerned that the co-location of an acute hospital and a LTCH with significant patient movement from the acute hospital to the LTCH may violate the intent of the prohibition of LTCH units under section 1886(d)(1)(B) of the Act, a prohibition that was established in order to protect the Medicare system against unnecessary and inappropriate payments. We are finalizing a payment policy premised upon the fact that LTCH HwHs or satellites that admit more than a specified percentage of patients from their hosts are functioning as units and we are adjusting payments to the LTCH HwH or satellite accordingly. However, as explained earlier, we have revised the policy as proposed to reflect unique location factors and we allow for full payments beyond the threshold if the transferred patient has reached outlier status at the acute hospital. In this final rule, we have also provided for grandfathering of existing LTCH HwHs or satellites and certain LTCH HwHs that will be designated as LTCHs prior to October 1, 2005 and an additional 3-year phase-in to full compliance requirements. In these revisions, we have attempted to respond to valid concerns raised by our commenters as well as maintain the integrity of the statutory scheme in section 1886(d)(1)(B) of the Act which precludes LTCH units.

Although we strongly disagree that our payment policy will have the effect of restricting patient care at LTCH HwHs or satellites, we will respond to the commenters regarding the sections of the Act that they believe we are violating. As explained above, we do not believe that this policy interferes with the practice of medicine or provision of health care services under section 1801 of the Act. The policies that we are finalizing, as we explained earlier, are merely payment provisions. Nor are we violating section 1802 of the Act by interfering with a beneficiary's right to total self-determination regarding health care. This

interpretation of the provision is incorrect. The statute actually says, "Any individual entitled to insurance benefits under this title may obtain health services from any institution, agency or person qualified to participate under this title *if such institution, agency, or person undertakes to provide him such service.*" (emphasis added) In addition, our finalized rules do not preclude a beneficiary from seeking admission to a hospital of his or her choice. We continue to believe that we have not promulgated rules that will prohibit a LTCH from providing necessary services to Medicare patients, even if they are patients that are admitted from the co-located host hospital. Our LTCH HwH and satellite rules do not prohibit a hospital from admitting a patient. Rather, our LTCH HwH and satellite rules are payment rules that set forth how a LTCH HwH or satellite will be paid under a particular set of circumstances.

Comment: We received a comment from MedPAC that brought the following points to our attention: (1) The rapid growth in LTCH HwHs and rapid increases in Medicare spending for LTCH services; (2) the existence of a LTCH HwH quadrupled the probability that a beneficiary would use LTCH care; (3) freestanding LTCHs also have strong relationships with acute care hospitals, and that where on average LTCH HwHs receive 61 percent of their patients from their hosts, freestanding LTCHs receive 42 percent from their primary referring hospital; (4) concerns with LTCHs may be related to the payment systems and CMS policies for SNFs and acute care hospitals and should not therefore be considered in isolation; (5) there are some risks in CMS's proposed 25 percent policy; (a) The 25 percent rule that only applies to LTCH HwHs and not to freestanding LTCHs and may therefore be inequitable; (b) it does not ensure that patients go to the most appropriate post-acute setting; (c) this approach may be circumvented by an increase in the number of freestanding LTCHs instead of LTCH HwH. MedPAC shares our concern that the LTCH payment system creates an incentive for unbundling of the IPPS in addition to overpayment for the care provided by LTCHs and that this concern is great, particularly, in the case of a LTCH HwH. In MedPAC deliberations, the Commission considered recommending a moratorium on LTCH HwHs but did not adopt it. Finally, MedPAC stated that it reserves judgment on our proposed policies for LTCH HwHs pending more

empirical evidence demonstrating the unique risk posed by them.

Response: We appreciate the comments from MedPAC, which are consistent with our strong concerns with the growth in the number of LTCH HwH and our continuing questions about the relationships between treatment at acute care hospitals and LTCHs, as well as the linkage between payment policies and substitution of services especially among acute care hospitals, LTCHs, and some SNFs. While we also understand the reservations expressed in the comments, we want to emphasize that, as explained earlier, we are establishing these revised payment policies in this final notice for LTCH HwHs or satellites and not freestanding LTCHs because of the considerable growth in the number of LTCH HwH and because, ever since we first became aware of the existence of LTCH HwHs in 1994, we have been mindful of the strong resemblance that they bore to LTCH units of acute care hospitals, a configuration precluded by statute. The proposed policies are not intended to ensure that patients go to "the most appropriate post-acute setting." Rather, we believe that it is incumbent upon us to continually refine our payment systems to maintain the continued viability of the Medicare Trust Fund. In finalizing the revised LTCH HwH policy, therefore, as discussed previously in this preamble, we believe that this policy will help to protect the integrity of the IPPS DRG system as well as discouraging inappropriate payments under the LTCH PPS, the system that provides for the highest per discharge payment to a provider in the Medicare program. These policy goals typically require both proactive as well as reactive decisions on our part. We strongly support MedPAC's approach in their recent recommendations for developing standards that would identify the unique characteristics of a LTCH that warrant increased payments under the LTCH PPS. It is also important, as recommended by MedPAC to identify the specific types of patients that should be the unique patient load of LTCHs. Prior to the end of the 4 year transition period, CMS will reevaluate the HwHs criteria to assess the feasibility of developing facility and clinical criteria for determining the appropriate facilities and patients to be paid for under the Medicare LTCH PPS. If, during that time period, data from well-designed studies (or other compelling clinical evidence) indicate that developing this criteria is feasible, we would consider revisions to the HwH

regulations. We intend to analyze these issues and discuss any findings in the forthcoming FY 2006 LTCH PPS notice.

Comment: Several commenters allege that the proposed requirement for compliance with the 25 percent test will undermine two existing requirements of the Medicare program: Discharge planning and the involvement of the Quality Improvement Organizations (QIOs). Regarding discharge planning, the commenters argue that the 25 percent test will impact the host hospitals' requirement for discharge planning by limiting the most obvious site for continued treatment, which would be the onsite LTCH, and they believe that our proposed policy will encroach upon the responsibility of the QIOs to determine whether or not a case meets the standard of medical necessity.

Response: We do not agree with the commenters that the proposed policies in any way undermine the discharge planning function at the acute care hospital, set forth in § 482.43, or affect the involvement of QIOs in medical review at § 412.508. First of all, we must assert that the 25 percent test (which as a result of the changes in this final notice, for some hospitals, will actually be higher than 25 percent) does not set a cap or quota on the number of patients from the host hospital that the LTCH is permitted to admit. We are establishing payment policy based on a policy rationale first established in the September 1, 1994 final rule for the IPPS (59 FR 45390) wherein we stated that "the extent to which a facility accepts patients from outside sources can be an important indicator of its status as a separate facility, not merely a unit of another hospital." As noted elsewhere in these responses, we have revised existing regulations to specify a new standard solely for the purpose of determining appropriate Medicare payments. Accordingly, the finalized policy is a change only to payment policy and should not directly impact discharge planning. Under § 482.43 " * * * [a] hospital must have in effect a discharge planning process that applies to all patients." Paragraph (b)(3) of this regulation specifies that "[T]he discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services." (emphasis added.) Although we expect that the financial implications of the payment policy adjustments that we are finalizing may be factored into determinations of whether or not a particular post-acute provider is willing to admit a specific patient, there are additional factors that could typically affect the "availability of

services" (that is, the decision by the post-acute provider about whether to admit the patient in question). These factors include available bed space or ongoing compliance with regulations specific to each provider-type, such as the need for a LTCH to annually meet its greater than 25-day average length of stay requirements. Therefore, in light of the factors that must be considered by a post-acute hospital, we believe that rather than undermining the discharge planning process, the payment policy for LTCH HwHs or satellites that we are finalizing in this notice may join other issues that generally would be evaluated prior to accepting a patient from another hospital.

In response to the commenters' assertions that our proposed regulations undermine the role of QIOs as a vehicle to identify and prevent inappropriate utilization of LTCH HwHs or satellites, we note that, despite the importance of QIO activities in specific case review, and identification of treatment trends, we do not believe that, at least presently, the involvement of QIOs would be effective in dealing with problems of inappropriate payments for patients admitted to the LTCH HwH or satellite from the host hospital since so few discharges are actually subjected to QIO review.

Comment: We received a comment from an organization representing fiscal intermediaries requesting further information on implementation procedures should the proposed policies be finalized. In particular, there were questions about implementing on a systems level any of the three options proposed under the proposed 25 percent rule. The commenter suggests that we base payments for LTCH HwHs on one methodology for all Medicare patients, regardless of source of referral and therefore supports the option by which if the percentage of patients that a LTCH receives from its acute care hospital host exceeds 25 percent that the LTCH will no longer be paid as an excluded hospital. Another comment from an industry association urged us to subject any procedure by which a fiscal intermediary would evaluate compliance with a 25 percent test to public comment, because the commenter believes that our " * * * proposals are too vague and complicated for public comment at this time."

Response: Although we understand that establishing a "bright-line" policy whereby if hospitals fail the 25 percent (or the applicable percentage) test they would not be paid as excluded hospitals, is technically less complicated for fiscal intermediaries,

we believe that the policy that we have established appropriately addresses our policy concerns and is also equitable to those LTCHs that exist as LTCH HwHs or satellites and their host hospitals. We further believe that as discussed earlier in this preamble, there are ample systems-wide precedents (for example, transfer policy under the IPPS) for the type of policy adjustments that we are finalizing. Finally, the systems procedures that we establish in order to implement our policies are communicated in program memoranda that we will issue to our fiscal intermediaries following the October 1 effective date of the final rule and are not subject to notice and comment rule-making.

Comment: The majority of those commenters who disagreed with any of the specifics of our proposed policies for HwHs acknowledged our concerns about the unprecedented growth in the number of LTCH HwHs and the potential for inappropriate discharging of Medicare patients from the host hospitals to the LTCH HwH. Several commenters commended us for our "efforts to identify systemic abuses and to make policy changes that will result in cost savings." A number of commenters believe that our concern goes back to the broader issue which is that, presently, there is no clear and enforceable definition of LTCHs on a facility level and there are no appropriate medical standards for patient admission or retention. Moreover, there is no established criteria for what would constitute an appropriate discharge pattern from an acute care hospital to an on-site LTCH. Three commenters claim that our proposed policy does not address underlying issues of payment for an inappropriate level of care. There was significant concurrence among the majority of commenters, regardless of the degree to which they either endorsed or disagreed with our proposed policies, that we should study admission, discharge, and treatment patterns between acute care hospitals and all LTCHs, co-located or free-standing, and establish facility-level and patient criteria that could lead to criteria for "certification" as recommended by MedPAC in its June 2004 Report to the Congress. (Several commenters noted that one LTCH industry group has established a set of admission standards already being used by its member LTCHs.) Two commenters further encouraged us to establish a workgroup in collaboration with the Congress, providers, industry groups, and other

interested parties to explore these issues.

Response: We thank the commenters for agreeing with our concerns regarding the unprecedented growth in the number of LTCH HwHs the potential for inappropriate patient shifting between host hospitals and LTCH HwHs, and significantly, our efforts to identify abuses that threaten the viability of the Medicare Trust Fund. We agree with commenters that it may be worthwhile to examine patient and facility issues. Further examining of these issues may be beneficial in establishing the most effective and cost-efficient utilization of LTCHs and in assuring that Medicare beneficiaries receive the appropriate level of treatment and care in that setting. We continue to believe, however, that the policies that we have revised in this final notice are an appropriate response to concerns about Medicare payments to host hospitals and LTCH HwHs or satellites expressed throughout this preamble.

We also endorse the widespread enthusiastic industry support garnered by the recommendations in MedPAC's June 2004 Report to the Congress on "Defining long-term care hospitals." Although we continue to believe that the policy revisions regarding payments for patients from host hospitals to LTCH HwHs or satellites are necessary and appropriate to address the immediate problem we have identified with LTCH HwHs or satellites, which is underscored by the recent growth in those facilities, we believe that MedPAC has definitely identified the most significant issues for Medicare regarding payment policy for LTCHs, in general. We intend to address MedPAC's suggestions in a more thorough evaluation and discussion of the issues MedPAC has raised, in future **Federal Register** publications updating the next year's LTCH PPS. We further believe that MedPAC's June 2004 Report to the Congress has made a substantial contribution to a frank and fair exchange on issues dealing with payments to LTCHs. We wish to commend the Commission on a level of analysis that helped focus CMS on the growth in LTCH HwHs.

We are also aware that versions of admission criteria for LTCHs have been produced and have heard that some LTCHs have begun to use them. In response to the two commenters who urged us to convene a workgroup made up of providers, industry groups, and the Congress, we value our frequent contacts with all of these groups and will determine whether we will convene this group in the future.

We are finalizing revisions to separateness and control regulations at § 412.22(e) and adding new regulation at § 412.534, Special payment provisions for long-term care hospitals within hospitals.

Effective for cost reporting periods beginning on or after October 1, 2004, we are limiting the finalized policy revisions to addressing LTCH HwHs and also satellites of LTCHs (either LTCH HwH or free-standing). The policies will also be applicable for any type of host, including an IRF. We are finalizing policy to eliminate the existing three "Performance of basic hospital functions" options under existing § 412.22(e)(5) for qualifying as a LTCH HwH (the 15 percent rule and the basic functions test, and the 75/25 test). If a LTCH HwH meets existing separateness and control of administrative and medical governance provisions at § 412.22(e)(1) through (e)(4), payment will be made under the LTCH PPS as specified in § 412.534. Under § 412.534, if a LTCHs or satellite's discharges admitted from its host hospital exceed 25 percent (or the applicable percentage) of its discharges for the LTCH HwHs or satellite's cost reporting period, an adjusted payment will be made of the lesser of the otherwise full payment under the LTCH PPS and an amount that would be equivalent to what Medicare would otherwise pay under the IPPS. In determining whether a hospital meets this percent test, patients transferred from the host hospital that have already qualified for outlier payments at the host would not count as part of the host 25 percent (or the applicable percentage) and the payment for those patients would also not be subject to the adjustment. Those patients would be eligible for full payment under the LTCH PPS. (Discharges admitted from the host before the LTCH crosses the 25 percent (or the applicable percentage) threshold would be paid without the adjustment under the LTCH PPS.)

We are also finalizing additional adjustments to the 25 percent policy for specific circumstances. For rural acute care hospitals with LTCH HwHs or satellites, instead of the 25 percent criterion, the majority, (that is, 50 percent or more) of the discharges would have to be from the hospitals other than the host. In addition, in determining the percentage of discharges admitted from the host, any patient that had been a Medicare outlier at the host and then admitted to the LTCH HwH or satellite would be considered as if they were admitted from a non-host hospital. For urban single or MSA dominant hospitals, we

would allow the LTCH HwH or satellite to discharge patients admitted from the host up to the host's percentage of total Medicare discharges in the MSA for like hospitals. We would apply a floor of 25 percent and a ceiling of more than 50 percent to this variation. In addition, in determining the percentage of patients admitted from the host, any patient that had been Medicare outliers at the host and then admitted to the LTCH HwH or satellite would be considered as if they were admitted from a non-host hospital.

We are finalizing a 4-year phase-in of this policy for existing LTCH HwHs and satellites and also for LTCHs-under-formation that satisfy the following two-prong requirement: On or before October 1, 2004 they have certification as acute care hospitals, under Part 489; and before October 1, 2005 designation as a LTCH. For cost reporting periods beginning on or after October 1, 2004 and before October 1, 2005 these hospitals will be grandfathered, with the first year as a "hold harmless" followed by a percentage transition over the 3 years beginning in FY 2006. Grandfathered LTCH HwHs will need to continue to meet the existing separateness criteria at § 412.22(e) which includes compliance with either paragraph (e)(5)(i), (ii), or (iii) for that first cost reporting period. We are requiring that even for grandfathered facilities, for cost reporting periods beginning on or after October 1, 2004 and before October 1, 2005, the percentage of discharges admitted from the host hospital may not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period, which we have chosen since we are implementing the revised policy for cost reporting periods beginning on or after October 1, 2004 (FY 2005). We are establishing a transition percentage threshold for the percentage of discharges that may be admitted from the host before the payment adjustment applies to the discharge that were admitted from the host in excess of the threshold. After the first grandfathered cost reporting period, these LTCH HwHs and satellites will be required to meet a percentage transition over the 3 years beginning in FY2006. For the second year (cost reporting periods beginning on or after October 1, 2005, but before October 1, 2006) the percentage of the threshold will be the lesser of the percentage of their admissions from their host for their cost reporting period beginning on or after October 1, 2003 or 75 percent. For the third year (cost reporting periods beginning on or after October 1, 2006, but before October 1, 2007), the

percentage of the threshold will be the lesser of the percentage of their discharges admitted from their host for their cost reporting period beginning on or after October 1, 2003 or 50 percent, and for cost reporting periods beginning on or after October 1, 2007, the percentage threshold will be 25 percent or the applicable percentage.

Technical Change. In § 412.22(e) of our regulations, we refer to a hospital-within-a-hospital as a hospital that “occupies space in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital” (emphasis added). The reference to “entire” buildings is incorrect. We should have referred to “separate” buildings. Therefore, in the May 18, 2004 proposed rule, we proposed to correct this error.

C. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs, under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation in 42 CFR Part 485, Subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR Part 413.

2. Payment Amounts for CAH Services (Section 405(a) of Public Law 108–173 and §§ 413.70 and 413.114 of the Regulations)

Prior to the enactment of Public Law 108–173, section 1814(l) of the Act provides that the Medicare payment amount for inpatient services furnished by a CAH is the reasonable costs of the CAH in providing the services. Section 1834(g)(1) of the Act provides that the Medicare amount of payment for outpatient services furnished by a CAH is also made on a reasonable cost basis, unless the CAH makes an election, under section 1834(g) of the Act, to receive a payment amount that is the sum of the reasonable cost of hospital outpatient facility services plus 115 percent of the amount otherwise paid for professional services. Section 1883(a)(3) of the Act provides for payment to a CAH for covered skilled nursing facility services furnished under an agreement entered into under section 1883 of the Act on the basis of the reasonable costs of such services. Regulations implementing these provisions are set forth in § 413.70(a),

for inpatient CAH services; in § 413.70(b), for payment under the standard method for the reasonable costs of facility services, and outpatient CAH services; in § 413.70(b)(3), for the optional method of payment for outpatient services (reasonable costs for facility services plus fee schedule for professional services); and in § 413.114, for SNF services of a CAH with a swing-bed agreement.

Section 405(a) of Public Law 108–173 amended sections 1814(l), 1834(g)(1), and 1883(a)(3) of the Act to provide that, effective for services furnished during cost reporting periods beginning on or after January 1, 2004, the amount of the payment for inpatient, outpatient, and SNF services, respectively, furnished by a CAH is equal to 101 percent of the reasonable cost of the CAH in providing these services.

In the May 18, 2004 proposed rule (69 FR 28327–28328), we proposed to revise §§ 413.70(a)(1), (b)(2), and (b)(3) and § 413.114 of our regulations to incorporate the change in the payment percentage made by section 405(a) of Public Law 108–173. We also proposed to make a technical correction to § 413.70(b)(2)(i) to remove paragraphs (b)(2)(i)(C) and (D). We proposed to delete these paragraphs to conform the regulations to provisions of the outpatient hospital PPS.

We note that in the IPPS final rule published in the **Federal Register** on August 1, 2001 (66 FR 39936), we added a new paragraph (a)(1)(iv) to § 413.70. However, when the change was incorporated into the Code of Federal Regulations, paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) were inadvertently omitted. Our proposed revision of § 413.70(a)(1) would correct the omission of these three paragraphs.

We did not receive any public comments on our proposals. Accordingly, in this final rule, we are adopting the proposals as final without modification.

3. Condition for Application of Special Professional Service Payment Adjustment (Section 405(d) of Public Law 108–173 and § 413.70(b) of the Regulations)

As stated earlier, section 1834(g) of the Act provides for two methods of payment for outpatient CAH services. Under the provisions of section 1834(g) of the Act, a CAH will be paid under a reasonable cost method unless it elects payment under an optional method. Under the reasonable cost payment method, facility services are paid on a reasonable cost payment basis by the fiscal intermediary to the CAH, and physician and other professional

services to CAH outpatients are paid for under the physician fee schedule, with payments being made by the carrier. Under the optional method (frequently referred to as “method 2”), CAHs submit bills for both facility and professional services to the fiscal intermediary. If a CAH elects the optional method of billing for outpatient services, Medicare payment for its facility services are made at the same level as would apply under the reasonable cost reimbursement method, but services of professionals to outpatients are paid for at 115 percent of the amounts that would otherwise be paid for under the physician fee schedule. To make the optional method election feasible and to help prevent possible duplicate billing, we require practitioners furnishing services to outpatients of a CAH to agree to reassign to the CAH their rights to bill the Medicare program for those services.

Existing regulations at § 413.70(b) set forth these payment options and specify that an election of the optional method, once made for a cost reporting period, remains in effect for all of that period and applies to all services furnished to CAH outpatients during that period. This means that, under existing regulations, a CAH may elect the optional method payment only if all of its practitioners agree to reassign their billing rights for outpatient services to the CAH.

Section 405(d)(1) of Public Law 108–173 amended section 1834(g)(2) of the Act by adding a sentence after paragraph (B) to specify that the Secretary may not require, as a condition for a CAH to make an election of the optional method of payment, that each physician or other practitioner providing professional services in the CAH must assign billing rights with respect to the services. However, the optional payment method does not apply to those physicians and practitioners who have not assigned such billing rights. In other words, section 405(d) of Public Law 108–173 amended the Medicare law to authorize CAHs to elect the optional payment method even if some practitioners do not reassign to the CAH their rights to bill for professional services to CAH outpatients. However, it also specifies that the 15-percent increase in payment for those services is not available for professional services for which billing rights are not reassigned to the CAH.

The provisions of section 405(d)(1) of Public Law 108–173 are effective for cost reporting periods beginning on or after July 1, 2004. However, section 405(d)(2)(B) of Public Law 108–173 also states, in a special rule of application,

that in the case of a CAH that made an election before November 1, 2003, the provisions of section 405(d)(1) of Public Law 108–173 are effective for cost reporting periods beginning on or after July 1, 2001.

Consistent with section 405(d)(2)(B) of Public Law 108–173, we do not intend to attempt recovery of certain amounts paid improperly in the past to CAHs for professional services that the CAHs billed under the optional payment method, even though the CAHs had not obtained reassignments of billing rights from all physicians and other practitioners furnishing professional services to their outpatients, as required by § 413.70 as in effect at that time. However, in the May 18, 2004 proposed rule (69 FR 28328), we proposed to clarify that the special rule of application in section 405(d)(2)(B) of Public Law 108–173 is not to be interpreted to permit a CAH to obtain payment under the optional payment method for any cost reporting period based on an election made for a prior period or on an optional payment method election that was withdrawn or revoked prior to the start of the cost reporting period for which it was made.

To illustrate the application of section 405(d)(2)(B) of Public Law 108–173, assume that on October 1, 2002, a CAH elected method 2 for its cost reporting period starting on January 1, 2003, but did not obtain reassignments from all physicians treating its outpatients, as required by regulations in effect at that time. Under section 405(d)(2)(B) of Public Law 108–173, CMS would not recover any amounts from the CAH for payments for services furnished during that cost reporting period (January 1, 2003, through December 31, 2004) that are attributable to that election, even though the election was inappropriate based on the regulations that were in effect at the time it was made. Assume further that the same CAH recognized its error and did not make a method 2 election for its cost reporting period beginning January 1, 2004, thus receiving payment under method 1. The fact that the election of October 1, 2002, was made prior to November 1, 2003, is not material in this case and cannot be interpreted to justify method 2 payment for the cost reporting period beginning January 1, 2004, because that method 2 election related to an earlier cost reporting period and not to the cost reporting period beginning January 1, 2004. The same result would occur if the CAH had elected method 2 on October 1, 2003, but subsequently revoked that election on October 15, 2004.

In the proposed rule, we proposed to revise § 413.70(b)(3)(i) to reflect the changes made by section 405(d) of Public Law 108–173. We proposed to specify in § 413.70(b)(3)(i) that a CAH may elect to be paid for outpatient services in any cost reporting period beginning on or after July 1, 2004, under the method described in §§ 413.70(b)(3)(ii) and (b)(3)(iii). In § 413.70(b)(3)(i)(A), we proposed to clarify that such an election is to be made at least 30 days before the start of the cost reporting period for which the election is made. In § 413.70(b)(3)(i)(B), we proposed to specify that the provision applies to all services furnished to outpatients during that cost reporting period by a physician or other practitioner who has reassigned his or her rights to bill for those services to the CAH in accordance with the reassignment regulations under 42 CFR Part 424, Subpart F. In that paragraph, we also proposed to specify that if a physician or other practitioner does not reassign his or her billing rights to the CAH in accordance with 42 CFR Part 424, Subpart F, payment for the physician's or practitioner's services to CAH outpatients will be made on a fee schedule or other applicable basis specified in 42 CFR Part 414, Subpart B. We also proposed to add a new paragraph (C) to § 413.70(b)(3)(i) to state that, in case of a CAH that made an election under § 413.70(b)(3) before November 1, 2003, for a cost reporting period beginning before December 1, 2004, the rules in paragraph (b)(3)(i)(B) are effective for cost reporting periods beginning on or after July 1, 2001. In addition, we proposed in § 413.70(b)(3)(i)(B) to clarify that an election for the optional method would be effective only for any cost reporting period for which it was made and does not apply to an election that was withdrawn or revoked before the start of the cost reporting period for which it was made.

We did not receive any public comments on our proposals. Accordingly, in this final rule, we are adopting the proposals as final without modification.

4. Coverage of Costs for Certain Emergency Room On-Call Providers (Section 405(b) of Public Law 108–173 and §§ 413.70(b)(4) and 485.618 of the Regulations)

Under existing regulations at § 413.70(b)(4), which implement section 1834(g)(5) of the Act, Medicare payments to a CAH may include the costs of compensation and related costs of on-call emergency room physicians who are not present on the premises of

a CAH, are not otherwise furnishing services, and are not on-call at any other provider or facility when determining the reasonable cost of outpatient CAH services. Section 405(b) of Public Law 108–173 amended section 1834(g)(5) of the Act to expand the reimbursement to a CAH of compensation costs for on-call emergency room providers beyond physicians to include physician assistants, nurse practitioners, and clinical nurse specialists for the costs associated with covered Medicare services furnished on or after January 1, 2005.

In the May 18, 2004 proposed rule (69 FR 28329), we proposed to revise § 413.70(b)(4)(i) and (ii) to include the expanded list of emergency room on-call providers for whom reimbursement for reasonable compensation and related costs in a CAH would be available. We also proposed to make a conforming change to § 485.618(d) governing the standard for emergency room personnel who are on call under the CAH conditions of participation.

Comment: One commenter recommended that the proposed change to § 485.618(d), under which a clinical nurse specialist is added to the list of practitioners who may be on call to provide emergency services to CAH patients, be revised by adding a comma after the phrase “clinical nurse specialist.” The commenter believed this change will help to clarify that all practitioners who have on-call responsibilities, and not only clinical nurse specialties, should have training or experience in emergency care.

Response: We agree and have made this change to § 485.618(d) and a conforming change to § 413.70(b)(4)(ii)(B) in this final rule.

Accordingly, in this final rule, we are adopting the proposed changes to § 485.618(d) as final with one further technical change, as discussed above, to clarify that all practitioners who have on-call responsibilities should have training or experience in emergency care.

5. Authorization of Periodic Interim Payments for CAHs (Section 405(c) of Public Law 108–173 and Proposed §§ 413.64(h)(2)(vi) and 413.70(d) of the Regulations)

Section 1815(e)(2) of the Act provides that payments may be made on a periodic interim payment (PIP) basis for specified covered Medicare services. Section 405(c)(1) of Public Law 108–173 amended section 1815(e)(2) of the Act by adding a new subsection (E) to provide for payments for inpatient services furnished by CAHs on a PIP basis, effective for payments made on or

after July 1, 2004. Section 405(c)(2) of Public Law 108–173 directs the Secretary to develop alternative methods for the timing of the payments under the PIP method.

We have already established in existing regulations under § 413.64(h) provisions for making payments under the PIP method to providers for certain Medicare covered services. The principles and rules of § 413.64 have been incorporated into regulations governing payment on a PIP basis to acute care IPPS hospitals as well as to other providers, such as SNFs and LTCHs, that are paid on a prospective basis. We believe these principles and rules could be equally applied to CAHs. Therefore, in the May 18, 2004 proposed rule (69 FR 28329), to implement the provisions of section 405(c) of Public Law 108–173, we proposed to add a new § 413.64(h)(2)(vi) to specify inpatient services furnished by CAHs as an additional type of covered service for which PIP is available, effective for payments made on or after July 1, 2004.

It has been our longstanding policy under § 413.64(h)(6) that payment will be made biweekly under the PIP method, unless the provider requests a longer fixed interval (not to exceed 1 month) between payments. We believe that this provision grants adequate flexibility for the timing of payments under the PIP method to all qualifying providers, including CAHs. Under the proposed policy for CAHs, if a CAH chooses to receive its payments less frequently than biweekly, it could inform its Medicare fiscal intermediary. Section 413.64(h)(6) does not provide for the payments to be made more frequently than biweekly to providers for which PIP is currently available. We believe this is equally appropriate for the payments for inpatient services furnished by CAHs.

In summary, we proposed to apply the same rules and procedures for payments under the PIP method that we apply to acute care hospitals and certain other Medicare providers. Therefore, CAHs, in applying for and receiving payments for inpatient services under the PIP provision, would be operating under the same rules as other providers for which PIP is available under § 413.64(h), including the flexibility discussed above of the timing of their payments as provided for under § 413.64(h)(6). We also proposed to establish a new paragraph (d) under § 413.70 to provide that, for payments on or after July 1, 2004, a CAH may elect to receive PIP for inpatient services furnished by CAHs, subject to the provisions of § 413.64(h). The new § 413.70(d) summarizes the application

of the PIP provisions under § 413.64(h)(6) for CAH inpatient services and notes the availability of accelerated payments for CAHs that are not receiving PIPs.

Comment: Two commenters noted that section 405(c) of Public Law 108–173 provides that PIP for CAHs applies to payments made on or after July 1, 2004. One commenter believed that the new paragraph (d) under § 413.70 providing for PIP for CAHs “subject to the provisions of § 413.64(h)” suggests that payment of PIP would be for cost reports beginning on or after July 1, 2004. The commenters stated that some fiscal intermediaries have indicated that existing CAH facilities will not be able to receive PIP until the start of their first cost reporting period beginning on or after July 1, 2004 and that a CMS regional office has provided direction that the election of PIP is limited to the beginning of a CAH cost reporting period. The commenters asked CMS to clarify that qualifying CAHs are eligible for PIP, effective for payments made on or after July 1, 2004, not for cost reports beginning on or after that date.

Response: Qualifying CAHs are eligible for PIP for payments made on or after July 1, 2004. New § 413.64(h)(2)(vi) specifies that for inpatient CAH services furnished by a CAH, PIP is available for qualifying CAHs, effective for payments made on or after July 1, 2004. New § 413.70(d) also provides that a CAH may elect to receive PIP effective for payments made on or after July 1, 2004. Section 413.64(h)(3) has long provided that a provider that establishes to the satisfaction of its fiscal intermediary that it meets the requirements to receive PIP may elect to receive PIP, beginning with the first month after its request that the fiscal intermediary finds administratively feasible. This provision provides fiscal intermediaries some flexibility in beginning PIP for a provider, but we expect that fiscal intermediaries will begin PIP for providers, including CAHs, within a reasonable period of time after the fiscal intermediary has determined that the provider qualifies for PIP.

Comment: One commenter indicated that some fiscal intermediaries have interpreted the regulations at § 413.64(h) that a new CAH cannot receive PIP until at least one CAH cost report has been filed. Another commenter indicated that one CMS regional office has suggested that PIP is only available to those CAHs that have at least one full 12-month cost report under cost-based reimbursement.

Response: Section 413.64(h)(3)(ii) has long contained the requirement that, to qualify for PIP, the provider has filed at least one completed Medicare cost

report accepted by the fiscal intermediary as providing an accurate basis for computation of payment. However, the requirement contains an exception in the case of a provider requesting payment under PIP upon first entering the Medicare program. Therefore, a new CAH to the Medicare program need not have filed a cost report to be able to qualify for PIP. However, in the absence of a completed cost report, the fiscal intermediary must have other information in order to satisfy itself that it can make accurate PIP payments. A provider without a completed cost report needs to supply all information that the fiscal intermediary requests in order for the intermediary to make its determination as to whether it can make accurate payments to the provider under the PIP method. Section 413.64(h)(5) provides that approval of PIP is conditioned upon the intermediary’s best judgment as to whether accurate payments can be made under the PIP method. Therefore, if the fiscal intermediary is satisfied with the information it has received that it can make accurate payments under the PIP method, it will approve PIP for the provider. If the fiscal intermediary is not satisfied that it can make accurate payments, it is not to approve PIP for the provider.

A CAH need not have at least one full 12-month cost report under cost-based reimbursement to qualify for PIP. However, as discussed above, a fiscal intermediary is not to approve PIP unless it is satisfied that PIP will result in accurate payments. For a provider without a full 12-month cost report under cost reimbursement, the fiscal intermediary may request additional information from the provider in order to assure itself that it can make accurate payment to the provider under PIP. If the fiscal intermediary is satisfied with the information it has received that it can make accurate payments under the PIP method, it will approve PIP for the provider. If the fiscal intermediary is not satisfied, it is not to approve PIP for the provider.

After careful consideration of the comments received, we do not believe any changes are necessary, and we are adopting our proposal as final without modification.

Technical Changes to § 413.64. In the May 18, 2004 proposed rule, we proposed to use this opportunity to remove §§ 413.64(h)(3)(iv) and 413.64(h)(4), which contain an outdated requirement that a provider must repay any outstanding current financing payments before being permitted to be paid under the PIP method. Current financing payments have not been

available since 1973. We did not receive any public comments on this proposed technical change. Therefore, we are adopting it as final.

6. Revision of the Bed Limit for CAHs (Section 405(e) of Pub. L. 108–173 and §§ 485.620(a) and 485.645(a)(2) of the Regulations)

Prior to the enactment of Public Law 108–173, sections 1820(c)(2)(B)(iii) and 1820(f) of the Act restricted CAHs to 15 acute care beds and a total of 25 beds if the CAH had been granted swing-bed approval. The number of beds used at any time for acute care inpatient services could not exceed 15 beds.

Section 405(e) of Public Law 108–173 amended sections 1820(c)(2)(B)(iii) and 1820(f) of the Act to allow CAHs a maximum of 25 acute care beds for inpatient services, regardless of the swing-bed approval. This amendment is effective on January 1, 2004 and applies to CAHs designated before, on, or after this date. However, section 405(e)(3) of Public Law 108–173 also notes that any election made in accordance with the regulations promulgated to carry out the bed size amendments only applies prospectively.

We implemented this provision via a survey and certification letter on January 1, 2004. (See Survey and Certification Letter No. 0414, issued December 11, 2003.) Effective January 1, 2004, this provision allows any currently participating CAH, or applicant for CAH approval, to maintain up to 25 inpatient beds. If swing-bed approval has been granted, all 25 beds can be used interchangeably for acute care or swing-bed services. However, no CAH will be considered to have had 25 acute care beds prior to January 1, 2004. In the May 18, 2004 proposed rule (69 FR 28329), we proposed to amend our regulations at §§ 485.620(a) and 485.645(a)(2) to reflect the increase in the number of beds permitted in a CAH, in accordance with the amendments made by section 405(e) of Public Law 108–173.

We received no comments within the scope of this proposal and, in this final rule, we are adopting as final, without modification, our proposed amendments to §§ 485.620(a) and 485.645(a)(2) to reflect the increase in the number of beds to 25 permitted in a CAH, in accordance with the amendments made by section 405(e) of Public Law 108–173.

7. Authority to Establish Psychiatric and Rehabilitation Distinct Part Units of CAHs (Section 405(g)(1) of Pub. L. 108–173 and New § 485.646 of the Regulations)

As stated earlier, sections 1820(c)(2)(B) and 1861(mm) of the Act set forth the criteria for designating a CAH. Under this authority, the Secretary has established in regulations the minimum requirements a CAH must meet to participate in Medicare (42 CFR Part 485, Subpart F). The CAH designation is targeted to small rural hospitals with a low patient census and short patient stays.

Under the law in effect prior to Public Law 108–173, CAHs are excluded from operating distinct part units (that is, separate sections of hospitals that are dedicated to providing inpatient rehabilitation or psychiatric care and are paid under payment methods different from those used for the acute care areas of the hospitals). The statute (section 1886(d)(1)(B) of the Act) and implementing regulations under 42 CFR Part 412, Subpart B require distinct part units to be units of “subsection (d) hospitals,” which are hospitals paid under the IPPS. Because CAHs are not “subsection (d) hospitals” paid under IPPS, but instead are paid for inpatient care on a reasonable cost basis under section 1814(l) of the Act, they are effectively prohibited from having distinct part units.

Section 405(g)(1) of Public Law 108–173 modified the statutory requirements for CAHs under section 1814(l) and section 1820(c)(2) of the Act to allow CAHs to establish distinct part rehabilitation and psychiatric units of up to 10 beds each, which will not be included in the revised total 25 CAH bed count under section 405(e) of Public Law 108–173 (discussed in detail in section VI.D.6. of this preamble). In addition, as explained more fully below, the average 96-hour stay does not apply to the 10 beds in the distinct part units and inpatient admissions; days of inpatient care in these distinct part units are not taken into account in determining the facility’s compliance with the requirement for a facility-wide average length of stay that does not exceed 96 hours.

Section 405(g)(1) of Public Law 108–173 provides under section 1820(c)(2)(E)(i) of the Act that a distinct part rehabilitation or psychiatric unit of a CAH must meet the conditions of participation that would otherwise apply to the distinct part unit of a hospital if the distinct part unit were established by a subsection (d) hospital in accordance with the matter following

clause (v) of section 1886(d)(1)(B) of the Act, including any applicable regulations adopted by the Secretary. CAHs will now be permitted to operate distinct-part psychiatric and rehabilitation units, and it is clear that the law, consistent with this change, requires the same level of health and safety protection for patients in distinct part units of a CAH that is currently required for patients in distinct part units operated by an acute care hospital. The amendments to section 405(g)(1) Public Law 108–173 are effective for the cost reporting periods beginning on or after October 1, 2004.

As CAHs were excluded from operating distinct part units prior to the enactment of section 405(g) Public Law 108–173, the CAH conditions of participation did not address the necessary requirements and standards for operating such units. As noted previously, section 1820(c)(2)(E)(i) of the Act makes it clear that the requirements, including conditions of participation, for operating these units in a CAH are to be the same as is currently required for these units operated by an acute care hospital. Accordingly, we proposed that, in accordance with the requirements of section 405(g) Public Law 108–173, a rehabilitation or psychiatric distinct part unit of a CAH must meet all of the hospital conditions of participation at 42 CFR Part 482, Subparts A, B, C, and D and the criteria for exclusion from the IPPS at 42 CFR Part 412 as described below. These requirements will only apply to the services provided in the distinct part unit of a CAH and not the entire CAH.

Currently, psychiatric distinct part units of hospitals are subject to specific Medicare regulations established in 42 CFR 412.27 regarding the types of patients admitted, the scope of services furnished, and the qualifications of staff. For example, psychiatric distinct part units may admit only patients whose condition requires inpatient hospital care for a psychiatric principal diagnosis. The regulations at § 412.27(b) further requires a hospital that wishes to establish a psychiatric distinct part unit to furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, and occupational and recreational therapy. The hospital must maintain medical records for the unit that permit determination of the degree and intensity of services provided to individuals treated in the unit. Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership

required for an intensive treatment program, and who is board certified in psychiatry (42 CFR 412.27(d)(2)). The distinct part unit must have a director of social services, a qualified director of psychiatric nursing services who is a registered nurse with a master's degree in psychiatric or mental health nursing, or its equivalent from an accredited school of nursing, or is qualified by education and experience in the care of individuals with mental illness. There must also be an adequate number of registered nurses to provide 24-hour coverage as well as licensed practical nurses and mental health workers. These and other applicable requirements are set forth in greater detail in § 412.27.

Rehabilitation distinct part units of hospitals are currently subject to criteria in 42 CFR 412.29. This section specifies that such a unit must meet either the requirements for new units (§ 412.30(a)) or those for existing units (§ 412.30(c)). In addition, the units must furnish through qualified personnel rehabilitation nursing, physical and occupational therapy, and, as needed, speech therapy and social services or psychological services, and orthotics and prosthetics. The unit must have a director of rehabilitation services who is trained or experienced in medical management of inpatients who require rehabilitation services and is a doctor of medicine or a doctor of osteopathy. Rehabilitation distinct part units may treat only patients likely to benefit significantly from an intensive inpatient program, utilizing services such as physical, occupational, or speech therapy. These and other applicable requirements are set forth in greater detail in § 412.29 and § 412.30.

To implement the requirements of section 1820(c)(2)(E)(i) of the Act, as added by section 405(g)(1) of Public Law 108-173, in the May 18, 2004 proposed rule (69 FR 28330), we proposed to add a new § 485.647 to 42 CFR Part 485, Subpart F. In proposed § 485.647(a)(1), we proposed to specify that if a CAH provides inpatient psychiatric services in a distinct part unit, the services provided in that unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482, with the common requirements for IPPS-excluded units in § 412.25(a)(2) through (f), and with the additional requirements of § 412.27 for psychiatric units excluded from the IPPS. In proposed § 485.647(a)(2), we proposed to specify that if a CAH provides inpatient rehabilitation services in a distinct part unit, the services provided in that unit must comply with the hospital requirements

specified in Subparts A, B, C, and D of Part 482, with the common requirements for IPPS-excluded units in § 412.25(a)(2) through (f), and with the additional requirements of § 412.29 and § 412.30, which relate specifically to rehabilitation units excluded from the IPPS. To provide for consistent application of section 405(g)(1) Public Law 108-173 and avoid any confusion, we also proposed to revise § 412.22, which contains the common requirements for excluded hospital units, to state that, for purposes of 42 CFR Part 412, Subpart B, the term "hospital" includes a CAH.

As noted earlier, sections 1820(c)(2)(E)(ii) and (c)(2)(E)(iii) of the Act, as added by section 405(g)(1) of Public Law 108-173, provide that each distinct part unit of a CAH may have up to 10 beds and that, in determining the number of beds a CAH has for purposes of compliance with the 25-bed limit described earlier, the beds in a distinct part unit are not to be taken into account. We interpret the exclusion of these beds from consideration for purposes of the 25-bed limit as also indicating that the admissions and lengths of stay in distinct part unit beds are not to be considered in determining the facility-wide average length stay of a CAH for purposes of the 96-hour limitation on CAH's average length of inpatient stay. We proposed to codify these rules in paragraphs (b)(1) through (b)(3) of proposed § 485.647.

Section 1820(c)(2)(E)(iv) of the Act, as added by section 405(g)(1) of Public Law 108-173, imposes severe sanctions on CAHs that fail to operate their distinct part units in compliance with applicable requirements. That section states that if a psychiatric or rehabilitation unit of a CAH does not meet the requirements of section 1820(e)(2)(E)(i) of the Act with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Payment to the CAH for services in the unit may resume only after the CAH unit has demonstrated to CMS that the unit meets the requirement of section 1820(e)(2)(E)(1) of the Act. We proposed to codify this requirement by adding a new paragraph (g) to § 412.25, which contains the common requirements for excluded units.

Section 405(g)(1) of Public Law 108-173 amended section 1814(l) of the Act by adding a new paragraph (2) to that provision. New section 1814(l)(2) of the Act states that, in the case of a distinct-part psychiatric or rehabilitation unit of a CAH, the amount of payment for inpatient CAH services of such a unit is to equal the amount that would be paid

if these services were inpatient hospital services of a psychiatric or rehabilitation unit, respectively, of the kind described in the matter following clause (v) of section 1886(d)(1)(B) of the Act. To implement the requirements of section 1814(l)(2) of the Act, we proposed that, for CAHs that establish rehabilitation or psychiatric distinct part units, or both, in their facility, Medicare payment for inpatient services provided in those units would be made under the applicable existing payment methodology described below for IRFs and IPFs.

Presently, IRFs are paid under a per discharge PPS that became effective for cost reporting periods beginning on or after January 1, 2002. The regulations governing the IRF PPS are located under 42 CFR Part 412, Subpart P (§ 412.600 through § 412.632).

At this time psychiatric hospitals and units that are excluded from the IPPS are paid for their inpatient operating costs on a reasonable cost basis, subject to a hospital-specific limit. However, as required by statute, a per diem PPS for Medicare payments for inpatient hospital services furnished in psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)) was proposed in the **Federal Register** on November 28, 2003 (68 FR 66920). We are in the process of developing the final rule for this proposed rule. When finalized, the IPF PPS will replace the reasonable cost based payment system currently in effect.

To clarify the requirements of section 1814(l)(2) of the Act regarding payment for inpatient CAH services of a distinct part psychiatric or rehabilitation unit of a CAH, in the May 18, 2004 proposed rule, we proposed to revise the title and first sentence of paragraph (a)(1) of § 413.70, and to add a new paragraph (a)(4) to that section, to clarify that payment for inpatient services of a CAH distinct part unit is not made in accordance with the otherwise applicable rules for payment for inpatient CAH services, but under other rules described in new § 413.70(e). We also proposed in new paragraph § 413.70(e), that payment for inpatient services of distinct part rehabilitation units of CAHs is made in accordance with regulations governing the IRF PPS at 42 CFR Part 412, Subpart F (§ 412.600 through § 412.632). We also proposed to state that payment for inpatient services of distinct part psychiatric units of CAHs is made in accordance with regulations governing IPPS-excluded psychiatric units of hospitals at 42 CFR 413.40.

Comment: One commenter expressed concern with the requirement that a CAH must have an "adequate" number of doctors with appropriate qualifications "to provide essential psychiatric services." The commenter was concerned that, due to the small size of CAHs and the limited number of psychiatrists in rural areas, CAHs may hire psychiatrists who spend only a small portion of their time at the CAH. The commenter suggested that we consider requiring clinical directors to devote a specified minimum amount of time to each psychiatric unit they serve to offset the possibility of an inadequate supply of physicians.

Response: We believe the clinical director must devote the appropriate amount of time to meet the needs of the patients in the unit. We stated in the proposed rule that CAHs that operate a distinct-part psychiatric unit must comply with the same health and safety requirements as other Medicare-certified acute care hospitals that operate distinct-part psychiatric units. Currently, distinct-part psychiatric units of hospitals are subject to specific Medicare regulations regarding the staff and scope of services for psychiatric inpatient care. In addition to a clinical director, the distinct-part psychiatric unit must have a director of social services, a qualified director of psychiatric nursing services who is a registered nurse with a master's degree in psychiatric or mental health nursing, or its equivalent from an accredited school of nursing, or is qualified by education and experience in the care of individuals with mental illness. We believe that these requirements, and others set forth in greater detail in § 412.27, are required to safeguard the care of individuals in a CAH distinct-part psychiatric unit.

Comment: One commenter stated that requiring CAH distinct part psychiatric and rehabilitation units to meet all of the hospital conditions of participation at 42 CFR Part 42, Subparts A, B, C and D will require both the JCAHO and the State survey agencies to conduct two surveys when assessing CAHs. The commenter stated that this requirement would result in a burdensome oversight strategy that would cause CAHs to decide not to add distinct part units.

Response: Section 405(g)(1) of Public Law 108-173 states that a distinct-part rehabilitation or psychiatric unit of a CAH must meet the conditions of participation that would otherwise apply to a distinct-part unit of a hospital. Therefore, we believe that it is clear that the Congress wants the same level of health and safety protection for patients in a distinct-part unit operated

by a CAH as those that are currently required for patients in a distinct-part unit operated by an acute care hospital.

Therefore, it will be necessary for a distinct-part psychiatric or rehabilitation unit of a CAH to undergo a survey to demonstrate compliance with the requirements stipulated in the statute. Until a CAH receives approval and a provider number from CMS for any DPUs, the services furnished in those units will not be eligible for Medicare reimbursement. The CAH is not required to furnish such uncompensated services to Medicare beneficiaries prior to its approval.

Comment: As previously noted, proposed § 412.25(g) would require denial of payment to a CAH for services of a distinct-part psychiatric or rehabilitation unit of a CAH if that unit does not meet the requirements of proposed § 485.647 with respect to a cost reporting period. Under the proposal, no payment may be made to the CAH for services furnished in that unit for that period. The section further states that payment to the CAH for services in the unit may resume only after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

One commenter stated that the rule is unclear as to whether, if a failure to meet proposed § 485.647 is both noted and corrected in the same cost reporting period, would payment resume as soon as the noncompliance is corrected. The commenter recommended that the section be revised to state that payment will be denied only from the date on which the deficiency was noted to the date on which it was corrected.

Response: We do not believe that the commenter's recommendation is supported by the statute. As noted above, section 405(g)(1) of Public Law 108-173, states that if a psychiatric or rehabilitation unit of a CAH does not meet the requirements of section 1820(c)(2)(E)(i) of the Act with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Because the law is so specific on this issue, we do not have the flexibility to resume payment for services of a unit during any part of the same period in which the unit fails to meet applicable requirements of section 1820(c)(2)(E)(i) of the Act, as implemented by the regulations in new § 485.649. On the contrary, the law would permit payment to the CAH for services for such a unit to resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647. We have revised § 412.25(g)

to clarify that. Payment to the CAH for services provided in such a unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

Although we considered carefully the comments received regarding distinct-part units of CAHs, we concluded that they did not raise considerations that would require changes to the proposed rule. Therefore, in this final rule, we are adopting as final the proposed amendments to § 413.70(a)(1) and the proposed addition of § 413.70(a)(4), § 413.70(e), and § 485.647 to implement the requirements under section 405(g)(1) of Public Law 108-173 for CAHs to establish and receive payment under Medicare for psychiatric and rehabilitation distinct part units. In the May 18 2004, proposed rule, we proposed to implement this provision under proposed § 485.647. However, the statute would permit payment to the CAH for services of such a unit to resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of proposed § 485.647. In this final rule, we are revising § 412.25(g) to clarify that payments to the CAH for services provided in such a unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

Comment: Several commenters questioned how distinct-part unit beds are to be classified in a CAH if the facility had distinct-part unit beds prior to converting to a CAH. The commenters inquired if the distinct-part unit beds will be considered new or converted beds.

Response: In order for Medicare to classify a provider as a CAH, the provider must meet specific regulatory requirements. Therefore, we believe a CAH evolved into a different provider classification from the type of provider it was prior to converting to a CAH. Under the statute in effect prior to Public Law 108-173, a CAH was not allowed to establish an inpatient rehabilitation DPU. Section 405(g)(1) of Public Law 108-173 modified the statutory requirements for CAHs under section 1820(c)(2) of the Act to allow a CAH to establish a rehabilitation DPU of up to 10 beds. A CAH that meets all inpatient rehabilitation DPU regulatory requirements, on or after the effective date of this final rule, will be allowed to establish an inpatient rehabilitation DPU whose size does not exceed 10 beds. According to § 412.30(b)(1)(i), a

new unit is a hospital unit that the hospital has not previously sought to exclude from the IPPS. In addition, before the hospital unit may be considered a new unit, § 412.30(b)(1)(ii) of our regulations requires that the hospital have “obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds in the unit.” Because a CAH is a different provider from the entity it was prior to converting to being a CAH, and was not previously allowed to establish an inpatient rehabilitation DPU, a CAH never sought exclusion for any inpatient rehabilitation unit. Therefore, if a CAH establishes an inpatient rehabilitation DPU, that DPU will be considered to be a new unit in accordance with § 412.30(b)(1)(i) of our regulations, as long as the CAH also meets the requirements specified in § 412.30(b)(1)(ii) of our regulations.

Comment: One commenter requested that their hospital be grandfathered into the CAH program and be allowed to maintain a 15-bed psychiatric distinct-part unit.

Response: We do not have the authority to grandfather a hospital into the CAH program. A facility can be certified as a CAH if the facility is designated as a CAH by the State survey agency or by CMS and found to meet the conditions of participation in 42 CFR Part 485, Subpart F. Regardless, the statute does not allow CAHs to exceed the 10-bed limit for distinct-part units.

We considered carefully the comments received regarding distinct-part units of CAHs. To implement the requirements under section 405(g)(1) of Public Law 108–173 for CAHs to establish and receive payment under Medicare for psychiatric and rehabilitation distinct part units, in this final rule, we are adopting the proposed amendments to § 413.70(a)(1) and the proposed addition of §§ 413.70(a)(4), 413.70(e), and 485.647 as final, with one modification. That is, we are revising § 412.25(g) to clarify that payments to the CAH for services provided in such a unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

8. Waiver Authority for Designation of a CAH as a Necessary Provider

Section 405(h) of Public Law 108–173 amended section 1820(c)(B)(i)(II) of the Act by adding language that terminates a State’s authority to waive the location requirement for a CAH by designating the CAH as a necessary provider,

effective January 1, 2006. Currently, a CAH is required to be located more than a 35-mile drive (or in the case of mountainous terrain or secondary roads, a 15-mile drive) from a hospital or another CAH, unless the CAH is certified by the State as a necessary provider of health care services to residents in the area. Under this provision, after January 1, 2006, States will no longer be able to designate a CAH based upon a determination that it is a necessary provider of health care.

In addition, section 405(h) of Public Law 108–173 amended section 1820(h) of the Act to include a grandfathering provision for CAHs that are certified as necessary providers prior to January 1, 2006. Under this provision, any CAH that is designated as a necessary provider in its State’s rural health plan prior to January 1, 2006, will be permitted to maintain its necessary provider designation.

In the May 18, 2004 proposed rule (69 FR 28331), we proposed to revise our regulations at § 485.610(c) to incorporate the amendments made by section 405(h) of Public Law 108–173.

Comment: Commenters were concerned that some hospitals may receive the necessary provider designation by the State before January 1, 2006, but would not have had enough time to complete the State survey and certification process in order to be fully converted to a CAH by January 1, 2006. The commenters recommended that we grandfather a hospital that is certified as a necessary provider by January 1, 2006, as long as that hospital is continuing the process toward conversion to a CAH.

Response: Both the preamble and the regulations text concerning this issue in the proposed rule state that a CAH that is designated as a necessary provider in its State’s rural health plan as of January 1, 2006, will maintain its necessary provider designation after January 1, 2006. However, in keeping with the clear intent of section 405(h) of Public Law 108–173, if a facility is not a CAH as of January 1, 2006, the ability to be designated as a necessary provider before becoming a CAH will no longer exist after January 1, 2006. Extending the time to allow for such a facility to convert to a CAH would violate this intent. Therefore, we are not accepting these commenters’ recommendation.

Comment: One commenter stated several CAHs in Nebraska are considering replacing their aged facilities and wanted to know if a CAH could retain its necessary provider status if it relocates. The commenter inquired if the necessary provider status would remain with the provider number

and not be determined by the physical location of the building.

Response: There are many factors involved with a relocation of a CAH that may or may not change a CAH’s status as a necessary provider. It is not possible to make a statement in this final rule that would apply to all situations. The issue of retaining a necessary provider status after a CAH relocates is a local certification issue that the regional offices will evaluate on a case-by-case basis.

In this final rule, we are adopting as final, without modification, the provisions of § 485.610(c) that incorporates the amendments made by section 405(h) of Public Law 108–173.

9. Payment for Clinical Diagnostic Laboratory Tests

Medicare payment for clinical diagnostic laboratory tests provided to the outpatients of CAHs was established through the regulatory process and published in the **Federal Register** as part of the FY 2004 IPPS final rule (68 FR 45346, August 1, 2003). Payment to a CAH for clinical diagnostic laboratory tests for outpatients is made on a reasonable cost basis only if the individuals for whom the tests are performed are outpatients of the CAH and are physically present at the CAH at the time specimens are collected. Otherwise, payment for these tests is made on a fee schedule basis.

We published this final rule to clarify our policy in this area and ensure that all relevant issues were publicly noted. For reasons which are set forth in detail in the FY 2004 IPPS final rule, we do not agree that providing reasonable cost payment to individuals who are not present at the CAH when the specimen is collected is appropriate. We believe that extending reasonable cost payment in these instances is inconsistent with Medicare law and regulations and duplicates existing coverage. It also creates confusion for beneficiaries and others by blurring the distinction between CAHs and other types of providers (for example, SNFs and HHAs) and increases the costs of providing care to Medicare patients without enhancing either the quality or the availability of that care.

Following publication of the FY 2004 IPPS final rule, we received a number of letters and statements in Open Door Calls indicating that some commenters continue to believe that this policy will impose a hardship on Medicare beneficiaries in rural areas. Several of these commenters argued that it might cause frail elderly nursing home patients to have to be moved to a CAH to have blood drawn or other specimen

collection performed instead of sending a laboratory technician to the patient's bedside for the same purpose. We agree with the commenters that this would not be an appropriate result. However, we would note that there are also alternative ways in which specimen collection and travel are payable under Medicare (for example, the laboratory benefit under Part B or HHAs that have laboratory provider numbers). Therefore, we do not expect beneficiaries to face reduced access to services under this policy.

In response to continuing claims of potential access problems, we invited commenters to submit further, more specific comments that provide specific information on actual, rather than merely potential or anticipated access problems. In response, we received many communications asserting that these problems would occur, but no credible documentation that they actually are occurring. As a result of these responses, we did not propose any further change in policy on this issue in the May 18, 2004 proposed rule (69 FR 28331–28332). We indicated that we would like to renew our request for specific, verifiable documentation as to any actual access problems being generated by this policy, and would review carefully any such documentation we receive to determine whether current policy should be reconsidered.

Comment: Some commenters asserted that CMS policy in this area is shortsighted and not in the best interest of rural beneficiaries or hospitals, or that it would restrict access to laboratory services in rural areas, but provided no documentation of access problems or other evidence to support their assertions.

Response: While we read the commenters' letters with interest, we noted that they merely restated former comments, but did not provide any objective evidence in support of their comments that maintaining the current policy regarding payment for clinical diagnostic laboratory tests would compromise access to these tests in rural areas. Therefore, we made no changes in our policy in this area based on these comments.

Comment: One commenter stated that five CAHs in the commenter's State (Kansas) have either eliminated or seriously limited the processing of specimens drawn from off-site locations in response to the payment policy for clinical diagnostic laboratory tests.

Response: We appreciate this additional information and will take it into account as we consider whether

any revision should be made to this policy.

10. Continued Participation by CAHs in Counties Reclassified as Urban Based on the 2000 Census

Under section 1820(c)(2)(B)(i) of the Act, a facility is eligible for designation as a CAH only if it is located in a county or equivalent unit of local government in a rural area (as defined in section 1886(d)(2)(D) of the Act), or is being treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. The regulations implementing this location requirement are located at 42 CFR 485.610(b)(2). As previously noted, some facilities currently participating as CAHs are located in counties which are located in areas considered as "rural areas" in FY 2004 under the definition in section 1886(d)(2)(D) of the Act but will, as of October 1, 2004, be considered to be located in MSAs because of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003. We received a number of comments on this issue.

Comment: Several commenters recommended that CMS exercise executive discretion to allow continued CAH participation by facilities which are currently (that is, for FY 2004) participating as CAHs but are located in counties which will be considered part of MSAs effective October 1, 2004, as a result of data from the 2000 census and implementation of the new MSA definitions announced by OMB on June 6, 2003. The commenters stated that if such facilities' CAH participation were terminated, they would be likely to again seek State licensure and Medicare participation as hospitals in order to be able to continue operations. However, this change to hospital status would not be automatic but would require the facility either to be re-licensed as a hospital by the State and to successfully demonstrate compliance with the hospital conditions of participation (COPs) based either on a CMS survey conducted by the State survey agency under contract with CMS, or on hospital accreditation by the JCAHO or the American Osteopathic Association (AOA). Once the facility has resumed participation as defined under section 1886(d) of the Act, the facility could then be treated as a "rural" hospital under section 1886(d)(8)(E)(ii)(II) of the Act, which provides such treatment for any hospital located in an area designated by law or regulation of the State as a rural area. If the facility were to obtain such a designation and met other criteria for CAH conversion, it would then be qualified for designation

by the State and certification by CMS as a CAH, notwithstanding its location in an MSA. The commenters believed such a sequence of changes in the status of a facility (that is, from being a CAH to being a hospital to again being a CAH) would be costly and time consuming for both the facility and CMS, and would not serve any useful purpose, because at the conclusion of the process the facility would resume participating as a CAH, as it did during FY 2004. Therefore, some of these commenters recommended that CMS continue to treat CAHs in such counties as being rural for an indefinite time period. Other commenters recommended that CAHs in such counties be considered rural until at least January 1, 2006, in order to allow them an opportunity to obtain rural designations under applicable State law or regulations from their State legislatures or regulatory agencies.

Another commenter did not recommend any particular course of action to be taken by CMS, but asked whether there were any plans to develop a grandfather provision to avoid a break in CAH participation by facilities affected by the new census results.

Response: We agree with the commenters' concerns and are revising § 485.610 by adding a new paragraph (b)(3) to provide special treatment for such facilities. Under the new paragraph, a CAH that is located in a county that, in FY 2004, was not part of a MSA as defined by the OMB, but as of FY 2005 was included as part of a MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, would nevertheless be considered to meet the rural location requirement and, therefore, could continue participating without interruption as a CAH from October 1, 2004, through the earlier of the date on which the CAH obtains a rural designation under § 412.103, or December 31, 2005. Such a facility would be allowed to continue participating as a CAH and would not be required to convert back to being a hospital unless it was not able to obtain a rural designation under § 412.103. We are also amending § 412.103 to clarify that such a CAH is eligible for rural designation under that section.

Comment: One commenter suggested that changes in the status of an area from rural to urban as a result of the most recent census data and implementation of the new MSA definitions be applied only for purposes of determining the wage index values for providers paid under a system that

uses a wage index adjustment, and not for determining a rural location for purposes of eligibility of a facility to participate in Medicare as a CAH.

Response: We reviewed this suggestion but concluded that section 1820 of the Act, which specifically refers to rural areas as, defined in sections 1886(d)(2)(D) and 1886(d)(8)(E) of the Act, do not authorize us to implement the new census results and MSA designation rules in such a selective way. Therefore, in this final rule, we are not adopting this recommendation.

11. Proposed Technical Changes in Part 489

In several sections of Part 489, we have discovered a need to update cross-references to conform them to the redesignation of the Medicare transfer rules from § 489.24(d) to § 489.24(d). Specifically, as we proposed in the May 18, 2004 proposed rule (69 FR 28332), we are correcting the cross-reference to “§ 489.24(d)” in §§ 489.20(m) and 489.53(b)(2) to read “§ 489.24(e)”.

12. Issues Beyond the Scope of the Proposed Rule

In the proposed rule published on May 18, 2004, we proposed changes affecting CAHs only if they were related to MSA definitions and the results of the 2000 census, or to the provisions of section 405 of Public Law 108–173. In addition, as previously noted, we requested documentation regarding the effects of the rule on payment for clinical diagnostic laboratory tests by a CAH, but did not propose any change in that rule.

In response to the proposed rule, many commenters chose to raise issues that are beyond the scope of our proposals. In this final rule, we are not summarizing or responding to those comments in this document. However, we will review the comments and consider whether to take other actions, such as revising or clarifying CMS program operating instructions or procedures, based on the information and recommendations in the comments.

VII. Changes to the Disclosure of Information Requirements for Quality Improvement Organizations (QIOs)

A. Background

Section 1152 of the Act defines a utilization and quality control peer review organization (now referred to as a quality improvement organization (QIO). Section 1153 provides for contracts with such organizations to review items and services furnished by physicians, other practitioners, and

providers to Medicare patients to verify that the items and services are reasonable, medically necessary, and allowable under the Act; meet professionally recognized standards of health care; and are furnished in the appropriate setting. Section 1154 of the Act outlines the functions of a QIO, which include responsibility for: (1) Collecting and maintaining information necessary to carry out its responsibilities; (2) examining pertinent records maintained by the practitioner or provider verifying the medical necessity and quality of services provided by any practitioner or provider of health care services to Medicare patients; (3) ensuring that health care practitioners and providers maintain evidence of medical necessity and quality of health care services provided to Medicare patients; and (4) exchanging information with intermediaries, carriers, and other public or private review organizations as appropriate. Section 1160 of the Act provides that information acquired by QIOs in the exercise of their duties and functions must be held in confidence. Information cannot be disclosed except as allowed under section 1160 of the Act and the existing regulations governing the release of QIO peer review information in 42 CFR Part 480. Specifically, Part 480 sets forth the policies and procedures for disclosure of information collected, acquired, or generated by a QIO (or the review component of a QIO subcontractor) in the performance of its responsibilities under the Act and the Medicare regulations, as well as the acquisition and maintenance of information needed by a QIO to comply with its responsibilities under the Act.

QIOs assist institutions and practitioners seeking to improve the quality of care given to Medicare beneficiaries. CMS aims to ensure that adequate protections of information collected by QIOs are in place and, at the same time, to ensure that the quality improvement activities of these institutions and practitioners are not unnecessarily hindered by regulations. It has come to our attention that the existing regulations omit information disclosure procedures that would allow for the effective and efficient exchange of information that is an essential part of quality improvement activities. In addition, it has come to our attention that, although the QIO does not need the consent of the institution to release nonconfidential information, the existing 30-day advance notice requirement to an institution prior to releasing public information or any other nonconfidential information that

identifies an institution, when an institution consents to or requests the release of information, impedes the ability of QIOs to conduct quality improvement work. If the institution requests or consents to the release of the information, the institution is already aware of the QIO's intention to disclose the nonconfidential information. Therefore, we see no reason to require the additional 30-day advance notice. Likewise, there is no reason to require a 30-day notice for practitioners who request the release of information for quality improvement activities or other permissible releases under the regulations.

B. Provisions of the May 18, 2004 Proposed Regulations

In the May 18, 2004 IPPS proposed rule (69 FR 28332), we proposed to make several changes in the regulations in Part 480 to expedite the exchange of information and minimize delays and expenditures currently required of QIOs, institutions, and practitioners as discussed below.

Existing § 480.105(a) requires that a QIO must notify an identified institution of its intent to disclose nonconfidential information about the institution and provide a copy of the information at least 30 calendar days before the disclosure. Section 480.105 also includes certain notice requirements a QIO must meet before disclosing confidential information that identifies practitioners and physicians. Section 480.106 presently includes several exceptions to these notice requirements. We proposed to revise § 480.106 to establish additional exceptions to the notice requirements in § 480.105(a) and (b)(2). We proposed to specify that the notice requirements in § 480.105(a) and (b)(2) would not apply if (1) the institution or practitioner has requested, in writing, that the QIO make the disclosure; (2) the institution or practitioner has provided written consent for the disclosure; or (3) the information is public information as defined in § 480.101 and specified in § 480.120.

Existing § 480.133(a)(2)(iii) specifies that a QIO may disclose to any person, agency, or organization confidential information on a particular practitioner or reviewer with the consent of that practitioner or reviewer, provided that the information does not identify other individuals. In the May 18, 2004 IPPS proposed rule (69 FR 28369), we proposed to revise § 480.133(a)(2)(iii) to allow for the release of information at the written request of the practitioner or reviewer, in addition to information releasable with the consent of the

practitioner or reviewer under the existing provision. Specifically, the proposed revised § 480.133(a)(2)(iii) would provide that a QIO may disclose confidential information about a particular practitioner or reviewer at the written request of, or with the written consent of that practitioner or reviewer. The recipient of the information would have the same redisclosure rights and responsibilities as the requesting or consenting practitioner or reviewer would, under the authority of Subpart B of Part 480. In addition, we proposed a similar revision to § 480.140 relating to the release of quality review study information. Specifically, we proposed to revise § 480.140 by adding a new paragraph (d) (the existing paragraphs (d) and (e) would be redesignated as paragraphs (e) and (f), respectively) to provide that a QIO may disclose quality review study information with identifiers of particular practitioners or institutions at the written request of, or with the written consent of, the identified practitioner(s) or institution(s). The recipient of the information would have the same redisclosure rights and responsibilities as the requesting or consenting practitioner or institution would, under the authority of Subpart B of Part 480. (We note that we published a correction to the language for this proposal in the **Federal Register** on June 25, 2004 (69 FR 35920). In that notice, we indicated that we had inadvertently referred to a “reviewer” and a “consenting reviewer” in this provision. We should have indicated an “institution” and a “consenting institution.”)

In the May 18, 2004 proposed rule, we indicated that we believed these proposed revisions would reduce the existing burden on practitioners, institutions, and QIOs and, at the same time, ensure that necessary protections on information remain in place. We also believed that the proposed revisions would allow QIOs, institutions, and practitioners to share vital information in an effective manner and further our efforts to ensure the highest quality of care possible for Medicare beneficiaries.

C. Technical Changes

In the May 18, 2004 IPPS proposed rule (69 FR 28369), we proposed to revise the title of Part 480 under Subchapter F of Chapter IV of 42 CFR to conform it to a previous regulatory change in the name of the organization conducting medical reviews under Medicare from a peer review organization to a quality improvement organization. The proposed new title is “Part 480—Acquisition, Protection, and

Disclosure of Quality Improvement Organization Information”.

In a final rule published in the **Federal Register** on November 24, 1999 (64 FR 66279), we redesignated Part 476 as Part 480. However, as part of the redesignation process, we inadvertently failed to make appropriate changes to the cross-references in various sections under the redesignated Part 480. In the May 18, 2004 proposed rule, we proposed to correct those cross-references.

We received a number of public comments in support of the proposals for QIO information requirements and therefore, are adopting as final the proposals and the title change without further modification.

VIII. Policy Changes Relating to Medicare Provider Agreements for Compliance With Bloodborne Pathogens Standards, Hospital Conditions of Participation, and Fire Safety Requirements for Certain Health Care Facilities

A. Hospital Conditions of Participation for Discharge Planning

1. Background

As part of the definition of “hospital,” sections 1861(e)(1) through (e)(8) of the Act set forth specific requirements that a hospital must meet to participate in the Medicare program. Section 1861(e)(9) of the Act specifies that a hospital also must meet other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in hospitals. Implementing regulations for section 1861(e) of the Act, setting forth the conditions of participation (CoPs) that a hospital must meet to participate in the Medicare program, are located in 42 CFR Part 482.

The purposes of these CoPs are to protect patient health and safety and to ensure that high quality care is furnished to all patients in Medicare-participating hospitals. In accordance with section 1864 of the Act, State survey agencies conduct surveys of hospitals to determine compliance with the Medicare CoPs, using interpretive guidelines and survey procedures found in the State Operations Manual (SOM), CMS Publication No. 7. In accordance with section 1865 of the Act and the implementing regulations at 42 CFR 488.5(a) and 488.6, hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Osteopathic Association (AOA), or other national accreditation organizations are not routinely surveyed by States for

compliance with the CoPs, but are deemed to meet most of the hospital CoPs based on their accreditation. However, all hospitals that participate in the Medicare program are required to be in compliance with the CoPs, regardless of their accreditation status. Under section 1905(a) of the Act, the hospital CoPs also apply to hospitals participating in Medicaid (§ 440.10(a)(3)(iii) and § 482.1(a)(5)).

Under § 489.10(d), a Medicare provider agreement is subject to the State survey agency’s determination of whether a hospital meets the CoPs. The State survey agency makes corresponding recommendations to CMS about the hospital’s certification; that is, whether the hospital has met the standards or requirements necessary to provide Medicare and Medicaid services and receives Federal and State reimbursement.

Section 4321(a) of Public Law 105–33 (BBA) amended section 1861(ee)(2) of the Act to require that Medicare-participating hospitals, as part of the discharge planning process, share with each patient, as appropriate, a list of available home health services through individuals and entities, including Medicare-certified home health agencies (HHAs) that participate in Medicare, serve the geographic area in which the patient resides, and request to be listed by the hospital as available. In addition, section 4321(a) prohibits hospitals from limiting or steering patients to any specific HHA or qualified provider that may provide posthospital home health services and requires hospitals to identify (in a form and manner specified by the Secretary) any HHA or other entity to whom the individual is referred in which the hospital has a disclosable financial interest consistent with section 1866(a)(1)(S) of the Act or which has a financial interest in the hospital if the patient is referred to that entity.

Congress enacted section 4321 of Public Law 105–33 to protect patient choice and enable Medicare beneficiaries to make more informed choices about the providers from which they receive certain Medicare services. We believe that this provision was intended to address concerns that some hospitals were referring patients only to HHAs in which they had a financial interest, and that shared financial relationships were influencing referrals to other entities. Hospitals essentially have a captive patient population and, through the discharge planning process, can influence a patient’s choice regarding who provides posthospitalization services.

Congress also enacted section 926 of Public Law 108–173 (MMA) to improve the administration of the Medicare program by protecting patient choice and enabling Medicare beneficiaries to make more informed choices about the providers from which they receive Medicare services. Section 926(a) of Public Law 108–173 requires the Secretary to publicly provide information that enables hospital discharge planners, Medicare beneficiaries, and the public to identify SNFs that are participating in the Medicare program. Section 926(b) of Public Law 108–173 amended section 1861(ee)(2)(D) of the Act to require Medicare-participating hospitals, as part of the discharge planning process, to include a discharge planning evaluation of a patient's likely need for posthospital extended care services and the availability of these services through facilities that participate in the Medicare program and that serve the geographic area in which the patient resides. The amendments to the Act made by section 926(b) of Public Law 108–173 apply to discharge plans made on or after a date specified by the Secretary, which may be no later than 6 months after the Secretary provides for the availability of information required by section 926(a) of Public Law 108–173.

2. Implementation

We implemented the requirements of section 4321(a) of Public Law 105–33 relating to information on HHAs through a HCFA (now CMS) directive that was issued to the Regional Offices and State survey agencies on October 31, 1997. Enforcement has been carried out through the State agency survey and certification process. We note that even though it was not a requirement under section 4321(a) to provide currently available information on HHAs to the public (as now required under section 1861(ee)(2)(D) of the Act, as amended), we have established a “Home Health Compare” link on the CMS Web site, <http://www.medicare.gov>, that identifies HHAs that are currently participating in the Medicare or Medicaid program.

3. Provisions of the Proposed Regulations

In the May 18, 2004 IPPS proposed rule (69 FR 28196, 28333), we proposed to incorporate in our regulations under § 482.43 the requirements of section 4321(a) of Public Law 105–33 relating to providing information on HHAs to hospital patients as part of the discharge planning process. We noted that we had previously issued a proposed rule on December 19, 1997 (62 FR 66726) to

implement the provisions of section 4321(a) of Public Law 105–33. However, section 902 of Public Law 108–173 now requires us to finalize rules within 3 years after publication of the proposed rule, except under “exceptional circumstances.” While it is not clear whether Congress intended this policy to apply retroactively, out of an abundance of caution, we issued a new proposed rule because of the length of time that has elapsed since the issuance of the 1997 proposed rule. Moreover, the provisions of Public Law 108–173 contain information requirements for SNFs substantially similar to the ones required for HHAs. In developing the May 18, 2004 proposed rule, we took into consideration the issues raised in the public comments we received on the December 19, 1997 proposed rule relating to HHAs.

Information on SNFs related to the requirement imposed by section 926(a) of Public Law 108–173 is currently available to the public and can be accessed at the CMS Web site, <http://www.medicare.gov>, by clicking on the “Nursing Home Compare” link or by calling 1–800–MEDICARE (800–633–4227). Nursing Home Compare, launched in November 2002, meets the statutory requirement of section 926(a) by enabling hospital discharge planners, Medicare beneficiaries, and the public to identify the 17,000 nursing homes that participate in the Medicare or Medicaid program. Nursing Home Compare can be used to locate a nursing home by State and county, by proximity (city or zip code), or by name. In addition, Nursing Home Compare provides detailed information about the past performance of every Medicare-certified and Medicaid-certified nursing home in the country. The data on this Web site describe nursing home characteristics, quality measures, inspection results, and nursing staff information. The Nursing Home Compare tool received 9.3 million page views in 2003 and was the most popular tool on <http://www.medicare.gov>. If an interested individual does not have access to the Internet, the individual can call 1–800–MEDICARE (800–633–4227) and request a printout of the nursing homes in a designated area.

In the May 18, 2004 proposed rule, we proposed to amend the regulations at § 482.43 to incorporate the provisions of section 4321(a) of Public Law 105–33 and section 926(b) of Public Law 108–173 into the hospital CoPs. Specifically, we proposed to add new paragraphs (c)(6), (c)(7), and (c)(8) to include the requirement for hospitals to provide lists of Medicare-certified HHAs and SNFs as part of the discharge planning

process. We proposed that the discharge planning evaluation would be required to include a list of Medicare-certified HHAs that have requested to be placed on the list as available to the patient and that serve the geographic area in which the patient resides. We proposed to require the SNF list to include Medicare-certified SNFs located in the geographic area in which the patient requests. However, we did not propose to require that the list of Medicare-certified SNFs contain exclusively those SNFs that are located in the area in which the patient resides. Because many available Medicare-certified SNFs are not located in proximity to where the patient resides, especially in rural areas, we believe that a requirement that restricts information to those SNFs in the areas where the patient resides is too restrictive and would limit the availability of posthospital extended care services to Medicare beneficiaries.

Section 4321(a) of Public Law 105–33 requires listing the availability of home health services through individuals and entities. We have received inquiries regarding the identity of those individuals and entities. In the May 18, 2004 IPPS proposed rule (69 FR 28333) we proposed that, because section 1861(m) of the Act identifies home health services as “specific items or services furnished to an individual, who is under the care of a physician, by an HHA, or by others under arrangements with an HHA,” section 4321(a) is referring to Medicare-participating HHAs.

We proposed that the hospital present the list of HHAs or SNFs only to patients for whom home health care or posthospital extended care services are indicated as appropriate, as determined by the discharge planning evaluation. We do not expect that patients without a need for home health care or posthospital extended care services would receive the list. In addition, we proposed to require the hospital to document in the patient's medical record that a list of HHAs or SNFs was presented to the patient or an individual acting on the patient's behalf. Hospitals would not have to duplicate the list in the patient's medical record. The information in the medical record would serve as documentation that the requirement was met. The hospital would have the flexibility to determine exactly how and where in the patient's medical record this information would be documented.

We proposed that we would allow a hospital the flexibility to implement the requirement to present the lists in a manner that is most efficient and least burdensome in its particular setting. A

hospital can simply print a list from the Home Health Compare or Nursing Home Compare site on the CMS Web site, <http://www.medicare.gov> or develop and maintain its own list of HHAs and SNFs. When the patient requires home health services, the CMS Web site list can be printed based on the geographic area in which the patient resides. When the patient requires posthospital extended care services, the CMS Web site list would be printed based on the geographic area requested by the patient. Or, in the rare instance when a hospital does not have Internet access, the hospital can call 1-800-MEDICARE (1-800-633-4227) to request a printout of a list of HHAs or SNFs in the desired geographic area. Information on this Web site should not be construed as an endorsement or advertisement for any particular HHA or SNF.

Under the proposed rule, if a hospital chooses to develop its own list of HHAs or SNFs, the hospital would have the flexibility of designing the format of the list. However, the list should be utilized neither as a recommendation nor endorsement by the hospital of the quality of care of any particular HHA or SNF. If a HHA or SNF does not meet all of the criteria for inclusion on the list (Medicare-certified and is located in the geographic area in which the patient resides or in the geographic area requested by the patient), we did not propose to require the hospital to place that HHA or SNF on the list. In addition, in accordance with the provisions of the Act, we proposed that HHAs must request to be listed by the hospital as available. We also proposed that the list must be legible and current (updated at least annually), and that the listed information be shared with the patient or an individual acting on the patient's behalf at least once during the discharge planning process. However, we indicated that, under the proposal, information regarding the availability of HHAs or SNFs may need to be presented more than once during the discharge planning process to meet the patient's need for additional information or as the patient's needs and condition change.

In the May 18, 2004 proposed rule (69 FR 28333), we proposed to require that, as part of the discharge planning process, the hospital must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of posthospital services and must, when possible, respect patient and family preferences when they are expressed (proposed § 482.43(c)(7)). In addition, the hospital may not use the discharge plan to specify or otherwise limit the patient's

choice of qualified providers that may provide home health care or posthospital extended care services. The intent of the proposed provision was to provide the patient with the freedom of choice to determine which HHA or SNF will provide care in accordance with section 1802 of the Act, which states that beneficiaries may obtain health services from any Medicare-participating provider.

Finally, we proposed to require the hospital to identify in each discharge plan those HHAs or SNFs to which the patient is referred that the hospital has a disclosable financial interest or HHAs or SNFs that have a financial interest in the hospital (proposed § 482.43(c)(8)). For the purposes of implementing section 4321(a) of Public Law 105-33, we proposed to define a disclosable "financial interest" as any financial interest that a hospital is required to report according to the provider enrollment process, which is governed by section 1124 of the Act and implementing regulations located in 42 CFR Part 420, Subpart C, and accompanying manual provisions. If a hospital refers patients about to be discharged and in need of posthospital services only to entities it owns or controls, the hospital would be infringing on the rights of the patient to choose the facility he or she would like to go to for services. The proposed disclosable financial interest requirement is an effort to increase the beneficiary's awareness of the actual or potential financial incentives for a hospital as a result of the referral. To allow hospitals the flexibility of determining how these financial interests are disclosed to the patient, we did not propose to require a specific form or manner in which the hospital must disclose financial interest. The hospital could simply highlight or otherwise identify those entities in which a financial interest exists directly on the HHA and SNF lists. Or, the hospital could choose to maintain a separate list of those entities in which a financial interest exists.

In the May 18, 2004 IPS proposed rule (69 FR 28335), we indicated that hospitals and managed care organizations (MCOs) have expressed concern as to whether the change made by section 4321(a) of Public Law 105-33 was intended to apply to patients in managed care plans. MCO members are limited as to what services they may obtain from sources other than through the MCO. We believe that providing MCO members with a standardized list of all HHAs or SNFs in the requested geographic area could be misleading and potentially financially harmful

because MCO enrollees may be liable for services that they obtain from providers other than the MCO, and patients may interpret a list of HHAs or SNFs that are not available to them under their health plan to mean that they are authorized by the MCO. This does not mean that Medicare MCO members in particular are denied the freedom of choice they are entitled to under section 1802 of the Act. Medicare beneficiaries exercise their freedom of choice when they voluntarily enroll in the MCO and agree to adhere to the plan's coverage provisions.

The list provided to MCO patients should include available and accessible HHAs or SNFs in a network of the patient's MCO. Hospitals also have the option, in the course of discussing discharge planning with patients, to determine whether the beneficiary has agreed to excluded services or benefits or coverage limitations through enrollment in a MCO. If this is the case, the hospital could inform the patient of the potential consequences of going outside the plan for services.

We also indicated in the proposed rule that we had received many inquiries about how the requirements contained in section 4321(a) of Public Law 105-33 are monitored and enforced. Once codified in the hospital CoPs, a hospital's obligations under both section 4321(a) of Public Law 105-33 and section 926 (b) of Public Law 108-173 would be monitored as part of the hospital survey and certification process. Anyone aware of instances in which patients were inappropriately influenced or steered toward a particular HHA or SNF in a way that violated the regulation would have the opportunity to file a complaint with the State survey agency. The State survey agency would then investigate and follow up with the complainant. Noncompliance with the hospital CoPs could result in a hospital losing its ability to participate in the Medicare program.

Requiring hospitals to provide a list of Medicare-certified HHAs or SNFs would provide patients with more options and assist them in making informed decisions about the providers from which they receive Medicare services. Specifically, the intent of the proposed modifications to the discharge planning CoPs was to provide the patient with the freedom of choice to determine which HHA or SNF available in the geographic area in which the patient resides or the geographic area requested by the patient, would provide them care in accordance with section 1802 of the Act, which states that beneficiaries may

obtain health services from any Medicare-participating provider.

We received numerous comments from providers and provider organizations regarding the hospital CoP for discharge planning. Commenters supported our intent to protect patient choice and enable patients and their families to make more informed decisions. Commenters focused on various operational issues, such as format and scope of HHA and SNF lists to be provided, the process for updating lists, the feasibility of providing SNF information based on geographic location, a hospital's responsibility in providing information to Medicare managed care enrollees, and expanding the requirement beyond HHAs and SNFs.

Comment: Commenters requested that the HHAs and SNFs be listed alphabetically on different lists according to provider type. In addition, the commenters requested that the list include the services that the HHA offers (for example, skilled nursing, physical therapy, occupational therapy, speech therapy, clinical social work, mental health nursing, and home health aides). Commenters stated that including the list of services that the HHA offers would make it clear to patients which agency they can choose according to their needs and the services the agency provides. Commenters stated that hospital lists are often confusing and contain numerous types of providers and services offered in a single document. Another commenter stated that hospitals should be required to provide HHAs with notice that the list is being updated, and should provide HHAs with a copy of the list once compiled to ensure that the HHAs are listed and the information provided is accurate.

Response: Hospitals have the flexibility to either print a list of HHAs or SNFs from the CMS Web site or develop and maintain their own lists. Hospitals that choose to develop and maintain their own lists have the flexibility to determine the format. We agree that the list should be user friendly and that information regarding HHAs and SNFs should not be mingled within the same list. However, as long as HHA information is categorized separately from SNF information, the two lists could be included in the same document. We expect hospital discharge planners to be able to assist patients in identifying the HHAs and SNFs appropriate to fit the patient's needs. This information is available on the CMS Web site and can be included on the HHA list at the discretion of each hospital. We do not

believe it is necessary to prescribe a process for hospitals to update their lists. We expect hospitals to update their lists at least annually. Hospitals have the flexibility to develop their own process for this update. Information on the CMS Web site is updated as new information becomes available. We believe the commenters' concerns are addressed by the CMS Web site. We encourage hospitals to use the Home Health and Nursing Home Compare Web sites to access information. We believe that utilization of the CMS Web sites will be the most efficient and least burdensome way for many hospitals to implement these requirements.

Comment: Several commenters stated that requiring hospitals to provide lists of Medicare certified SNFs located in the geographic area chosen by the patient updating the list for frequent changes, and identifying SNFs with which disclosable financial interests exist would impose an additional, unnecessary, and unreasonable burden on hospital discharge planners. They further stated that current regulations already require hospitals to provide choices to Medicare beneficiaries for posthospital services. Commenters stated that the proposed rule acknowledges "hospitals currently access this information as an essential component of the discharge planning process." Commenters also stated that the equipment required for Internet access, the labor involved in telephoning an agency with limited hours of operation, as well as actual time to obtain information telephonically, add to the costs of providing care.

Response: In this final rule, we are implementing a statutory requirement contained in section 926 of Public Law 108-173. Congress enacted this legislation to improve the administration of the Medicare program by protecting patient choice and enabling Medicare beneficiaries to make more informed decisions about the providers from which they receive Medicare services. Hospitals have the flexibility to implement this requirement in a way that makes the most sense for them. One option would be for a hospital to print out or call the 800 number to request a list of SNFs located in the selected geographic areas or entire state that the hospital serves on a regular basis, for example, annually. It is not necessary to generate a new, separate list for every patient. If Internet access is not available to discharge planners or calling the 1-800-MEDICARE (800-663-4227) are both determined to be unfeasible, the hospitals will be free to develop and

maintain their own lists. We expect hospitals to keep the lists current. Hospitals have the flexibility in determining how and how frequently they update their lists. The intent is to protect patient choice and provide patients and their families with the information necessary to make informed decisions. As the commenters pointed out, we believe that discharge planners currently access this information as an essential component of the discharge planning process. Therefore, we believe the additional burden is minimal.

Comment: A commenter expressed agreement with our proposal that SNF information should be presented based on the geographic area requested by the patient. Commenters further stated that the same requirement should be imposed on hospitals with respect to HHAs. The commenter recommended deleting the reference to serving "the geographic area (as defined by the HHA)" and deleting the requirement that "HHAs must request to be listed by the hospital as available."

Response: Section 4321(a) of the BBA specifically requires that HHAs serving the area in which the patient resides request to be listed by the hospital as available. We believe the HHA is in the best position to identify its service area and, presumably, would not misrepresent its service area by requesting to be listed for an area they do not serve. Section 926 of Public Law 108-173 does not contain a similar requirement for SNFs.

Comment: A commenter stated that her hospital currently provides a list of HHAs and indicates for patients any agencies in which the hospital has a financial interest. The Commenters states that this process works well in supporting patient choice. However, two commenters stated that expanding this requirement to SNFs does not work because nursing home placement is primarily driven by bed availability and special care accommodations; location is secondary. The commenter stated that patients who are given a list of nursing homes in a 10-mile radius will be overwhelmed by the number of nursing homes and confused as to where to begin. The commenter further stated that such a list would only create expectations that the patient can go to any of these facilities and that they truly do have options when in reality options may be extremely limited or nonexistent due to lack of available of beds. The commenter supports a process that communicates to the patient what research was done in checking bed availability and gives the patient a list of true options for choice if options do in fact exist. The commenters also

suggested that SNF quality information might be helpful if options are limited due to bed availability.

Response: We appreciate the commenters' support of the HHA list and patient choice. We recognize that bed availability is a major issue in terms of SNF placement. Our intent is to provide patients with real options. We would not expect that the patient be given an exhaustive list of SNFs with no available beds. The intent is to provide patients and their families with information in order to make informed decisions. As the discharge planner identifies which SNFs have available beds, this information should be shared with the patient and patient's family. The nursing home compare Web site currently provides nursing home quality information. A hospital may elect to share this quality information with the patient and patient's family or simply direct them to this Web site as a resource.

Comment: One commenters suggested delaying implementation of the SNF list as a formal requirement until a better system for identifying SNF bed availability and special care accommodations could be developed. The commenters made the following recommendations: (1) Update the Nursing Home Compare tool to include a section on special care accommodations available (for example, skilled, nonskilled, residential, Alzheimer, and availability of specialized ancillary staff), as well as the number of unskilled beds, Medicaid designated beds/specialty beds by category, to facilitate planning efforts; (2) amend the Home Health Compare "search" function to include the ability to identify agencies based on the main service area of the agency versus the geographic location of the agency; (3) eliminate the sorting of HHAs by zip code; (4) revise the print format to fit 8 1/2 x 11 size paper; and (5) develop State or regional databases that will facilitate patient placement in available SNF beds. The commenters also requested that future policy changes be released in notices in addition to the **Federal Register** to facilitate more comments and recommendations.

Response: Delaying implementation of this requirement is not an option. Section 926 of Public Law 108-173 requires that information regarding SNFs that participate in the Medicare program be available on hospital discharge plans within 6 months of enactment of the law. Revision of the content and format of the Home Health and Nursing Home Compare websites is beyond the scope of this rule. However, we have forwarded the commenters'

recommendations to appropriate agency staff for consideration. We alert the public to notices published in the **Federal Register** in a variety of ways. These ways include several of listings that may be accessed on the CMS Web site at <http://www.cms.hhs.gov> (for example, the Quarterly Provider Update and current publications and press releases). In addition, the public may register at CMS Web site to receive email updates. Public notice is also provided at the monthly Open Door Forums.

Comment: One commenters expressed concern regarding the identification and disclosure of SNF providers that accept Medicare+Choice because current tools only indicate Medicare and Medicaid participation. Another commenter requested that we modify the proposed regulations to explicitly indicate the responsibilities of hospitals with regard to managed care organization (MCO) enrollees.

Response: We believe that identifying MCO participating HHAs or SNFs is currently part of a hospital's discharge planning process. We also believe that providing MCO members with a standardized list of all HHAs or SNFs that does not identify those that are authorized by the MCO could be misleading. Patients may interpret this type of list to mean that all of the HHAs or SNFs listed are authorized by the MCO. It could be potentially financially harmful because MCO enrollees may be liable for services that they obtain from providers other than the MCO. The list provided to MCO patients should include all available and accessible HHAs or SNFs as well as those authorized by a patient's MCO. The hospital could simply identify these MCO authorized HHAs or SNFs for the patient by highlighting them on the list. The patient has the freedom to choose a HHA or SNF not authorized by the MCO. If the patient chooses a HHA or SNF not authorized by the MCO, the hospital should inform the patient of the potential consequences of going outside the plan for services. Therefore, we are adding § 482.43(c)(6)(ii) to ensure that patients enrolled in MCOs are provided with listings that identify authorized HHAs or SNFs.

Comment: Commenters recommended that the lists be made available to all patients who potentially require any type of posthospital services, not just those determined by the discharge planning evaluation to require HHA or SNF services. Another commenter stated that all beneficiaries should be provided with written information advising them that they may be entitled to home health services.

Response: We note that the language of the statute only requires that lists of HHAs and SNFs be provided to the appropriate patients. In addition, we believe it would be unnecessarily burdensome to require that hospitals develop and provide a list of all posthospital services to their patients. Hospitals are free to provide all patients with written information advising them that they may be entitled to home health services. However, we do not believe that the intent of the statute is to require that this information be provided to all patients.

Comment: A commenter suggested that hospitals be required to direct the patients and their family to the Home Health Compare website. The commenter stated that the website provides both a useful tool for locating area specific HHAs while providing a means for patients to conduct a comparative review.

Response: We appreciate the commenter's support of the Home Health Compare website. Hospitals are free to direct patients and their families to this website as part of their discharge planning process. However, we believe requiring hospitals to direct patients and their families to the Home Health Compare website is not appropriate because some patients and their families may not have Internet access.

Comment: A commenter requested that the words "when possible" be removed from § 482.43(c)(7). The commenter stated that in her experience hospitals would just say that they could not reach the agency and not even call the agency in question. Two commenters suggested that the hospital be required to document when they called and to whom the discharge planner spoke. The commenter requested the following language be added: "The hospital discharge planner or anyone else from the hospital may not recommend that a patient use a particular agency or tell the patient that they have to use the hospital agency because they are in that hospital." Lastly, the commenter requested that the word "respect" be changed to "honor."

Response: We understand the commenters' concern that hospitals may steer patients to certain HHAs. However, we believe there are legitimate circumstances when it may not be possible to respect patient and family preferences. For example, a preferred HHA or SNF may not be able to accommodate the patient's needs within the required timeframe or a preferred HHA may be unable to provide the required services. We believe a requirement to include documentation

of these circumstances would create an unnecessary burden for hospitals. Section 482.43(c)(7) stipulates that the hospital must not exclude qualified providers that are available to the patient. Steering a patient to a particular agency or limiting access to an agency constitutes excluding qualified providers. Such practices would be a violation of this regulatory provision. We note that the meanings of “respect” and “honor” are similar, and, therefore, we are retaining the word “respect”.

Comment: One commenter requested that we use the statutory language in section 1861(ee)(2)(H) of the Act, requiring that plans “not specify or otherwise limit the qualified provider which may provide posthospital home health services.” The commenter stated that it might be useful to include within the rule the particular prohibition set out in the statute.

Response: We agree with the commenter and are revising § 482.83(c)(7) to reflect this change.

Comment: Commenters recommended that the regulation be modified to include hospice among the posthospital care providers where a list of hospices is made available to the patient, along with the other protections on the patient’s freedom of choice. Another commenter stated that hospitals should be required to provide lists of all providers and services available to patients upon discharge.

Response: Section 1861(ee) of the Act requires hospitals to have a discharge planning process that meets certain enumerated requirements. Included in that statutory provision is the requirement that the discharge planning evaluation incorporate an evaluation of the patient’s likely need for appropriate posthospital services and the availability of those services. Section 4321 of the BBA amended the discharge planning requirements to require that the discharge planning evaluation indicate the availability of home health services provided by individuals or entities that participate in the Medicare program. Specifically, section 4321(a) of the BBA provided that the discharge planning evaluation include an evaluation of the patient’s likely need for posthospital services and the availability of those services; “including the availability of home health services through individuals and entities that participate in the program under this title and that serve the area in which the patient resides and that request to be listed by the hospital as available.” We have interpreted this provision to require that hospitals need only indicate the availability of home health services provided by HHAs that request to be

listed in the discharge plan, as opposed to the universe of individuals and entities that participate in the program. We believe that our interpretation is consistent with the BBA provision. As noted previously, section 4321(a) requires that hospitals, in their discharge planning evaluation, provide a listing regarding the “availability of home health services.” Section 1861(m) of the Act defines home health services as services “furnished by a home health agency” (as opposed to other posthospital entities). Section 926 of Public Law 108–173 further amended 1861(ee) to include information regarding skilled nursing facilities that participate in the Medicare program. Therefore, in accordance with the Act, we interpret these provisions as not applying to individuals or entities that provide posthospital services other than HHAs and SNFs. However, we expect the discharge planner to facilitate patient choice in any posthospital extended care services as part of the discharge planning process even though the statute does not require a specific list beyond HHAs and SNFs. We are revising § 482.43(c)(7) to clarify our policy regarding patient choice in posthospital care services.

Comment: Commenters stated that CMS should provide authorization to state surveyors to find a violation of the hospital CoPs if the overall effect of a discharge/referral practice evidences a clear intent to subvert or violate the purpose of section 4321 of the BBA. One commenter also stated that CMS should specify that exclusion of a hospital’s own HHA from the list does not permit the hospital to “steer” a beneficiary to that agency, and that it is improper for a hospital to limit inclusion on the list to accredited HHAs. Another commenter requested that CMS address the issue of whether review of a patient’s hospital record by an HHA that the patient has not selected violates the HIPAA privacy requirements.

Response: Compliance with the hospital CoPs is monitored by the State survey agencies as part of the survey and certification process or, in the case of accredited hospitals, by JCAHO, the AOA or other CMS approved accreditation organizations. Noncompliance with the regulations contained within the hospital CoPs can result in a hospital losing its status as a Medicare participating provider. Anyone aware of instances where patients are being inappropriately influenced or steered toward a particular HHA, SNF or other entity in which the hospital or individual has a financial interest can file a complaint with the appropriate State survey

agency. The list provided to the patient must include certified HHAs, both accredited and nonaccredited, to meet the intent of the statute.

In addition, disclosing a patient’s hospital record to an HHA that the patient has not selected would be a violation of HIPAA, Public Law 104–191. Regulations implementing HIPAA are published in 45 CFR Parts 160 and 164.

Comment: One commenter recommended that details discussed in the preamble be included as regulation text. These details include: use of the Home Health Compare website; hospitals that create their own lists should include, at a minimum, those providers who request inclusion on the list; and hospital lists should be updated annually.

Response: A hospital has the flexibility to implement the requirements in a manner that is most efficient and least burdensome in its particular setting. Hospitals may choose to develop their own list of HHAs or utilize the Home Health Compare website. We do not believe reference to the Home Health Compare website needs to be in the regulation as hospitals are free to develop their own list. The regulation requires that the hospital list include HHAs that: Participate in the Medicare program; serve the geographic area (as defined by the HHA) in which the patient resides; and request to be listed by the hospital as available. In terms of frequency of updating the list, we have decided to be less prescriptive and not require the hospital to update the list annually as discussed in the preamble of the proposed rule. Instead, we expect hospitals to keep their lists current. This provides hospitals the flexibility to determine how often it is necessary to update their lists.

Comment: One commenter stated that HHAs new to the Medicare program are not listed on the Home Health Compare website until they have submitted OASIS data for at least 6 months. The commenter also stated that when a search is conducted using zip code or county, Home Health Compare only brings up agencies who have served a patient within that zip code or county within the past year. The commenter requested that Medicare-certified HHAs be allowed to request inclusion on the hospital list at any time.

Response: We appreciate the points made by the commenter. However, the regulation does not prescribe the timeframe in which a HHA can request inclusion on a hospital list. The hospital has the freedom to determine a

timeframe if they determine that a timeframe is necessary.

Comment: One commenter requested that hospital staff, other than discharge planners, not discuss particular posthospital providers with patients before the patient has selected a provider.

Response: We agree that it may be confusing to patients if hospital staff other than those involved in the discharge planning process discuss posthospital providers with patients. However, discharge planning is a multidisciplinary process that includes staff beyond the discharge planner. The intent of this regulation is to support the patient's freedom to choose. No one on the hospital staff may specify or otherwise limit the qualified providers that are available to the patient.

Comment: One commenter stated that financial interests should be disclosed to patients before exercising their right to choose a HHA, not after the patient is referred.

Response: We agree that financial interests should be disclosed to patients before patients exercise their right to choose a HHA. We do not interpret the term "referred" to mean that a patient has made a decision and has chosen a particular HHA. We interpret this to mean that a patient is referred to a list of HHAs. The discharge plan must identify those HHAs in which a disclosable financial interest exists. HHAs in which a disclosable financial interest exists can simply be highlighted in some fashion on the list.

Comment: One commenter stated that the discharge planning process should provide the same information to all patients regardless of payer. Another commenter requested clarification as to whether or not this policy is intended to apply to both PPS hospitals and CAHs.

Response: The hospital CoPs apply to all patients in Medicare- and Medicaid-participating hospitals regardless of payer. We expect all patients to receive the same information. The hospital CoPs are not applicable to CAHs.

Comment: One commenter stated that, if hospitals are creating their own lists, there are no standards for the process that HHAs are to follow to ensure placement on the hospital listing.

Response: The standards for ensuring placement on the hospital list are outlined in the regulation. The hospital must include in the discharge plan a list of HHAs or SNFs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, in the geographic area

requested by the patient. HHAs must request to be listed by the hospital as available.

Comment: One commenter urged CMS to move forward with implementing the remainder of the BBA provisions at sections 4321(b) and (c).

Response: In the November 22, 2002 **Federal Register** (67 FR 70373), we published a proposed rule entitled, "Medicare Program: Nondiscrimination in Posthospital Referral to Home Health Agencies and Other Entities" (CMS-1223-P), which specified our proposal to implement sections 4321(b) and (c) of the BBA. The final rule is currently in the agency clearance process.

Based on public comments, we are making two revisions to the regulations text in this final rule. In § 482.43, we are adding a new paragraph (c)(6)(ii) that states, "For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and posthospital extended care services through individuals and entities that have a contract with the managed care organizations."

In addition, we are revising § 482.43(c)(7) to read, "The hospital, as part of the discharge planning process, must inform the patient or patient's family of their freedom to choose among participating Medicare providers of posthospital care services and must, when possible, respect patient and family preferences when they are expressed" and "The hospital must not specify or otherwise limit the qualified providers that are available to the patient."

The remainder of the proposed provisions is adopted as final without change.

B. Compliance With Bloodborne Pathogens Standards

1. Background

Section 1866(a)(1) of the Act sets forth provider agreement requirements that Medicare-participating hospitals must meet. Implementing regulations for these requirements are set forth at 42 CFR 489.20.

Section 947 of Public Law 108-173 amended section 1866(a)(1) of the Act to require that, by July 1, 2004, hospitals not otherwise subject to the Occupational Safety and Health Act (OSHA) (or a State occupational safety and health plan that is approved under section 18(b) of that Act) must comply with the OSHA bloodborne pathogens (BBP) standards at 29 CFR 1910.1030 as part of their Medicare provider agreements. These OSHA standards can be found on OSHA's Web site at <http://www.osha.gov/SLTC/>

bloodborne pathogens. Section 947 of Public Law 108-173, which applies to hospitals participating in Medicare as of July 1, 2004, was enacted to ensure that all hospital employees who may come into contact with human blood or other potentially infectious materials in the course of their duties are provided proper protection from bloodborne pathogens. This amendment further provides that a hospital that fails to comply with OSHA's BBP standards may be subject to a civil money penalty. The civil money penalty will be imposed and collected in the same manner that civil money penalties are imposed and collected under 29 U.S.C. section 666 and section 1128A(a) of the Act. However, failure to comply with the BBP standards will not lead to termination of a hospital's provider agreement.

Currently, most hospitals are subject either to the OSHA BBP standards or to other BBP standards (generally, State standards) that meet or exceed the OSHA standards. However, non-Federal public hospitals located in States that do not have their own BBP standards are not subject to OSHA standards, including the OSHA BBP standards. Twenty-six States and the District of Columbia, and Guam do not have their own BBP standards under an OSHA-approved State plan. Therefore, an estimated 600,000 employees of such non-federal public hospitals located in those 26 States, the District of Columbia, and Guam are not afforded the same protections from BBPs as employees of all other hospitals in the United States. The States and territories that would be affected by the change made by section 947 of Public Law 108-173 are Alabama, Arkansas, Colorado, Delaware, Florida, Georgia, Idaho, Illinois, Kansas, Louisiana, Maine, Massachusetts, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Texas, West Virginia, Wisconsin, the District of Columbia, the Virgin Islands, and Guam.

2. Provisions of the Proposed Regulations

In the May 18, 2004 IPPS proposed rule (69 FR 28196, 28372), we proposed to incorporate the provisions of Public Law 108-173 in § 489.20 of the Medicare regulations governing provider agreements by adding a new paragraph (t). In paragraph (t), we proposed that hospitals not otherwise subject to the OSHA BBP standards must comply with the OSHA BBP standards at 29 CFR 1910.1030 as part of their Medicare provider agreement.

We proposed to further specify that if a hospital fails to comply with OSHA's BBP standards, the hospital may be subject to a civil money penalty. The civil money penalty would be imposed and collected in the same manner that civil money penalties are imposed and collected under 29 U.S.C. 666 and section 1128A(a) of the Act. However, as we noted previously, failure to comply with the BBP standards would not lead to termination of a hospital's provider agreement. In addition, we proposed to refer in the proposed provision to the Federal Civil Penalties Inflation Adjustment Act. This reference was intended to alert the reader that the civil money penalty amounts determined under 29 U.S.C. 666 and section 1128A(a) of the Act may, under the Federal Civil Penalties Inflation Adjustment Act, be increased to adjust for inflation.

We did not receive any timely public comments in response to the section in the May 18, 2004 proposed rule regarding implementation of OSHA's Bloodborne Pathogens regulations for hospitals. Therefore, we are finalizing the proposed bloodborne pathogens for hospitals regulatory provisions without modification.

C. Fire Safety Requirements for Certain Health Care Facilities

1. Background

On January 10, 2003, we published a final rule in the **Federal Register** (68 FR 1374) that adopted the 2000 edition of the Life Safety Code (LSC) published by the National Fire Protection Association (NFPA) as the fire safety requirements (with specified exceptions) that we are applying to the following types of providers participating in the Medicare and Medicaid programs: Long-term care facilities, hospitals, intermediate care facilities for the mentally retarded (ICF/MRs), ambulatory surgical centers (ASCs), hospices that provide inpatient services, religious nonmedical health care institutions, CAHs, and Programs of All-Inclusive Care for the Elderly (PACE).

In addition to adopting the 2000 edition of the LSC, we stated our intent to delete references to all previous editions of the LSC. However, as a result of a technical error, the reference to previous editions of the LSC in § 483.70(a)(1) of the regulations for long-term care facilities was not deleted. Allowing long-term care facilities to comply with the 1967, 1973, and 1981 editions of the LSC would not adequately protect long-term care facility patients from the threat of fire and other emergencies. These editions

do not recognize newer technology, nor the advances in fire safety that have been developed in the ensuing years. In addition, the existing conflicting regulatory language is confusing and contrary to the best interests of long-term care facilities and their patients. Therefore, in the May 18, 2004 IPPS proposed rule (69 FR 28196, 28371), we proposed to correct this technical error. We did not propose to make any substantive policy change.

In the January 10, 2003 final rule, we also specified that we were not adopting the provisions of Chapter 19.3.6.3.2, exception number 2 of the LSC regarding the use of roller latches for application to religious nonmedical health care institutions, hospices, hospitals, long-term care facilities, PACE programs, ICF/MRs and CAHs. We prohibit the use of roller latches in existing and new buildings, except for ASCs under Chapter 20 and Chapter 21 of the LSC, and provide for the replacement of existing roller latches, phased in over a 3-year period beginning March 11, 2003. We indicated that allowing health care facilities to continue using roller latches would not adequately protect patients in those facilities. Through fire investigations, roller latches have proven to be an unreliable door latching mechanism requiring extensive on-going maintenance to operate properly. Many roller latches in fire situations failed to provide adequate protection to patients in their room during an emergency. Roller latches that are not maintained pose a threat to the health and safety of patients and staff. We added that we had found through our online survey, certification, and reporting (OSCAR) system data that doors that include roller latches are consistently one of our most cited deficiencies. In fact, in SNFs, roller latches in corridor doors are consistently the number one cited deficiency under the life safety requirements.

We learned that the language regarding the date when these facilities must be in compliance with the prohibition on the use of roller latches may be misinterpreted and needs to be clarified. Therefore, in the May 18, 2004 proposed rule, we proposed to clarify our intent by revising the regulations as discussed under section VIII.C.2. of this preamble. We did not propose to make any substantive policy changes.

Under our proposal, the flexibility of the January 10, 2003 final rule would remain the same. The Secretary has broad authority to grant waivers to facilities under section 1819(d)(2)(B) and section 1919(d)(2)(B) of the Act. The proposed amendments would

continue to allow the Secretary to grant waivers on a case-by-case basis if the safety of the patients would not be compromised and if specific provisions of the LSC would result in unreasonable hardship on the provider. The Secretary also may accept a State's fire and safety code instead of the LSC if the State's fire and safety code adequately protects patients. Further, the NFPA's Fire Safety Evaluation System (FSES), an equivalency system, provides alternatives to meeting various provisions of the LSC, thereby achieving the same level of fire protection as the LSC.

2. Proposed Changes to the Regulations

In the May 18, 2004 IPPS proposed rule (69 FR 28337), we proposed to revise § 483.70(a) to delete references to the 1967, 1973, and 1981 editions of the LSC. We also proposed to revise the following regulations applicable to the specified facilities to clarify that the facility must be in compliance with Chapter 19.2.9, Emergency Lighting, beginning March 13, 2006. In addition, we proposed to also specify that, beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 (concerning roller latches), does not apply to the facility.

- a. For religious nonmedical health care institutions: § 403.744(a) and (c).
- b. For hospices, § 418.100(d)(1), (d)(4), and new (d)(5).
- c. For PACE programs, § 460.72(b)(1)(i), ((b)(3)), and new (b)(4).
- d. For hospitals, § 482.41(b).
- e. For long-term care facilities, § 483.70(a).
- f. For ICF/MRs, § 483.470(j).
- g. For CAHs, § 485.623(d)(1), (d)(5), and new (d)(6).

We did not receive any timely public comments in response to the section in the May 18, 2004 proposed rule regarding changes to the Life Safety Code regulations for religious nonmedical health care institutions, hospices, programs of all-inclusive care for the elderly, hospitals, long-term care facilities, ICFs/MR, and CAHs. Therefore, we are adopting as final, without modification, the proposed changes to the LSC regulations.

IX. MedPAC Recommendations

We are required by section 1886(e)(4)(B) of the Act to respond to MedPAC's IPPS recommendations in our annual IPPS rules. We have reviewed MedPAC's March 1, 2004 "Report to the Congress: Medicare Payment Policy" and have given it careful consideration in conjunction with the policies set forth in this document. For further information

relating specifically to the MedPAC report or to obtain a copy of the report, contact MedPAC at (202) 653-7220, or visit MedPAC's Web site at: <http://www.medpac.gov>.

We note that MedPAC, in its March 1, 2004 report, included only one recommendation concerning Medicare inpatient hospital payment policies. MedPAC's Recommendation 3A-1 states that Congress should increase payment rates for the IPPS by the projected rate of increase in the hospital market basket for FY 2005. We note that section 501(a)(3) of Public Law 108-173 requires that the payment rates for the IPPS be increased by the market basket percentage increase for all hospitals during FYs 2005, 2006, and 2007. However, section 501(a) also provides for reducing the update by 0.4 percentage points for any hospital that fails to submit data on a list of 10 quality indicators. We discuss this recommendation further in Appendix B of this final rule in the context of our recommendation concerning the update factor for inpatient hospital operating costs and for hospitals and hospital distinct-part units excluded from the IPPS.

X. Other Required Information

A. Requests for Data From the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are available in computer tape or cartridge format; however, some files are available on diskette as well as on the Internet at <http://www.hcfa.gov/stats/pufiles.htm>. In the May 18, 2004 proposed rule, we published a list of data files that are available for purchase from CMS or that may be downloaded from the Internet free of charge (68 FR 28337 through 28339).

B. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to evaluate fairly whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the May 18, 2004 proposed rule, we solicited public comments on each of these issues for the information collection requirements in the proposed rule discussed below under which associated burdens are subject to the PRA.

Section 412.22 Excluded Hospitals and Hospital Units: General Rules

In summary, this section outlines the requirements for excluded hospitals and hospital units. This section states that a LTCH that occupies space in a building used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital must notify its fiscal intermediary and CMS in writing of its co-location.

The collection requirement has not changed. While this requirement is subject to the PRA, this requirement is currently approved in OMB No. 0938-0897, with a current expiration date of July 31, 2006.

Section 412.25 Excluded Hospital Units: Common Requirements

In summary, this section applies the excluded hospital unit requirements to psychiatric or rehabilitation CAH units that are now permitted under the provisions of Public Law 108-173. This section states that if a psychiatric rehabilitation unit of a CAH does not meet the applicable requirements, payment will not be made and will resume only after the unit has demonstrated to CMS that it meets the applicable requirements.

We believe the collection requirements are exempt as defined in 5 CFR 1320.4, information collections conducted or sponsored during the conduct of a criminal or civil action, or during the conduct of an administrative action or investigation, or audit. We also believe the collection requirements to be exempt as defined in 5 CFR 1320.3(c)(4) because we believe this would affect less than 10 persons.

Section 412.64 Federal Rates for Inpatient Operating Costs for Federal Fiscal Year 2005 and Subsequent Fiscal Years

In summary, this section outlines the requirements and process for determining the adjustment of the wage index to account for the commuting patterns of hospital workers. This section states that a hospital may waive the application of the wage index adjustment by notifying CMS in writing within 45 days after the publication of the annual notice of proposed rulemaking for the IPPS.

The burden associated with this requirement is the time and effort for the hospital to prepare a written notice asking to waive the application of the wage index adjustment and to send the notice to CMS.

The burden associated with this requirement is estimated to be 30 minutes per hospital. Therefore, we estimate it would take 5 total annual hours (30 minutes × 10 hospitals seeking a waiver).

Section 412.101 Special Treatment: Inpatient Hospital Payment Adjustment for Low-Volume Hospitals

In summary, this section outlines the requirements for determining a payment adjustment for low-volume hospitals. This section states that, in order to qualify for the higher incremental costs adjustment, the hospital must provide its fiscal intermediary with evidence that it meets the distance requirement specified in this section.

The burden associated with this requirement is the time and effort for the hospital to provide the fiscal intermediary with evidence that it meets the specified distance requirement.

The burden associated with this requirement is estimated to be 1 hour per hospital. Therefore, we estimate it would take 500 total annual hours (1 hour × 500 hospitals seeking the incremental costs adjustment).

Section 412.103 Special Treatment: Hospitals Located in Urban Areas and That Apply for Reclassification as Rural

In summary, this section outlines the requirements and process for a rural hospital to become reclassified. This section states that a prospective payment hospital that is located in an urban area may be reclassified as a rural hospital if it submits an application in accordance with this section.

In the May 18, 2004 proposed rule, we proposed to revise this section. However, the collection requirement remains the same. While this requirement is subject to the PRA, this

requirement is currently approved in OMB No. 0938–0573, with a current expiration date of October 31, 2005.

Section 412.211 Puerto Rico Rates for Federal Fiscal Year 2004 and Subsequent Fiscal Years

In summary, this section outlines the requirements and process for determining the adjusted prospective payment rate for inpatient hospital services in Puerto Rico. This section states that a hospital may waive the application of the wage index adjustment for commuting hospital employees by notifying CMS in writing within 45 days after the publication of the annual notice of proposed rulemaking for the inpatient prospective payment system.

The burden associated with this requirement is the time and effort for the hospital to prepare a written notice asking to waive the application of the wage index adjustment and to send the notice to CMS.

The burden associated with this requirement is estimated to be 30 minutes per hospital. Therefore, we estimate it would take 5 total annual hours (30 minutes × 10 hospitals seeking a waiver).

Section 412.234 Criteria for All Hospitals in an Urban County Seeking Redesignation to Another Urban Area

In summary, this section outlines the requirements for determining an urban hospital's redesignation to another urban area. This section states that hospitals must submit appropriate wage data to the fiscal intermediary as outlined.

In the May 18, 2004 proposed rule, we proposed to revise this section. However, the collection requirement remains the same. While this requirement is subject to the PRA, this requirement is currently approved in OMB No. 0938–0907, with a current expiration date of December 31, 2005.

Section 413.70 Payment for Services of a CAH

In summary, this section outlines the requirements for a CAH to make an election to be paid for outpatient facility services plus the fee schedule for professional services under an optional single payment method. This section states that a CAH may make this election in any cost reporting period. This election must be made in writing, made on an annual basis, and delivered to the fiscal intermediary servicing the CAH at least 30 days before the start of each affected cost reporting period.

In the May 18, 2004 proposed rule, we proposed to revise this section.

However, the collection requirement remains the same. While this requirement is subject to the PRA, this requirement is currently approved in OMB No. 0938–0050, with a current expiration date of November 30, 2005.

Section 413.78 Direct GME Payments: Determinations of the Total Number of FTE Residents

In summary, this section outlines the requirements for the determination of the total number of FTE residents in determining direct GME payments to hospitals. Currently, this section states that, for residents who spend time in nonprovider settings, there must be a written agreement between the hospital and the outside entity that states that the resident's compensation for training time spent outside of the hospital setting is to be paid by the hospital. In the May 18, 2004 proposed rule, we proposed to remove the written agreement requirement from this section.

This requirement is exempt from the PRA in accordance with Public Law 99–272 or Public Law 108–173, or both.

Section 413.79 Direct GME Payments: Determination of the Weighted Number of FTE Residents

In summary, this section outlines the requirements for the determination of the weighted number of FTE residents for direct GME payments to hospitals. Under this section in the May 18, 2004 proposed rule, we proposed that a hospital seeking an adjustment to the limit on its unweighted resident count under section 422 of Public Law 108–173 must provide documentation justifying the adjustment. In addition, the section states that a hospital wishing to receive a temporary adjustment to its FTE resident cap because it is participating in a Medicare GME affiliated group must submit the Medicare GME affiliation agreement to the CMS fiscal intermediary and to CMS's Central Office. This section specifies the information that a request must contain.

These requirements are exempt from the PRA in accordance with Public Law 99–272 or Public Law 108–173, or both.

Section 413.80 Direct GME Payments: Determination of Weighting Factors for Foreign Medical Graduates

In summary, this section specifies the information that a hospital must submit to the fiscal intermediary to include foreign medical graduates in its FTE count for a particular cost reporting period.

This requirement is exempt from the PRA in accordance with Public Law 99–272 or Public Law 108–173, or both.

Section 413.83 Direct GME Payments: Adjustment of a Hospital's Target Amount or Prospective Payment Hospital-Specific Rate

In summary, this section outlines the requirements for seeking an adjustment to the hospital's target amount or hospital-specific rate. This section states that a hospital may request that the intermediary review the classification of operating costs that were previously misclassified for purposes of adjusting the hospital's target amount or hospital-specific rate. A hospital's request for review must include sufficient documentation demonstrating that an adjustment is warranted. This section also specifies the terms in which the information should be provided.

This requirement is exempt from the PRA in accordance with Public Law 99–272 or Public Law 108–173, or both.

Section 480.106 Exceptions to QIO Notice Requirements

In summary, in the May 18, 2004 proposed rule, we proposed to revise this section to add exceptions to the notice requirements for disclosure of QIO information to any person, agency, or organization. The notice requirements do not apply if the institution or practitioner has requested, in writing, that the QIO make the disclosure; the institution or practitioner has provided, in writing, consent for the disclosure; or the information is public information.

The burden associated with these requirements is the time and effort for the institution or practitioner to provide a written request that the QIO make the disclosure or consent to the disclosure.

We believe the collection requirements are exempt as defined in 5 CFR 1320.3(c)(4) because we believe this would affect less than 10 persons.

Section 480.133 Disclosure of Information About Practitioners, Reviewers, and Institutions

In summary, this section outlines the requirements concerning the disclosure of QIO information about practitioners, reviewers, and institutions. This section states that a QIO may disclose information on a particular practitioner or reviewer at the written request of, or with the written consent of, that practitioner or reviewer, with the recipient subject to the same rights and responsibilities on redisclosure as the requesting or consenting practitioner or reviewer.

We believe the collection requirements are exempt as defined in 5 CFR 1320.3(c)(4) because we believe this would affect less than 10 persons.

Section 480.140 Disclosure of Quality Review Study Information

In summary, this section outlines the requirements concerning the disclosure of quality review study information. This section states that a QIO may disclose quality review study information with identifiers of particular practitioners or institutions, or both, at the written request of, or with the written consent of, the identified practitioner(s) or institution(s). The consent or request must specify the information that is to be disclosed and the intended recipient of the information. The recipient would be subject to the same rights and responsibilities on redisclosure as the requesting or consenting practitioner or institution.

We believe the collection requirements to be exempt as defined in 5 CFR 1320.3(c)(4) because we believe this would affect less than 10 persons.

Section 482.43 Condition of Participation: Discharge Planning

In summary, this section outlines the requirements of the discharge planning process. This section states that the hospital must include in the discharge plan, a list of HHAs or SNFs that are available to the patient, that participate

in the Medicare program, that serve the geographic area, and that request to be listed by the hospital as available and to maintain documentation. This section also specifies other information that the discharge plan must contain.

The burden associated with these requirements is the time and effort for the hospital to provide a list to beneficiaries, for whom home health care or posthospital extended care services are necessary, and document the patient's medical record.

The burden associated with these requirements is estimated to be 5 minutes per hospital per discharge. Therefore, we estimate the total national burden to be 327,684 hours annually to comply with these requirements (652 discharges per hospital per year \times 6,031 hospitals \times 5 minutes each).

We did not receive any comments on the proposed information collection and recordkeeping requirements.

The new information collection and recordkeeping requirements, described above, have been submitted to the OMB for review under the authority of the PRA. These requirements will not be effective until they have been approved by OMB.

C. Waiver of Proposed Rulemaking for Technical Correction to LTCH Regulations

We ordinarily publish a notice of proposed rulemaking in the **Federal**

Register to provide a period for public comment before the provisions of a notice take effect. However, we can waive this procedure if we find good cause that notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporate a statement of the findings and the reasons for it into the notice issued.

In section VI.A.6 of the preamble of this final rule, we discuss a technical correction that we are making to the regulations to reinstate § 412.22(h)(6) to the regulations governing payments to LTCHs under the LTCH PPS. We find it unnecessary to undertake notice and comment rulemaking with respect to the addition of § 412.22(h)(6) to the regulation text because this correction merely reinstates a paragraph of regulation text implemented in one final rule and inadvertently erroneously removed by another final rule. We also note that the policy codified in § 412.22(h)(6) underwent notice and comment rulemaking before being finalized. Thus, because the public has already had the opportunity to comment on this policy, additional comment would be unnecessary.

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Crosswalk of Contents of §413.86

Existing Section	New Section
§413.86(a)	§413.75(a)
§413.86(a)(1)	§413.75(a)(1)
§413.86(a)(2)	§413.75(a)(2)
§413.86(b)	§413.75(b)
§413.86(c)	§413.75(c)
§413.86(d)	§413.76
§413.86(d), introductory text	§413.76, introductory text
§413.86(d)(1)	§413.76(a)
§413.86(d)(2)	§413.76(b)
§413.86(d)(3)	§413.76(c)
§413.86(d)(3)(i)	§413.76(c)(1)
§413.86(d)(3)(ii)	§413.76(c)(2)
§413.86(d)(3)(iii)	§413.76(c)(3)
§413.86(d)(3)(iv)	§413.76(c)(4)
§413.86(d)(3)(v)	§413.76(c)(5)
§413.86(d)(4)	§413.76(d)
§413.86(d)(5)	§413.76(e)
§413.86(d)(5)(i)	§413.76(e)(1)
§413.86(d)(5)(ii)	§413.76(e)(2)
§413.86(d)(6)	§413.76(f)
§413.86(e)	§413.77
§413.86(e)(1)	§413.77(a)
§413.86(e)(1)(i)	§413.77(a)(1)
§413.86(e)(1)(i)(A)	§413.77(a)(1)(i)
§413.86(e)(1)(i)(B)	§413.77(a)(1)(ii)
§413.86(e)(1)(ii)	§413.77(a)(2)
§413.86(e)(1)(ii)(A)	§413.77(a)(2)(i)
§413.86(e)(1)(ii)(B)	§413.77(a)(2)(ii)
§413.86(e)(1)(ii)(C)	§413.77(a)(2)(iii)
§413.86(e)(1)(iii)	§413.77(a)(3)
§413.86(e)(1)(iv)	§413.77(a)(4)
§413.86(e)(1)(v)	§413.77(a)(5)
§413.86(e)(2), introductory text	§413.77(b), introductory text
§413.86(e)(2)(i)	§413.77(b)(1)
§413.86(e)(2)(ii)	§413.77(b)(2)
§413.86(e)(3), introductory text	§413.77(c), introductory text
§413.86(e)(3)(i)	§413.77(c)(1)
§413.86(e)(3)(ii)	§413.77(c)(2)
§413.86(e)(4), introductory text	§413.77(d), introductory text--NEW
§413.86(e)(4)(i), introductory text	§413.77(d)(1), introductory text
§413.86(e)(4)(i)(A), introductory text	§413.77(d)(1)(i), introductory text
§413.86(e)(4)(i)(A)(1)	§413.77(d)(1)(i)(A)
§413.86(e)(4)(i)(A)(2)	§413.77(d)(1)(i)(B)
§413.86(e)(4)(i)(A)(3)	§413.77(d)(1)(i)(C)
§413.86(e)(4)(i)(B)	§413.77(d)(1)(ii)

Existing Section	New Section
§413.86(e)(4)(ii), introductory text	§413.77(d)(2), introductory text--NEW
§413.86(e)(4)(ii)(A)	§413.77(d)(2)(i)
§413.86(e)(4)(ii)(B)	§413.77(d)(2)(ii)
§413.86(e)(4)(ii)(C), introductory text	§413.77(d)(2)(iii), introductory text
§413.86(e)(4)(ii)(C)(1)	§413.77(d)(2)(iii)(A)
§413.86(e)(4)(ii)(C)(1)(i)	§413.77(d)(2)(iii)(A)(1)
§413.86(e)(4)(ii)(C)(1)(ii)	§413.77(d)(2)(iii)(A)(2)
§413.86(e)(4)(ii)(C)(1)(iii)	§413.77(d)(2)(iii)(A)(3)
§413.86(e)(4)(ii)(C)(2), introductory text	§413.77(d)(2)(iii)(B), introductory text--NEW
§413.86(e)(4)(ii)(C)(2)(i)	§413.77(d)(2)(iii)(B)(1)
§413.86(e)(4)(ii)(C)(2)(ii)	§413.77(d)(2)(iii)(B)(2)
§413.86(e)(4)(ii)(C)(2)(iii)	§413.77(d)(2)(iii)(B)(3)--NEW
§413.86(e)(4)(ii)(C)(2)(iv)	§413.77(d)(2)(iii)(B)(4)--NEW
--	§413.77(d)(2)(iii)(B)(5)--NEW
§413.86(e)(4)(ii)(C)(3)	§413.77(d)(2)(iii)(C)--NEW
§413.86(e)(5)	§413.77(e)
§413.86(e)(5)(i)	§413.77(e)(1)
§413.86(e)(5)(i)(A)	§413.77(e)(1)(i)
§413.86(e)(5)(i)(B), introductory text	§413.77(e)(1)(ii), introductory text
§413.86(e)(5)(i)(B)(1)	§413.77(e)(1)(ii)(A)
§413.86(e)(5)(i)(B)(2)	§413.77(e)(1)(ii)(B)
§413.86(e)(5)(i)(C)	§413.77(e)(1)(iii)
§413.86(e)(5)(ii)	§413.77(e)(2)
§413.86(e)(5)(iii)	§413.77(e)(3)
--	§413.77(f)--NEW
--	§413.77(g)--NEW
§413.86(f)	§413.78
§413.86(f), introductory text	§413.78, introductory text
§413.86(f)(1)	§413.78(a)
§413.86(f)(2)	§413.78(b)
§413.86(f)(3), introductory text	§413.78(c), introductory text
§413.86(f)(3)(i)	§413.78(c)(1)
§413.86(f)(3)(ii)	§413.78(c)(2)
§413.86(f)(4), introductory text	§413.78(d), introductory text
§413.86(f)(4)(i)	§413.78(d)(1)
§413.86(f)(4)(ii)	§413.78(d)(2)
§413.86(f)(4)(iii)	§413.78(d)(3)
§413.86(f)(4)(iv)	§413.78(d)(4)
--	§413.78(e), introductory text--NEW
--	§413.78(e)(1)--NEW

Existing Section	New Section
--	§413.78(e)(2)--NEW
--	§413.78(e)(3)--NEW
§413.86(g), introductory text	§413.79
§413.86(g), introductory text	§413.79, introductory text
§413.86(g)(1)	§413.79(a)
§413.86(g)(1)	§413.79(a) introductory text--NEW
§413.86(g)(1)	§413.79(a)(1)--NEW
§413.86(g)(1)	§413.79(a)(2)--NEW
§413.86(g)(1)	§413.79(a)(3)--NEW
§413.86(g)(1)	§413.79(a)(4)--NEW
§413.86(g)(1)	§413.79(a)(5)--NEW
§413.86(g)(1)(i)	§413.79(a)(6)
§413.86(g)(1)(ii)	§413.79(a)(7)
§413.86(g)(1)(iii), introductory text	§413.79(a)(8), introductory text
§413.86(g)(1)(iii)(A)	§413.79(a)(8)(i)
§413.86(g)(1)(iii)(B)	§413.79(a)(8)(ii)
§413.86(g)(1)(iv)	§413.79(a)(9)
--	§413.79(a)(10)--NEW
§413.86(g)(2)	§413.79(b)(1)
§413.86(g)(3)	§413.79(b)(2)
--	§413.79(c)(1), introductory text--NEW
--	§413.79(c)(1)(i) through (iii)--NEW
§413.86(g)(4), introductory text	§413.79(c)(2), introductory text
§413.86(g)(4)(i)	§413.79(c)(2)(i)
§413.86(g)(4)(ii)	§413.79(c)(2)(ii)
§413.86(g)(4)(iii)	§413.79(c)(2)(iii)
§413.86(g)(4)(iv)	§413.79(c)(2)(iv)
§413.86(g)(4)(v)	§413.79(c)(2)(v)
--	§413.79(c)(3)(i) through (ii)--NEW
--	§413.79(c)(4)--NEW
	§413.79(c)(5)--NEW
§413.86(g)(5), introductory text	§413.79(d), introductory text
§413.86(g)(5)(i)	§413.79(d)(1)
§413.86(g)(5)(ii)	§413.79(d)(2)
§413.86(g)(5)(iii)	§413.79(d)(3)
§413.86(g)(5)(iv)	§413.79(d)(4)
§413.86(g)(5)(v)	§413.79(d)(5)
§413.86(g)(5)(vi)	§413.79(d)(6)
§413.86(g)(5)(vii)	§413.79(d)(7)
§413.86(g)(6), introductory text	§413.79(e), introductory text
§413.86(g)(6)(i)	§413.79(e)(1)
§413.86(g)(6)(i)(A)	§413.79(e)(1)(i)

Existing Section	New Section
§413.86(g)(6)(i)(B)	§413.79(e)(1)(ii)
§413.86(g)(6)(i)(C)	§413.79(e)(1)(iii)
§413.86(g)(6)(i)(D)	§413.79(e)(1)(iv)
§413.86(g)(6)(i)(E)	§413.79(e)(1)(v)
§413.86(g)(6)(ii), introductory text	§413.79(e)(2), introductory text
§413.86(g)(6)(ii)(A)	§413.79(e)(2)(i)
§413.86(g)(6)(ii)(B)	§413.79(e)(2)(ii)
§413.86(g)(6)(iii)	§413.79(e)(3)
§413.86(g)(6)(iv)	§413.79(e)(4)
§413.86(g)(7)	§413.79(f)
§413.86(g)(7)(i)	§413.79(f)(1)
§413.86(g)(7)(ii)	§413.79(f)(2)
§413.86(g)(7)(iii)	§413.79(f)(3)
§413.86(g)(7)(iv)	§413.79(f)(4)
§413.86(g)(7)(v)	§413.79(f)(5)
§413.86(g)(8), introductory text	§413.79(g), introductory text
§413.86(g)(8)(i), introductory text	§413.79(g)(1), introductory text
§413.86(g)(8)(i)(A)	§413.79(g)(1)(i)
§413.86(g)(8)(i)(B)	§413.79(g)(1)(ii)
§413.86(g)(8)(ii)	§413.79(g)(2)
§413.86(g)(8)(iii)	§413.79(g)(3)
§413.86(g)(8)(iv)	§413.79(g)(4)
§413.86(g)(8)(v)	§413.79(g)(5)
§413.86(g)(9)	§413.79(h)
§413.86(g)(9)(i), introductory text	§413.79(h)(1), introductory text
§413.86(g)(9)(i)(A)	§413.79(h)(1)(i)
§413.86(g)(9)(i)(B)	§413.79(h)(1)(ii)
§413.86(g)(9)(ii), introductory text	§413.79(h)(2), introductory text
§413.86(g)(9)(ii)(A)	§413.79(h)(2)(i)
§413.86(g)(9)(ii)(B)	§413.79(h)(2)(ii)
§413.86(g)(9)(iii), introductory text	§413.79(h)(3), introductory text
§413.86(g)(9)(iii)(A), introductory text	§413.79(h)(3)(i), introductory text
§413.86(g)(9)(iii)(A)(1)	§413.79(h)(3)(i)(A)
§413.86(g)(9)(iii)(A)(2)	§413.79(h)(3)(i)(B)
§413.86(g)(9)(iii)(B), introductory text	§413.79(h)(3)(ii), introductory text
§413.86(g)(9)(iii)(B)(1)	§413.79(h)(3)(ii)(A)
§413.86(g)(9)(iii)(B)(2)	§413.79(h)(3)(ii)(B)
§413.86(g)(10), introductory text	§413.79(i), introductory text
§413.86(g)(10)(i)	§413.79(i)(1)
§413.86(g)(10)(ii)	§413.79(i)(2)
§413.86(g)(10)(iii)	§413.79(i)(3)
§413.86(g)(11), introductory text	§413.79(j), introductory text

Existing Section	New Section
§413.86(g)(11)(i)	§413.79(j)(1)
§413.86(g)(11)(ii)	§413.79(j)(2)
§413.86(g)(11)(iii)	§413.79(j)(3)
§413.86(g)(12), introductory text	§413.79(k), introductory text
§413.86(g)(12)(i), introductory text	§413.79(k)(1), introductory text
§413.86(g)(12)(i)(A)	§413.79(k)(1)(i)
§413.86(g)(12)(i)(B)	§413.79(k)(1)(ii)
§413.86(g)(12)(ii), introductory text	§413.79(k)(2), introductory text
§413.86(g)(12)(ii)(A)	§413.79(k)(2)(i)
§413.86(g)(12)(ii)(B), introductory text	§413.79(k)(2)(ii), introductory text
§413.86(g)(12)(ii)(B)(1), introductory text	§413.79(k)(2)(ii)(A), introductory text
§413.86(g)(12)(ii)(B)(1)(i)	§413.79(k)(2)(ii)(A)(1)
§413.86(g)(12)(ii)(B)(1)(ii)	§413.79(k)(2)(ii)(A)(2)
§413.86(g)(12)(ii)(B)(2)	§413.79(k)(2)(ii)(B)
§413.86(g)(12)(iii)	§413.79(k)(3)
§413.86(g)(12)(iv), introductory text	§413.79(k)(4), introductory text
§413.86(g)(12)(iv)(A)	§413.79(k)(4)(i)
§413.86(g)(12)(iv)(B), introductory text	§413.79(k)(4)(ii), introductory text
§413.86(g)(12)(iv)(B)(1)	§413.79(k)(4)(ii)(A)
§413.86(g)(12)(iv)(B)(2)	§413.79(k)(4)(ii)(B)
§413.86(g)(12)(v), introductory text	§413.79(k)(5), introductory text
§413.86(g)(12)(v)(A)	§413.79(k)(5)(i)
§413.86(g)(12)(v)(B)	§413.79(k)(5)(ii)
§413.86(g)(12)(v)(C)	§413.79(k)(5)(iii)
§413.86(g)(12)(vi)	§413.79(k)(6)
§413.86(g)(13)	§413.79(l)
§413.86(h)	§413.80
§413.86(h)(1), introductory text	§413.80(a), introductory text
§413.86(h)(1)(i)	§413.80(a)(1)
§413.86(h)(1)(ii)	§413.80(a)(2)
§413.86(h)(2)	§413.80(b)
§413.86(h)(3)	§413.80(c)
§413.86(h)(4)	§413.80(d)
§413.86(h)(5)	§413.80(e)
§413.86(h)(6)	§413.80(f)
§413.86(i)	§413.81
§413.86(i)(1), introductory text	§413.81(a), introductory text
§413.86(i)(1)(i)	§413.81(a)(1)
§413.86(i)(1)(ii)	§413.81(a)(2)
§413.86(i)(2)	§413.81(b)
§413.86(i)(3)(i)	§413.81(c)(1)
§413.86(i)(3)(ii)	§413.81(c)(2)

Existing Section	New Section
§413.86(j), introductory text	§413.75(d), introductory text
§413.86(j)(1)	§413.75(d)(1)
§413.86(j)(2)	§413.75(d)(2)
§413.86(j)(3)	§413.75(d)(3)
§413.86(j)(4)	§413.75(d)(4)
§413.86(j)(5)	§413.75(d)(5)
§413.86(j)(6)	§413.75(d)(6)
§413.86(j)(7)	§413.75(d)(7)
§413.86(k)	§413.82
§413.86(k)(1)	§413.82(a)
§413.86(k)(2)	§413.82(b)
§413.86(k)(3)	§413.82(c)
§413.86(l)	§413.83
§413.86(l)(1)	§413.83(a)
§413.86(l)(1)(i)	§413.83(a)(1)
§413.86(l)(1)(ii)	§413.83(a)(2)
§413.86(l)(2)(iii)	§413.83(a)(3)
§413.86(l)(2)	§413.83(b)
§413.86(l)(2)(i)	§413.83(b)(1)
§413.86(l)(2)(ii)	§413.83(b)(2)
§413.86(l)(2)(iii)	§413.83(b)(3)

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Note to Readers: Redesignated §§ 413.77, 413.78 and 413.79 were the only three sections of the redesignated §§ 413.75 through 413.83 that contain proposed policy changes in the May 18, 2004 proposed rule:

- §§ 413.77(d) introductory text, (d)(2), (d)(2)(iii)(B), (d)(2)(iii)(B)(3), (d)(2)(iii)(B)(4), (d)(2)(iii)(B)(5), (d)(2)(iii)(C), and (f).
- §§ 413.78(e), (e)(1), (e)(2), and (e)(3).
- § 413.79(a), (c)(1), (c)(2), (c)(3), (c)(4), and (c)(5).

These policy changes, any public comments we received, our responses to these comments and any further changes we have made in response to these comments are discussed in section IV.O. of the preamble of this final rule.

The remaining portions of the redesignated §§ 413.75 through 413.83 contain only coding, cross-reference, and conforming redesignation changes. In the May 18, 2004 proposed rule, we solicited comments on redesignation, coding, and cross-reference changes.

We were notified of one error in our proposed redesignation of the contents of § 413.86. We erroneously redesignated the contents of § 413.86(j) and (j)(1) through (j)(7) as paragraphs (g) and (g)(1) through (g)(7) under § 413.80 which relates to determination of weighting factors for foreign medical graduates. The contents of § 413.86(j)

and (j)(1) through (j)(7) are general GME requirements relating to the information that a hospital must furnish to include a resident in the FTE count for a particular cost reporting period. Therefore, in this final rule, we have correctly redesignated § 413.86(j) and (j)(1) through (j)(7) as paragraphs (d) and (d)(1) through (d)(7) under § 413.75.

List of Subjects

42 CFR Part 403

Health insurance, Hospitals, Incorporation by reference, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Incorporation by reference, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 480

Health care, Health records, Medicare, Peer Review Organizations (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

■ For the reasons stated in the preamble of this final rule, the Centers for Medicare & Medicaid Services is amending 42 CFR chapter IV as follows:
 ■ A. Part 403 is amended as follows:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C.1302 and 1395hh).

■ 2. Section 403.744 is amended by—

■ A. Revising paragraph (a).

■ B. Revising paragraph (c).

The revision reads as follows:

§ 403.744 Condition of Participation: Life safety from fire.

(a) *General.* An RNHCI must meet the following conditions:

(1) Except as otherwise provided in this section—

(i) The RNHCI must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101®2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted Life Safety Code does not apply to an RNHCI.

(2) [Reserved]

* * * * *

(c) *Phase-in period.* Beginning March 13, 2006, an RNHCI must be in compliance with Chapter 19.2.9, Emergency Lighting. Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to RNHCIs.

■ B. Part 412 is amended as follows:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 412.2 is amended by adding a new paragraph (b)(3) to read as follows:

§ 412.2 Basis of payment.

* * * * *

(b) *Payment in full.* * * *

(3) If a patient is admitted to an acute care hospital and then the acute care hospital meets the criteria at § 412.23(e) to be paid as a LTCH, during the course of the patient's hospitalization, Medicare considers all the days of the patient stay in the facility (days prior to and after the designation of LTCH status) to be a single episode of LTCH care. Medicare will not make payment under subpart H for any part of the hospitalization. Payment for the entire patient stay (days prior to and after the designation of LTCH status) will be made in accordance with the requirements specified in § 412.521. The requirements of this paragraph (b)(3) apply only to a patient stay in which a patient is in an acute care hospital and that hospital is designated as a LTCH on or after October 1, 2004.

* * * * *

■ 3. Section 412.4 is amended by revising paragraph (d) to read as follows:

§ 412.4 Discharges and transfers.

* * * * *

(d) *Qualifying DRGs.* (1) For purposes of paragraph (c) of this section, and subject to the provisions of paragraph (d)(2) of this section, the qualifying DRGs must meet the following criteria for both of the 2 most recent fiscal years for which data are available:

- (i) The DRG must have a geometric mean length of stay of at least 3 days.
- (ii) The DRG must have at least 14,000 cases identified as postacute care transfer cases.
- (iii) The DRG must have at least 10 percent of the postacute care transfers occurring before the geometric mean length of stay for the DRG.

(iv) If the DRG is one of a paired DRG based on the presence or absence of a comorbidity or complication, one of the DRGs meets the criteria specified under paragraphs (d)(1)(i) through (d)(1)(iii) of this section.

(v) To initially qualify, the DRG must meet the criteria specified in paragraphs(d)(1)(i) through (d)(1)(iv) of this section and must have a decline in the geometric mean length of stay for

the DRG during the most recent 5-year period of at least 7 percent. Once a DRG initially qualifies, the DRG is subject to the criteria specified under paragraphs (d)(1)(i) through (d)(1)(iv) of this section for each subsequent fiscal year.

(2) For purposes of paragraph (c), a discharge is also considered to be a transfer if it meets the following conditions:

- (i) The discharge is assigned to a DRG that contains only cases that were assigned to a DRG that qualified under this paragraph within the previous 2 years; and
- (ii) The latter DRG was split or otherwise modified within the previous 2 fiscal years.

* * * * *

■ 4. Section 412.22 is amended by—

■ A. Adding a sentence at the end of paragraph (a).

■ B. Revising paragraph (e).

■ C. Adding a new paragraph (h)(6).

The additions and revision read as follows:

§ 412.22 Excluded hospitals and hospital units: General rules.

(a) *Criteria.* * * * For purposes of this subpart, the term "hospital" includes a critical access hospital (CAH).

* * * * *

(e) *Hospitals-within-hospitals.* Except as provided in paragraph (f) of this section, a hospital that occupies space in a building also used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital, must meet the following criteria in order to be excluded from the prospective payment systems specified in § 412.1(a)(1):

(1) Except as specified in paragraph (e)(2) of this section, for cost reporting periods beginning on or after October 1, 1987, and before October 1, 2004—

(i) *Separate governing body.* The hospital has a governing body that is separate from the governing body of the hospital occupying space in the same building or on the same campus. The hospital's governing body is not under the control of the hospital occupying space in the same building or on the same campus, or of any third entity that controls both hospitals.

(ii) *Separate chief medical officer.* The hospital has a single chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of the hospital. The chief medical officer of the hospital is not employed by or under contract with either the hospital occupying space in the same building or on the same campus or any third entity that controls both hospitals.

(iii) *Separate medical staff.* The hospital has a medical staff that is separate from the medical staff of the hospital occupying space in the same building or on the same campus. The hospital's medical staff is directly accountable to the governing body for the quality of medical care provided in the hospital, and adopts and enforces by-laws governing medical staff activities, including criteria and procedures for recommending to the governing body the privileges to be granted to individual practitioners.

(iv) *Chief executive officer.* The hospital has a single chief executive officer through whom all administration authority flows, and who exercises control and surveillance over all administrative activities of the hospital. The chief executive officer is not employed by, or under contract with, either the hospital occupying space in the same building or on the same campus or any third entity that controls both hospitals.

(v) *Performance of basic hospital functions.* The hospital meets one of the following criteria:

(A) The hospital performs the basic functions specified in §§ 482.21 through 482.27, 482.30, 482.42, 482.43, and 482.45 of this chapter through the use of employees or under contracts or other agreements with entities other than the hospital occupying space in the same building or on the same campus, or a third entity that controls both hospitals. Food and dietetic services and housekeeping, maintenance, and other services necessary to maintain a clean and safe physical environment could be obtained under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals.

(B) For the same period of at least 6 months used to determine compliance with the criterion regarding the age of patients in § 412.23(d)(2) or the length-of-stay criterion in § 412.23(e)(2), or for hospitals other than children's or long-term care hospitals, for a period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the cost of the services that the hospital obtains under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals, is no more than 15 percent of the hospital's total inpatient operating costs, as defined in § 412.2(c). For purposes of this paragraph (e)(1)(v)(B), however, the costs of preadmission services are those specified under

§ 413.40(c)(2) rather than those specified under § 412.2(c)(5).

(C) For the same period of at least 6 months used to determine compliance with the criterion regarding the age of inpatients in § 412.23(d)(2) or the length-of-stay criterion in § 412.23(e)(2), or for hospitals other than children's or long-term care hospitals, for the period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the hospital has an inpatient population of whom at least 75 percent were referred to the hospital from a source other than another hospital occupying space in the same building or on the same campus.

(2) Effective for long-term care hospitals-within-hospitals for cost reporting periods beginning on or after October 1, 2004, the hospital must meet the governance and control requirements at paragraphs (e)(1)(i) through (e)(1)(iv) of this section.

(3) *Notification of co-located status.* A long-term care hospital that occupies space in a building used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital that meets the criteria of (e)(1) or (e)(2) of this section must notify its fiscal intermediary and CMS in writing of its co-location within 60 days of its first cost reporting period that begins on or after October 1, 2002.

* * * * *

(h) *Satellite facilities.* * * *

(6) The provisions of paragraph (h)(2)(i) of this section do not apply to any long-term care hospital that is subject to the long-term care hospital prospective payment system under Subpart O of this subpart, effective for cost reporting periods occurring on or after October 1, 2002, and that elects to be paid based on 100 percent of the Federal prospective payment rate as specified in § 412.533(c), beginning with the first cost reporting period following that election, or when the LTCH is fully transitioned to 100 percent of the Federal prospective rate, or to a new long-term care hospital, as defined in § 412.23(e)(4).

* * * * *

■ 5. Section 412.25 is amended by adding a new paragraph (g), to read as follows:

§ 412.25 Excluded hospital units: Common requirements.

* * * * *

(g) *CAH units not meeting applicable requirements.* If a psychiatric or rehabilitation unit of a CAH does not meet the requirements of § 485.647 with respect to a cost reporting period, no

payment may be made to the CAH for services furnished in that unit for that period. Payment to the CAH for services in the unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

- 6. Section 412.63 is amended by—
- A. Revising the heading of the section.
- B. Revising paragraph (a).
- C. Adding introductory text to paragraph (b).
- D. Revising paragraph (c)(1), (c)(5), and (c)(6)
- E. Revising paragraph (u).

The revisions and addition read as follow:

§ 412.63 Federal rates for inpatient operating costs for Federal fiscal years 1984 through 2004.

(a) *General rule.*

(1) CMS determines a national adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge in Federal fiscal years 1985 through 2004 involving inpatient hospital service of a hospital in the United States, subject to the PPS, and determines a regional adjusted PPS rate for operating costs for such discharges in each region for which payment may be made under Medicare Part A.

(2) Each such rate is determined for hospitals located in urban or rural areas within the United States and within each such region, respectively, as described under paragraphs (b) through (u) of this section.

* * * * *

(b) *Geographic classifications.* Effective for fiscal years 1985 through 2004, the following rules apply.

* * * * *

(c) *Updating previous standardized amounts.* (1) For discharges occurring in fiscal year 1985 through fiscal year 2003, CMS computes average standardized amounts for hospitals in urban areas and rural areas within the United States, and in urban areas and rural areas within each region. For discharges occurring in fiscal year 2004, CMS computes an average standardized amount for hospitals located in all areas.

* * * * *

(5) For fiscal years 1987 through 2004, CMS standardizes the average standardized amounts by excluding an estimate of indirect medical education payments.

(6) For fiscal years 1988 through 2003, CMS computes average standardized amounts for hospitals located in large urban areas, other urban areas, and rural areas. The term *large urban area* means

an MSA with a population of more than 1,000,000 or an NECMA, with a population of more than 970,000 based on the most recent available population data published by the Census Bureau. For fiscal year 2004, CMS computes an average standardized amount for hospitals located in all areas.

* * * * *

(u) *Applicable percentage change for fiscal year 2004.* The applicable percentage change for fiscal year 2004 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas.

* * * * *

■ 7. A new § 412.64 is added to Subpart D to read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

(a) *General rule.* CMS determines a national adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge in Federal fiscal year 2005 and subsequent fiscal years involving inpatient hospital services of a hospital in the United States subject to the prospective payment system for which payment may be made under Medicare Part A.

(b) *Geographic classifications.* (1) For purposes of this section, the following definitions apply:

(i) The term *region* means one of the 9 metropolitan divisions comprising the 50 States and the District of Columbia, established by the Executive Office of Management and Budget for statistical and reporting purposes.

(ii) The term *urban area* means—

(A) A Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget; or

(B) The following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Public Law 98–21, 42 U.S.S. 1395ww (note)): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

(C) The term *rural area* means any area outside an urban area.

(D) The phrase *hospital reclassified as rural* means a hospital located in a county that, in FY 2004, was part of an MSA, but was redesignated as rural after September 30, 2004, as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003.

(2) For hospitals within an MSA that crosses census division boundaries, the MSA is deemed to belong to the census division in which most of the hospitals within the MSA are located.

(3) For discharges occurring on or after October 1, 2004, a hospital located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives the Federal payment amount for the urban area to which the greater number of workers in the county commute if the rural county would otherwise be considered part of an urban area, under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or central counties of all adjacent MSAs. These EOMB standards are set forth in the notice of final revised standards for classification of MSAs published in the **Federal Register** on December 27, 2000 (65 FR 82228), announced by EOMB on June 6, 2003, and available from CMS, 7500 Security Boulevard, Baltimore, Maryland 21244.

(4) For purposes of this section, any change in an MSA designation is recognized on October 1 following the effective date of the change. Such a change in MSA designation may occur as a result of redesignation of an MSA by the Executive Office of Management and Budget.

(c) *Computing the standardized amount.* CMS computes an average standardized amount that is applicable to all hospitals located in all areas, updated by the applicable percentage increase specified in paragraph (d) of this section.

(d) *Applicable percentage change for fiscal year 2005 and for subsequent fiscal years.*

(1) Subject to the provisions of paragraph (d)(2) of this section, the applicable percentage change for fiscal year 2005 and for subsequent years for updating the standardized amount is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas.

(2) For fiscal years 2005, 2006, and 2007, the applicable percentage change specified in paragraph (d)(1) of this section is reduced by 0.4 percentage points in the case of a “subsection (d) hospital,” as defined under section 1886(d)(1)(B) of the Act, that does not submit quality data on a quarterly basis to CMS, as specified by CMS. Any reduction of the percentage change will apply only to the fiscal year involved

and will not be taken into account in computing the applicable percentage increase for a subsequent fiscal year.

(e) *Maintaining budget neutrality.*

(1) CMS makes an adjustment to the standardized amount to ensure that—

(i) Changes to the DRG classifications and recalibrations of the DRG relative weights are made in a manner so that aggregate payments to hospitals are not affected; and

(ii) The annual updates and adjustments to the wage index under paragraph (h) of this section are made in a manner that ensures that aggregate payments to hospitals are not affected.

(2) CMS also makes an adjustment to the rates to ensure that aggregate payments after implementation of reclassifications under subpart L of this part are equal to the aggregate prospective payments that would have been made in the absence of these provisions.

(f) *Adjustment for outlier payments.* CMS reduces the adjusted average standardized amount determined under paragraph (c) through (e) of this section by a proportion equal to the proportion (estimated by CMS) to the total amount of payments based on DRG prospective payment rates that are additional payments for outlier cases under subpart F of this part.

(g) *Computing Federal rates for inpatient operating costs for hospitals located in all areas.* For each discharge classified within a DRG, CMS establishes for the fiscal year a national prospective payment rate for inpatient operating costs based on the standardized amount for the fiscal year and the weighting factor determined under § 412.60(b) for that DRG.

(h) *Adjusting for different area wage levels.* CMS adjusts the proportion of the Federal rate for inpatient operating costs that are attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS based on survey data) reflecting the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (b) of this section) of the hospital compared to the national average level of hospital wages and wage-related costs. The adjustment described in this paragraph (h) also takes into account the earnings and paid hours of employment by occupational category.

(1) The wage index is updated annually.

(2) CMS determines the proportion of the Federal rate that is attributable to wages and labor-related costs from time to time, employing a methodology that

is described in the annual regulation updating the system of payment for inpatient hospital operating costs.

(3) For discharges occurring on or after October 1, 2004, CMS employs 62 percent as the proportion of the rate that is adjusted for the relative level of hospital wages and wage-related costs, unless employing that percentage would result in lower payments for the hospital than employing the proportion determined under the methodology described in paragraph (h)(2) of this section.

(4) For discharges on or after October 1, 2004 and before September 30, 2007, CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology:

(i) CMS computes the ratio of the lowest-to-highest wage index for each all-urban State;

(ii) CMS computes the average of the ratios of the lowest-to-highest wage indexes of all the all-urban States;

(iii) For each all-urban State, CMS determines the higher of the State's own lowest-to-highest rate (as determined under paragraph (h)(4)(i) of this section) or the average lowest-to-highest rate (as determined under paragraph (h)(4)(ii) of this section);

(iv) For each State, CMS multiplies the rate determined under paragraph (h)(4)(iii) of this section by the highest wage index value in the State;

(v) The product determined under paragraph (h)(4)(iv) of this section is the minimum wage index value for the State.

(5) An all-urban State is a State with no rural areas, as defined in this section, or a State in which there are no hospitals classified as rural. A State with rural areas and with hospitals reclassified as rural under § 412.103 in not an all-urban State.

(i) *Adjusting the wage index to account for commuting patterns of hospital workers.*

(1) *General criteria.* For discharges occurring on or after October 1, 2004, CMS adjusts the hospital wage index for hospitals located in qualifying counties to recognize the commuting patterns of hospital employees. A qualifying county is a county that meets all of the following criteria:

(i) Hospital employees in the county commute to work in an MSA (or MSAs) with a wage index (or wage indices) higher than the wage index of the MSA or rural statewide area in which the county is located.

(ii) At least 10 percent of the county's hospital employees commute to an MSA

(or MSAs) with a higher wage index (or wage indices).

(iii) The 3-year average hourly wage of the hospital(s) in the county equals or exceeds the 3-year average hourly wage of all hospitals in the MSA or rural statewide area in which the county is located.

(2) *Amount of adjustment.* A hospital located in a county that meets the criteria under paragraphs (i)(1)(i) through (i)(1)(iii) of this section will receive an increase in its wage index that is equal to a weighted average of the difference between the prereclassified wage index of the MSA (or MSAs) with the higher wage index (or wage indices) and the prereclassified wage index of the MSA or rural statewide area in which the qualifying county is located, weighted by the overall percentage of the hospital employees residing in the qualifying county who are employed in any MSA with a higher wage index.

(3) *Process for determining the adjustment.*

(i) CMS will use the most accurate data available, as determined by CMS, to determine the out-migration percentage for each county.

(ii) CMS will include, in its annual proposed and final notices of updates to the hospital inpatient prospective payment system, a listing of qualifying counties and the hospitals that are eligible to receive the adjustment to their wage indexes for commuting hospital employees, and the wage index increase applicable to each qualifying county.

(iii) Any wage index adjustment made under this paragraph (i) is effective for a period of 3 fiscal years, except that hospitals in a qualifying county may elect to waive the application of the wage index adjustment. A hospital may waive the application of the wage index adjustment by notifying CMS in writing within 45 days after the publication of the annual notice of proposed rulemaking for the hospital inpatient prospective payment system.

(iv) A hospital in a qualifying county that receives a wage index adjustment under this paragraph (g) is not eligible for reclassification under Subpart L of this part.

(j) *Wage index assignment for rural referral centers for FY 2005.*

(1) CMS makes an exception to the wage index assignment of a rural referral center for FY 2005 if the rural referral center meets the following conditions:

(i) The rural referral center was reclassified for FY 2004 by the MGCRB to another MSA, but, upon applying to the MGCRB for FY 2005, was found to be ineligible for reclassification because

its average hourly wage was less than 84 percent (but greater than 82 percent) of the average hourly wage of the hospitals geographically located in the MSA to which the rural referral center applied for reclassification for FY 2005.

(ii) The hospital may not qualify for any geographic reclassification under subpart L of this part, effective for discharges occurring on or after October 1, 2004.

(2) CMS will assign a rural referral center that meets the conditions of paragraph (j)(1) of this section the wage index value of the MSA to which it was reclassified by the MGCRB in FY 2004. The wage index assignment is applicable for discharges occurring during the 3-year period beginning October 1, 2004 and ending September 30, 2007.

(k) *Midyear corrections to the wage index.*

(1) CMS makes a midyear correction to the wage index for an area only if a hospital can show that—

(i) The intermediary or CMS made an error in tabulating its data; and

(ii) The hospital could not have known about the error, or did not have the opportunity to correct the error, before the beginning of the Federal fiscal year.

(2) A midyear correction to the wage index is effective prospectively from the date the change is made to the wage index.

(l) *Judicial decision.* If a judicial decision reverses a CMS denial of a hospital's wage data revision request, CMS pays the hospital by applying a revised wage index that reflects the revised wage data as if CMS's decision had been favorable rather than unfavorable.

■ 8. Section 412.87 is amended by revising paragraph (b)(3) to read as follows:

§ 412.87 Additional payment for new medical services and technologies: General provisions.

* * * * *

(b) Eligibility criteria. * * *

(3) The DRG prospective payment rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate, based on application of a threshold amount to estimated charges incurred with respect to such discharges. To determine whether the payment would be adequate, CMS will determine whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost

and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant DRGs if the new medical service or technology occurs in many different DRGs). Standardized charges reflect the actual charges of a case adjusted by the prospective payment system payment factors applicable to an individual hospital, such as the wage index, the indirect medical education adjustment factor, and the disproportionate share adjustment factor.

§ 412.88 [Amended]

■ 9. Section 412.88 is amended by removing paragraph (c).

■ 10. A new § 412.101 is added to read as follows:

§ 412.101 Special treatment: Inpatient hospital payment adjustment for low-volume hospitals.

(a) *General considerations.*

(1) CMS provides an additional payment to a qualifying hospital for the higher incremental costs associated with a low volume of discharges. The amount of any additional payment for a qualifying hospital is calculated in accordance with paragraph (b) of this section.

(2) In order to qualify for this adjustment, a hospital must have less than 200 discharges during the fiscal year, as reflected in its cost report specified in paragraph (a)(3) of this section, and be located more than 25 road miles from the nearest subsection (d) hospital.

(3) The fiscal intermediary makes the determination of the discharge count for purposes of determining a hospital's qualification for the adjustment based on the hospital's most recent submitted cost report.

(4) In order to qualify for the adjustment, a hospital must provide its fiscal intermediary with sufficient evidence that it meets the distance requirement specified under paragraph (a)(2) of this section. The fiscal intermediary will base its determination of whether the distance requirement is

satisfied upon the evidence presented by the hospital and other relevant evidence, such as maps, mapping software, and inquiries to State and local police, transportation officials, or other government officials.

(b) *Determination of the adjustment amount.* The low-volume adjustment for hospitals that qualify under paragraph (a) of this section is 25 percent for each Medicare discharge.

(c) *Eligibility of new hospitals for the adjustment.* A new hospital will be eligible for a low-volume adjustment under this section once it has submitted a cost report for a cost reporting period that indicates that it meets the number of discharge requirements during the fiscal year and has provided its fiscal intermediary with sufficient evidence that it meets the distance requirement, as specified under paragraph (a)(2) of this section.

■ 11. Section 412.102 is amended by revising the introductory text to read as follows:

§ 412.102 Special treatment: Hospitals located in areas that are reclassified from urban to rural as a result of a geographic redesignation.

Effective on or after October 1, 1983, a hospital reclassified as rural, as defined in subpart D of this part, may receive an adjustment to its rural Federal payment amount for operating costs for two successive fiscal years.

* * * * *

■ 12. Section 412.103 is amended by—

■ A. Revising paragraph (a) introductory text.

■ B. Adding a new paragraph (a)(4).

The revision and addition read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

(a) *General criteria.* A prospective payment hospital that is located in an urban area (as defined in subpart D of this part) may be reclassified as a rural hospital if it submits an application in accordance with paragraph (b) of this section and meets any of the following conditions:

* * * * *

(4) For any period after September 30, 2004 and before January 1, 2004, a CAH in a county that, in FY 2004, was not part of a MSA as defined by the Office of Management and Budget, but as of FY 2005 was included as part of an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, may be reclassified as being located in a rural area for purposes of meeting the rural location requirement in § 485.610(b) of this chapter if it meets any of the requirements in paragraphs (a)(1), (a)(2), or (a)(3) of this section.

* * * * *

■ 13. Section 412.104 is amended by revising paragraph (a) to read as follows:

§ 412.104 Special treatment: Hospitals with high percentage of ESRD discharges.

(a) *Criteria for classification.* CMS provides an additional payment to a hospital for inpatient services provided to ESRD beneficiaries who receive a dialysis treatment during a hospital stay, if the hospital has established that ESRD beneficiary discharges, excluding discharges classified into DRG 302 (Kidney Transplant), DRG 316 (Renal Failure), or DRG 317 (Admit for Renal Dialysis), where the beneficiary received dialysis services during the inpatient stay, constitute 10 percent or more of its total Medicare discharges.

* * * * *

■ 14. Section 412.105 is amended by—

- A. Revising paragraph (b).
- B. Revising paragraph (d)(3)(vii).
- C. Adding new paragraphs (d)(3)(viii) through (xii).
- D. Adding a new paragraph (d)(4).
- E. Redesignating the contents of paragraph (e) as paragraph (e)(1) and adding a new paragraph (e)(2).
- F. Redesignating the contents of paragraph (f)(1)(iv) as paragraph (f)(1)(iv)(A) and adding new paragraphs (f)(1)(iv)(B) and (f)(1)(iv)(C).

Cross-Reference Changes

■ G. In paragraphs (a), (f), and (g) as indicated in the left column of the table below, remove the cross-reference indicated in the middle column from wherever it appears, and add the cross-reference in the right column:

Section	Remove Cross-Reference	Add Cross-Reference
412.105(a)(1), introductory text	paragraph (f) and (h) of this section	paragraph (f) of this section
412.105(f)(1)(i)(A)	§415.200(a)	§415.152
412.105(f)(1)(ii)(C)	§413.86(f)(3) or §413.86(f)(4)	§413.78(c) or §413.78(d)
412.105(f)(1)(vi)	§413.86(b)	§413.75(b)
412.105(f)(1)(vi)	§413.86(g)(7)	§413.79(f)
412.105(f)(1)(vii)	§413.86(g)(13)	§413.79(l)
412.105(f)(1)(vii)	§§413.86(g)(6)(i) through (iv)	§§413.79(e)(1) through (e)(4)
412.105(f)(1)(viii)	§413.86(g)(8)	§413.79(g)
412.105(f)(1)(ix)	§§413.86(g)(9)(i) and (g)(9)(ii)	§§413.79(h)(1) and (h)(2)
412.105(f)(1)(ix)	§§413.86(g)(9)(i) and (g)(9)(iii)(B)	§§413.79(h)(1) and (h)(3)(ii)
412.105(f)(1)(ix)	§§413.86(g)(9)(i) and (g)(9)(iii)(A)	§§413.79(h)(1) and (h)(3)(i)
412.105(f)(1)(x)	§413.86(g)(13)	§413.79(l)
412.105(f)(1)(x)	§413.86(g)(12)	§413.79(k)
412.105(f)(1)(xi)	§413.86(g)(10)	§413.79(i)
412.105(f)(1)(xii)	§413.86(g)(11)	§413.79(j)
412.105(g)	§§413.86(d)(3)(i) through (d)(3)(v)	§§413.76(c)(1) through (c)(5)

The revisions and additions read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(b) *Determination of the number of beds.* For purposes of this section, the number of beds in a hospital is determined by counting the number of available bed days during the cost reporting period and dividing that number by the number of days in the cost reporting period. This count of available bed days excludes bed days associated with—

(1) Beds in a unit or ward that is not occupied to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system at any time during the 3 preceding months (the beds in the unit or ward are to be excluded from the determination of available bed days during the current month);

(2) Beds in a unit or ward that is otherwise occupied (to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system) that could not be made available for inpatient occupancy within 24 hours for 30 consecutive days;

(3) Beds in excluded distinct part hospital units;

(4) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, or ancillary labor/delivery services. This exclusion would not apply if a patient treated in an observation bed is ultimately admitted for acute inpatient care, in which case the beds and days would be included in those counts;

(5) Beds or bassinets in the healthy newborn nursery; and

(6) Custodial care beds.

* * * * *

(d) *Determination of education adjustment factor.*

* * * * *

(3) *Step three.* * * *

(vii) For discharges occurring on or after October 1, 2002 and before April 1, 2004, 1.35.

(viii) For discharges occurring on or after April 1, 2004 and before October 1, 2004, 1.47.

(ix) For discharges occurring during fiscal year 2005, 1.42.

(x) For discharges occurring during fiscal year 2006, 1.37.

(xi) For discharges occurring during fiscal year 2007, 1.32.

(xii) For discharges occurring during fiscal year 2008 and thereafter, 1.35.

(4) For discharges occurring on or after July 1, 2005, with respect to FTE residents added as a result of increases

in the FTE resident cap under paragraph (f)(1)(iv)(C) of this section, the factor derived from completing steps one and two is multiplied by 'c', where 'c' is equal to 0.66.

(e) *Determination of payment amount.*

(1) * * *

(2) For discharges occurring on or after July 1, 2005, a hospital that counts additional residents as a result of an increase in its FTE resident cap under paragraph (f)(1)(iv)(C) of this section will receive indirect medical education payments based on the sum of the following two indirect medical education adjustment factors:

(i) An adjustment factor that is calculated using the schedule of formula multipliers in paragraph (d)(3) of this section and the hospital's FTE resident count, not including residents attributable to an increase in its FTE cap under paragraph (f)(1)(iv)(C) under this section; and

(ii) An adjustment factor that is calculated using the applicable formula multiplier under paragraph (d)(4) of this section, and the additional number of FTE residents that are attributable to the increase in the hospital's FTE resident cap under paragraph (f)(1)(iv)(C) in this section.

(f) *Determining the total number of full-time equivalent residents for cost*

reporting periods beginning on or after July 1, 1991.

- (1) * * *
- (iv) (A) * * *

(B) Effective for portions of cost reporting periods beginning on or after July 1, 2005, a hospital's otherwise applicable FTE resident cap may be reduced if its reference resident level is less than its otherwise applicable FTE resident cap in a reference cost reporting period, in accordance with the provisions of § 413.79(c)(3) of this subchapter. The reduction is 75 percent of the difference between the otherwise applicable FTE resident cap and the reference resident level.

(C) Effective for portions of cost reporting periods beginning on or after July 1, 2005, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap (up to 25 additional FTEs) if the criteria specified in § 413.79(c)(4) of this subchapter are met.

* * * * *

- 15. Section 412.106 is amended by—
- A. Revising paragraphs (a)(1)(ii)(B) and (a)(1)(ii)(C).
- B. Adding a new paragraph (a)(1)(ii)(D).
- C. Revising paragraph (b)(2)(i) introductory text.
- D. In paragraph (a)(1)(iii), removing the cross-reference “§ 412.62(f)” and adding in its place “§ 412.62(f) or § 412.64”.
- E. Revising paragraphs (d)(2)(ii), (d)(2)(iii), and (d)(2)(iv) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

- (a) General considerations.
- (1) * * *
- (ii) * * *

(B) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, or ancillary labor/delivery services. This exclusion would not apply if a patient treated in an observation bed is ultimately admitted for acute inpatient care, in which case the beds and days would be included in those counts;

(C) Beds in a unit or ward that is not occupied to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system at any time during the 3 preceding months (the beds in the unit or ward are to be excluded from the determination of available bed days during the current month); and

(D) Beds in a unit or ward that is otherwise occupied (to provide a level of care that would be payable under the acute care hospital inpatient prospective

payment system) that could not be made available for inpatient occupancy within 24 hours for 30 consecutive days.

* * * * *

- (b) * * *
- (2) * * *

(i) Determines the number of patient days that—

* * * * *

(d) *Payment adjustment factor.*

* * * * *

(2) *Payment adjustment factors.*

* * * * *

(ii) If the hospital meets the criteria of paragraph (c)(1)(ii) of this section, the payment adjustment factor is equal to one of the following:

(A) If the hospital is classified as a rural referral center—

(1) For discharges occurring before April 1, 2001, the payment adjustment factor is 4 percent plus 60 percent of the difference between the hospital's disproportionate patient percentage and 30 percent.

(2) For discharges occurring on or after April 1, 2001, and before April 1, 2004, the following applies:

(i) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(ii) If the hospital's disproportionate patient percentage is greater than 19.3 percent and less than 30 percent, the applicable payment adjustment factor is 5.25 percent.

(iii) If the hospital's disproportionate patient percentage is greater than or equal to 30 percent, the applicable payment adjustment factor is 5.25 percent plus 60 percent of the difference between 30 percent and the hospital's disproportionate patient percentage.

(3) For discharges occurring on or after April 1, 2004, the following applies:

(i) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(ii) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(B) If the hospital is classified as a sole community hospital—

(1) For discharges occurring before April 1, 2001, the payment adjustment factor is 10 percent.

(2) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(i) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(ii) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent and less than 30 percent, the applicable payment adjustment factor is 5.25 percent.

(iii) If the hospital's disproportionate patient percentage is equal to or greater than 30 percent, the applicable payment adjustment factor is 10 percent.

(3) For discharges occurring on or after April 1, 2004, the following applies:

(i) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(ii) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(iii) The maximum payment adjustment factor is 12 percent.

(C) If the hospital is classified as both a rural referral center and a sole community hospital, the payment adjustment is—

(1) For discharges occurring before April 1, 2001, the greater of—

(i) 10 percent; or

(ii) 4 percent plus 60 percent of the difference between the hospital's disproportionate patient percentage and 30 percent.

(2) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the greater of the adjustments determined under paragraphs (d)(2)(ii)(A) or (d)(2)(ii)(B) of this section.

(3) For discharges occurring on or after April 1, 2004, the following applies:

(i) If the hospital's disproportionate patient percentage is less than 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(ii) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus

82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(D) If the hospital is classified as a rural hospital and is not classified as either a sole community hospital or a rural referral center, and has 100 or more beds—

(1) For discharges occurring before April 1, 2001, the payment adjustment factor is 4 percent.

(2) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(i) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between the hospital's disproportionate patient percentage and 15 percent.

(ii) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent, the applicable payment adjustment factor is 5.25 percent.

(3) For discharges occurring on or after April 1, 2004, the following applies:

(i) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(ii) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(iii) The maximum payment adjustment factor is 12 percent.

(iii) If the hospital meets the criteria of paragraph (c)(1)(iii) of this section—

(A) For discharges occurring before April 1, 2001, the payment adjustment factor is 5 percent.

(B) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(1) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between the hospital's disproportionate patient percentage and 15 percent.

(2) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent, the applicable payment adjustment factor is 5.25 percent.

(C) For discharges occurring on or after April 1, 2004, the following applies:

(1) If the hospital's disproportionate patient percentage is less than or equal

to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(2) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(3) The maximum payment adjustment factor is 12 percent.

(iv) If the hospital meets the criteria of paragraph (c)(1)(iv) of this section—

(A) For discharges occurring before April 1, 2001, the payment adjustment factor is 4 percent.

(B) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(1) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between the hospital's disproportionate patient percentage and 15 percent.

(2) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent, the applicable payment adjustment factor is 5.25 percent.

(C) For discharges occurring on or after April 1, 2004, the following applies:

(1) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(2) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(3) The maximum payment adjustment factor is 12 percent.

* * * * *

■ 16. Section 412.108 is amended by revising paragraph (a)(1) introductory text to read as follows:

§ 412.108 Special treatment: Medicare-dependent, small rural hospitals.

(a) *Criteria for classification as a Medicare-dependent, small rural hospital.*

(1) *General considerations.* For cost reporting periods beginning on or after April 1, 1990 and ending before October 1, 1994, or beginning on or after October 1, 1997 and ending before October 1, 2006, a hospital is classified as a

Medicare-dependent, small rural hospital if it is located in a rural area (as defined in subpart D of this part) and meets all of the following conditions:

* * * * *

■ 17. Section 412.204 is amended by—

■ A. Revising the introductory text of paragraph (a).

■ B. Revising the title and introductory text of paragraph (b).

■ C. Adding new paragraphs (c) and (d).

The revision and addition read as follows:

§ 412.204 Payment to hospitals located in Puerto Rico.

(a) *FY 1988 through FY 1997.* For discharges occurring on or after October 1, 1987 and before October 1, 1997, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

* * * * *

(b) *FY 1998 through March 31, 2004.* For discharges occurring on or after October 1, 1997 and before April 1, 2004, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

* * * * *

(c) *Period of April 1, 2004 through September 31, 2004.* For discharges occurring on or after April 1, 2004 and before October 1, 2004, payment for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

(1) 37.5 percent of the Puerto Rico prospective payment rate for inpatient operating costs, as determined under § 412.208 or § 412.210; and

(2) 62.5 percent of the national prospective payment rate for inpatient operating costs, as determined under § 412.212.

(d) *FY 2005 and thereafter.* For discharges occurring on or after October 1, 2004, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

(1) 25 percent of the Puerto Rico prospective payment rate for inpatient operating costs, as determined under § 412.208 or § 412.211; and

(2) 75 percent of a national prospective payment rate for inpatient operating costs, as determined under § 412.212.

■ 18. Section 412.210 is amended by—

■ A. Revising the title of the section.

■ B. Revising paragraph (a)(1) to read as follows:

§ 412.210 Puerto Rico rates for Federal fiscal years 1989 through 2003.

(a) *General rule.* (1) CMS determines the Puerto Rico adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge occurring in Federal fiscal years 1989 through 2003 that involves inpatient hospital services of a hospital in Puerto Rico subject to the prospective payment system for which payment may be made under Medicare Part A.

* * * * *

■ 19. New § 412.211 is added to read as follows:

§ 412.211 Puerto Rico rates for Federal fiscal year 2004 and subsequent fiscal years.

(a) *General rule.* CMS determines the Puerto Rico adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge occurring in Federal fiscal year 2004 and subsequent fiscal years that involves inpatient hospital services of a hospital in Puerto Rico subject to the prospective payment system for which payment may be made under Medicare Part A.

(b) *Geographic classifications.*

(1) For purposes of this section, the following definitions apply:

(i) The term *urban area* means a Metropolitan Statistical Area (MSA) as defined by the Executive Office of Management and Budget.

(ii) The term *rural area* means any area outside of an urban area.

(2) For discharges occurring on or after October 1, 2004, a hospital located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives the Federal payment amount for the urban area to which the greater number of workers in the county commute if the rural county would otherwise be considered part of an urban area, under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or central counties of all adjacent MSAs. These EOMB standards are set forth in the notice of final revised standards for classification of MSAs published in the **Federal Register** on December 27, 2000 (65 FR 82228), announced by EOMB on June 6, 2003, and available from CMS, 7500 Security Boulevard, Baltimore, Maryland 21244.

(c) *Computing the standardized amount.* CMS computes a Puerto Rico standardized amount that is applicable to all hospitals located in all areas,

increased by the applicable percentage change specified in § 412.64(d)(1).

(d) *Computing Puerto Rico Federal rates for inpatient operating costs for hospitals located in all areas.* For each discharge classified within a DRG, CMS establishes for the fiscal year a Puerto Rico prospective payment rate for inpatient operating costs equal to the product of—

(1) The average standardized amount for the fiscal year for hospitals located in all areas; and

(2) The weighting factor determined under § 412.60(b) for that DRG.

(e) *Adjusting for different area wage levels.* CMS adjusts the proportion of the Puerto Rico rate for inpatient operating costs that are attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS based on survey data) reflecting the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (b) of this section) of the hospital compared to the Puerto Rico average level of hospital wages and wage-related costs. The adjustment specified in this paragraph (e) also takes into account the earnings and paid hours of employment by occupational category.

(1) The wage index is updated annually.

(2) CMS determines the proportion of the Puerto Rico rate that is attributable to wages and labor-related costs from time to time, employing a methodology that is described in the annual update of the prospective payment system for payment of inpatient hospital operating costs published in the **Federal Register**.

(3) For discharges occurring on or after October 1, 2004, CMS employs 62 percent as the proportion of the rate that is adjusted for the relative level of hospital wages and wage-related costs, unless employing that percentage would result in lower payments for the hospital than employing the proportion determined under the methodology described in paragraph (e)(2) of this section.

(f) *Adjusting the wage index to account for commuting patterns of hospital workers.*

(1) *General criteria.* For discharges occurring on or after October 1, 2004, CMS adjusts the hospital wage index for hospitals located in qualifying areas to recognize the commuting patterns of hospital employees. A qualifying area is an area that meets all of the following criteria:

(i) Hospital employees in the area commute to work in an MSA (or MSAs)

with a wage index (or wage indices) higher than the wage index of the area.

(ii) At least 10 percent of the county's hospital employees commute to an MSA (or MSAs) with a higher wage index (or wage indices).

(iii) The 3-year average hourly wage of the hospital(s) in the area equals or exceeds the 3-year average hourly wage of all hospitals in the MSA or rural area in which the county is located.

(2) *Amount of adjustment.* A hospital located in an area that meets the criteria under paragraphs (f)(1)(i) through (f)(1)(iii) of this section will receive an increase in its wage index that is equal to a weighted average of the difference between the prereclassified wage index of the MSA (or MSAs) with the higher wage index (or wage indices) and the prereclassified wage index of the qualifying area, weighted by the overall percentage of the hospital employees residing in the qualifying area who are employed in any MSA with a higher wage index.

(3) *Process for determining the adjustment.*

(i) CMS will use the most accurate data available, as determined by CMS, to determine the out-migration percentage for each area.

(ii) CMS will include, in its annual proposed and final notices of updates to the hospital inpatient prospective payment system, a listing of qualifying areas and the hospitals that are eligible to receive the adjustment to their wage indexes for commuting hospital employees, and the wage index increase applicable to each qualifying area.

(iii) Any wage index adjustment made under this paragraph (f) is effective for a period of 3 fiscal years, except that hospitals in a qualifying county may elect to waive the application of the wage index adjustment. A hospital may waive the application of the wage index adjustment by notifying CMS in writing within 45 days after the publication in the **Federal Register** of the annual notice of proposed rulemaking for the hospital inpatient prospective payment system.

(iv) A hospital in a qualifying area that receives a wage index adjustment under this paragraph (f) is not eligible for reclassification under Subpart L of this part.

■ 20. Section 412.212 is amended by revising paragraph (b) to read as follows:

§ 412.212 National rate.

* * * * *

(b) *Computing Puerto Rico standardized amounts.* (1) For Federal fiscal years before FY 2004, CMS computes a discharge-weighted average of the—

(i) National urban adjusted standardized amount determined under § 412.63(j)(1); and

(ii) National rural adjusted average standardized amount determined under § 412.63(j)(2)(i).

(2) For fiscal years 2004 and subsequent fiscal years, CMS computes a discharge-weighted average of the national adjusted standardized amount determined under § 412.64(e).

* * * * *

■ 21. Section 412.230 is amended by—

- A. Revising paragraph (a)(1).
- B. Revising paragraph (a)(4).
- C. Removing paragraph (a)(5)(ii) and redesignating paragraphs (a)(5)(iii), (a)(5)(iv), and (a)(5)(v) as paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(5)(iv), respectively.
- D. Removing paragraph (d).
- E. Removing paragraph (e)(2)(i)(C).
- F. Redesignating paragraph (e) as paragraph (d).
- G. In redesignated paragraph (d)(1), removing the cross-reference “paragraphs (e)(3) and (e)(4)” and adding in its place “paragraphs (d)(3) and (d)(4)”.
- H. In redesignated paragraph (d)(2)(iii), removing the cross-reference “paragraph (e)(2)” and adding in its place “paragraph (d)(2)”.
- I. Revising redesignated paragraphs (d)(3)(i), (d)(3)(ii), and adding (d)(3)(iii)(C).
- J. In redesignated paragraph (d)(4), removing the cross-reference “paragraphs (e)(1)(i) and (e)(1)(iii)” and adding in its place “paragraph (d)(1)(i) and (d)(1)(iii)”.
- K. In redesignated paragraph (d)(4)(iii), removing the cross-reference “paragraph (e)” and adding in its place “paragraph (d)”.

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

(a) *General.* (1) *Purposes.* Except as specified in paragraph (a)(5)—

(i) For fiscal years prior to fiscal year 2005, an individual hospital may be redesignated from a rural area to an urban area, from a rural area to another rural area, or from a rural area to another urban area for the purposes of using the other area’s standardized amount for inpatient operating costs, the wage index value, or both.

(ii) Effective for fiscal year 2005 and subsequent fiscal years, an individual hospital may be redesignated from a rural area to an urban area, from a rural area to another rural area, or from a rural area to another urban area for the purposes of using the other area’s wage index value.

* * * * *

(4) *Application of criteria.* In applying the numeric criteria contained in paragraphs (b)(1), (b)(2), (d)(1)(iii), (d)(1)(iv)(A), and (d)(1)(iv)(B) of this section, rounding of numbers to meet the mileage or qualifying percentage standards is not permitted.

* * * * *

(d) *Use of urban or other rural area’s wage index.*

* * * * *

(3) *Rural referral center exceptions.*

(i) If a hospital was ever a rural referral center, it does not have to demonstrate that it meets the criterion set forth in paragraph (d)(1)(iii) of this section concerning its average hourly wage.

(ii) If a hospital was ever a rural referral center, it is required to meet only the criterion that applies to rural hospitals under paragraph (d)(1)(iv) of this section, whether or not it is actually located in an urban or rural area.

(iii) * * *

(C) With respect to redesignations for Federal fiscal year 2006 and later years, the hospital’s average hourly wage is, in the case of a hospital located in a rural area, at least 106 percent, and, in the case of a hospital located in an urban area, 108 percent of the average hourly wage of all other hospitals in the area in which the hospital is located.

* * * * *

■ 22. Section 412.232 is amended by—

- A. Revising paragraph (a)(1).
- B. Revising paragraph (a)(4).
- C. Revising paragraph (b).

§ 412.232 Criteria for all hospitals in a rural county seeking urban redesignation.

(a) *Criteria.* * * *

(1) The county in which the hospitals are located—

(i) For fiscal years prior to fiscal year 2005, must be adjacent to the MSA or NECMA to which they seek redesignation.

(ii) For fiscal years beginning with fiscal years 2005, must be adjacent to the MSA to which they seek redesignation.

* * * * *

(4) The hospital may be redesignated only if one of the following conditions is met:

(i) The prereclassified average hourly wage for the area to which they seek redesignation is higher than the prereclassified average hourly wage for the area in which they are currently located.

(ii) For fiscal years prior to fiscal year 2005, the standardized amount for the area to which they seek redesignation is higher than the standardized amount for the area in which they are located.

(b) *Metropolitan character.*

(1) For fiscal years prior to FY 2005, the group of hospitals must demonstrate that the county in which the hospitals are located meets the standards for redesignation to an MSA or an NECMA as an outlying county that were published in the **Federal Register** on March 30, 1990 (55 FR 12154) using Bureau of the Census data or Bureau of Census estimates made after 1990.

(2) For fiscal years beginning with FY 2005, the group of hospitals must demonstrate that the county in which the hospitals are located meets the standards for redesignation to an MSA as an outlying county that were published in the **Federal Register** on December 27, 2000 (65 FR 82228) using Census Bureau data or Census Bureau estimates made after 2000.

* * * * *

■ 23. Section 412.234 is amended by—

- A. Revising paragraph (a)(3).
- B. Revising paragraph (a)(4).
- C. Removing paragraph (c).
- D. Redesignating paragraph (d) as paragraph (c) and revising the redesignated paragraph (c).

The revisions read as follows.

§ 412.234 Criteria for all hospitals in an urban county seeking redesignation to another urban area.

(a) *General criteria.* * * *

(3) (i) For Federal fiscal years before fiscal year 2006, the counties in which the hospitals are located must be part of the Consolidated Metropolitan Statistical Area (CMSA) that includes the urban area to which they seek redesignation.

(ii) For fiscal years 2006 and thereafter, hospitals located in counties that are in the same Consolidated Statistical Area (CSA) (under the MSA definitions announced by the OMB on June 6, 2003) as the urban area to which they seek redesignation; or in the same Consolidated Metropolitan Statistical Area (CMSA) (under the standards published by the OMB on March 30, 1990) as the urban area to which they seek redesignation qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation.

(4) The hospital may be redesignated only if one of the following conditions is met:

(i) The prereclassified average hourly wage for the area to which they seek redesignation is higher than the prereclassified average hourly wage for the area in which they are currently located.

(ii) For fiscal years prior to fiscal year 2005, the standardized amount for the area to which they seek redesignation is

higher than the standardized amount for the area in which they are located.

* * * * *

(c) *Appropriate wage data.* The hospitals must submit appropriate wage data as provided for in § 412.230(d)(2).

§ 412.236 [Removed]

■ 24. Section 412.236 is removed.

§ 412.252 [Amended]

■ 25. In § 412.252, paragraph (b), the phrase "or in a NECMA" is removed.

■ 26. Section 412.274 is amended by revising paragraph (b)(1) to read as follows:

§ 412.274 Scope and effect of an MGCRB decision.

* * * * *

(b) *Effective date and term of the decision.*

(1) For reclassifications prior to fiscal year 2005, a standardized amount classification change is effective for 1 year beginning with discharges occurring on the first day (October 1) of the second Federal fiscal year following the Federal fiscal year in which the complete application is filed and ending effective at the end of that Federal fiscal year (the end of the next September 30).

* * * * *

■ 27. Section 412.312 is amended by —

■ A. Revising paragraph (b)(2)(ii).

■ B. Revising paragraph (e).

The revisions read as follows.

§ 412.312 Payment based on the Federal rate.

(b) *Payment adjustments.* * * *

(2) *Geographic adjustment factors.*

* * *

(ii) *Large urban add-on.* An additional adjustment is made for hospitals located in a large urban area to reflect the higher costs incurred by hospitals located in those areas. For purposes of the payment adjustment under this paragraph, the definition of large urban area set forth at § 412.63(c)(6) continues to be in effect for discharges occurring on or after September 30, 2004.

* * * * *

(e) *Payment for extraordinary circumstances.* For cost reporting periods beginning on or after October 1, 2001—

(1) Payment for extraordinary circumstances is made as provided for in § 412.348(f).

(2) Although no longer independently in effect, the minimum payment levels established under § 412.348(c) continue to be used in the calculation of exception payments for extraordinary circumstances, according to the formula in § 412.348(f).

(3) Although no longer independently in effect, the offsetting amounts established under § 412.348(c) continue to be used in the calculation of exception payments for extraordinary circumstances. However, for cost reporting periods beginning during FY 2005 and subsequent fiscal years, the offsetting amounts in § 412.348(c) are determined based on the lesser of—

(i) The preceding 10-year period; or

(ii) The period of time under which the hospital is subject to the prospective payment system for capital-related costs.

* * * * *

■ 28. Section 412.316 is amended by revising paragraph (b) to read as follows:

§ 412.316 Geographic adjustment factors.

* * * * *

(b) *Large urban location.* CMS provides an additional payment to a hospital located in a large urban area equal to 3.0 percent of what would otherwise be payable to the hospital based on the Federal rate.

(1) For discharges occurring on or before September 30, 2004, the payment adjustment under this section is based on a hospital's location for the purpose of receiving payment under § 412.63(a). The term "large urban area" is defined under § 412.63(c)(6).

(2) For discharges occurring on or after October 1, 2004, the definition of large urban area under § 412.63(c)(6) continues to be in effect for purposes of the payment adjustment under this section, based on the geographic classification under § 412.64.

* * * * *

■ 29. Section 412.320 is amended by revising paragraph (a)(1) to read as follows:

§ 412.320 Disproportionate share adjustment factor.

(a) *Criteria for classification.*

* * * * *

(1) The hospital is located in an urban area, has 100 or more beds as determined in accordance with § 412.105(b), and serves low-income patients as determined under § 412.106(b).

(i) For discharges occurring on or before September 30, 2004, the payment adjustment under this section is based on a hospital's location, for the purpose of receiving payment, under § 412.63(a).

(ii) For discharges occurring on or after October 1, 2004, the payment adjustment under this section is based on the geographic classifications specified under § 412.64.

* * * * *

■ 30. Section 412.374 is amended by—

■ A. Revising paragraph (a).

■ B. Redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively.

■ C. Adding a new paragraph (b).

The revisions and addition read as follows:

§ 412.374 Payments to hospitals located in Puerto Rico.

(a) *FY 1998 through FY 2004.*

Payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of the following:

(1) 50 percent of the Puerto Rico capital rate based on data from Puerto Rico hospitals only, which is determined in accordance with procedures for developing the Federal rate; and

(2) 50 percent of the Federal rate, as determined under § 412.308.

(b) *FY 2005 and FYs thereafter.* For discharges occurring on or after October 1, 2004, payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of the following:

(1) 25 percent of the Puerto Rico capital rate based on data from Puerto Rico hospitals only, which is determined in accordance with procedures for developing the Federal rate; and

(2) 75 percent of the Federal rate, as determined under § 412.308.

* * * * *

■ 31. Section 412.521 is amended by adding a new paragraph (e) to read as follows:

§ 412.521 Basis of payment.

* * * * *

(e) *Special payment provisions for patients in acute care hospitals that change classification status to LTCH status during a patient stay.* (1) If a patient is admitted to an acute care hospital and then the acute care hospital meets the criteria at § 412.23(e) to be paid as a LTCH during the course of the patient's hospitalization, Medicare considers all the days of the patient stay in the facility (days prior to and after the designation of LTCH status) to be a single episode of LTCH care. Payment for the entire patient stay (days prior to and after the designation of LTCH status) will include the day and cost data for that patient at both the acute care hospital and the LTCH in determining the payment to the LTCH under this subpart. The requirements of this paragraph (e)(1) apply only to a patient stay in which a patient is in an acute care hospital and that hospital is

designated as a LTCH on or after October 1, 2004.

(2) The days of the patient's stay prior to and after the hospital's designation as a LTCH as specified in paragraph (e)(1) of this section are included for purposes of determining the beneficiary's length of stay.

■ 32. Section 412.534 is added to read as follows:

§ 412.534. Special payment provisions for long-term care hospitals within hospitals and satellites of long-term care hospitals.

(a) *Scope.* The policies set forth in this section apply to discharges occurring in cost reporting periods beginning on or after October 1, 2004 from long-term care hospitals as described in § 412.23(e)(2)(i) meeting the criteria in § 412.22(e)(2), or satellite facilities of long-term care hospitals that meet the criteria in § 412.22(h).

(b) *Patients admitted from hospitals not located in the same building or on the same campus as the long-term care hospital.* Payments to the long-term care hospital for patients admitted to the long-term hospital or to a satellite of the long-term care hospital from another hospital that is not the co-located hospital are made under the rules in this subpart with no adjustment under this section.

(c) *Patients admitted from the hospital located in the same building or on the same campus as the long-term care hospital or satellite facility.* Payments to the long-term care hospital for patients admitted to it or to its satellite facility from the co-located hospital will be made under either paragraph (c)(1) or paragraph (c)(2) of this section.

(1) For any cost reporting period beginning on or after October 1, 2004 in which the long-term care hospital or its satellite facility has a Medicare inpatient population of whom no more than 25 percent were referred to the hospital or its satellite facility from the co-located hospital, payments are made under the rules at § 412.500 through § 412.541 in this subpart with no adjustment under this section.

(2) Except as provided in paragraph (d), (e), or (f) of this section, for any cost reporting period beginning on or after October 1, 2004 in which the long-term care hospital or satellite facility has a Medicare inpatient population of whom more than 25 percent were referred to the hospital or satellite facility from the co-located hospital, payments for the patients who are admitted from the co-located hospital and who cause the long-term care hospital or satellite facility to exceed the 25 percent threshold for discharges of patients from

the co-located hospital are the lesser of the amount otherwise payable under this subpart or the amount payable under this subpart that is equivalent to the amount that would be otherwise determined under the rules at Subpart A, § 412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's patients are made under the rules in this subpart at § 412.500 through § 412.541 with no adjustment under this section.

(3) In determining the percentage of patients admitted to the long-term care or satellite facility from the co-located hospital under paragraphs (c)(1) and (c)(2) of this section, patients on whose behalf an outlier payment was made to the co-located hospital are not counted towards the 25 percent threshold.

(d) *Special treatment of rural hospitals.* (1) In the case of a long-term care hospital or satellite facility that is located in a rural area as defined in § 412.62(f) and is co-located with another hospital for any cost reporting period beginning on or after October 1, 2004 in which the long-term care hospital or satellite facility has a Medicare inpatient population of whom more than 50 percent were referred to the long-term care hospital or satellite facility from the co-located hospital, payments for the patients who are admitted from the co-located hospital and who cause the long-term care hospital or satellite facility to exceed the 50 percent threshold for discharges of patients from the co-located hospital are the lesser of the amount otherwise payable under this subpart or the amount payable under this subpart that is equivalent to the amount that would otherwise be payable under § 412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's patients are made under the rules in this subpart at § 412.500 through § 412.541 with no adjustment under this section.

(2) In determining the percentage of patients admitted from the co-located hospital under paragraph (d)(1) of this section, patients on whose behalf outlier payment was made at the co-located hospital are not counted toward the 50 percent threshold.

(e) *Special treatment of urban single or MSA dominant hospitals.* (1) In the case of a long-term care hospital or satellite facility that is co-located with the only other hospital in the MSA or with a MSA-dominant hospital as defined in paragraph (e)(4) of this section, for any cost reporting period beginning on or after October 1, 2004 in which the long-term care hospital or satellite facility has a Medicare inpatient population of whom more than the percentage calculated under

paragraph (e)(2) of this section were referred to the hospital from the co-located hospital, payments for the patients who are admitted from the co-located hospital and who cause the long-term care hospital to exceed the applicable threshold for discharges of patients from the co-located hospital are the lesser of the amount otherwise payable under this subpart or the amount under this subpart that is equivalent to the amount that would otherwise be determined under Subpart A, § 412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's patients are made under the rules in this subpart with no adjustment under this section.

(2) For purposes of paragraph (e)(1) of this section, the percentage used is the percentage of total Medicare discharges in the Metropolitan Statistical Area in which the hospital is located that are from the co-located hospital for the cost reporting period for which the adjustment was made, but in no case is less than 25 percent or more than 50 percent.

(3) In determining the percentage of patients admitted from the co-located hospital under paragraph (e)(1) of this section, patients on whose behalf outlier payment was made at the co-located hospital are not counted toward the applicable threshold.

(4) For purposes of this paragraph, an "MSA-dominant hospital" is a hospital that has discharged more than 25 percent of the total hospital Medicare discharges in the MSA in which the hospital is located.

(f) *Transition period for long-term care hospitals and satellite facilities paid under this subpart.* In the case of a long-term care hospital or a satellite facility that is paid under the provisions of this Subpart O of Part 412 on October 1, 2004 or of a hospital that is paid under the provisions of this Subpart O on October 1, 2005 and whose qualifying period under § 412.23(e) began on or before October 1, 2004, the amount paid is calculated as specified below:

(1) For each discharge during the first cost reporting period beginning on or after October 1, 2004, and before October 1, 2005, the amount paid is the amount payable under this subpart, with no adjustment under this § 412.534.

(2) For each discharge during the cost reporting period beginning on or after October 1, 2005, and before October 1, 2006, the percentage that may be admitted from the host with no payment adjustment may not exceed the lesser of the percentage of patients admitted from

the host during fiscal year 2004 or 75 percent.

(3) For each discharge during the cost reporting period beginning on or after October 1, 2006, and before October 1, 2007, the percentage that may be admitted from the host with no payment adjustment may not exceed the lesser of the percentage of patients admitted from the host during fiscal year 2004 or 50 percent.

(4) For each discharge during cost reporting periods beginning on or after October 1, 2007, the percentage that may be admitted from the host with no payment adjustment may not exceed 25 percent or the applicable percentage determined under paragraph (d) or (e) of this section.

■ C. Part 413 is amended as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 1. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395hh, 1395rr, 1395tt, and 1395ww).

- 2. Section 413.40 is amended by—
- A. Republishing the introductory text of paragraphs (c)(4), (c)(4)(iii) and (c)(4)(iii)(A), and revising paragraphs (c)(4)(iii)(A)(1) and (c)(4)(iii)(A)(2).
- B. Republishing the introductory text of paragraph (c)(4)(iii)(B) and revising paragraph (c)(4)(iii)(B)(4)(i).
- C. Revising the introductory text of paragraphs (d)(4)(i) and (d)(4)(ii).

The revisions read as follows:

§ 413.40 Ceiling on the rate of increase in hospital inpatient costs.

* * * * *

(c) *Costs subject to the ceiling.*

* * * * *

(4) *Target amounts.* The intermediary will establish a target amount for each hospital. The target amount for a cost reporting period is determined as follows:

* * * * *

(iii) In the case of a psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital, the target amount is the lower of the amounts specified in paragraph (c)(4)(iii)(A) or (c)(4)(iii)(B) of this section.

(A) The hospital-specific target amount.

(1) In the case of all hospitals and units, except long-term care hospitals for cost reporting periods beginning during FY 2001, the hospital-specific target amount is the net allowable costs in a base period increased by the applicable update factors .

(2) In the case of long-term care hospitals, for cost reporting periods beginning during FY 2001, the hospital-specific target amount is the net allowable costs in a base period increased by the applicable update factors multiplied by 1.25.

(B) One of the following for the applicable cost reporting period—

* * * * *

(4) For cost reporting periods beginning during fiscal years 2001 and 2002—

(i) The amounts determined under paragraph (c)(4)(iii)(B)(3)(i) of this section are: increased by the market basket percentage up through the subject period; or in the case of a long-term care hospital for cost reporting periods beginning during FY 2001, the amounts determined under paragraph (c)(4)(iii)(B)(3)(i) of this section, increased by the market basket percentage up through the subject period and further increased by 2 percent.

* * * * *

(d) *Application of the target amount in determining the amount of payment.*

* * * * *

(4) *Continuous improvement bonus payments.* (i) For cost reporting periods beginning on or after October 1, 1997, eligible hospitals (as defined in paragraph (d)(5) of this section) receive payments in addition to those in paragraph (d)(2) of this section, as applicable. These payments are equal to the lesser of—

* * * * *

(ii) For cost reporting periods beginning on or after October 1, 2000, and before September 30, 2001, eligible psychiatric hospitals and units and long-term care hospitals (as defined in paragraph (d)(5) of this section) receive payments in addition to those in paragraph (d)(2) of this section, as applicable. These payments are equal to the lesser of—

* * * * *

■ 3. Section 413.64 is amended by—

- A. Revising the introductory text of paragraph (h)(2) and adding a new paragraph (h)(2)(vi).
- B. Removing paragraph (h)(3)(iv).
- C. Removing and reserving paragraph (h)(4).

The additions and revisions read as follows:

§ 413.64 Payments to providers: Specific rules.

* * * * *

(h) *Periodic interim payment method of reimbursement.*

* * * * *

(2) *Covered services furnished on or after July 1, 1987.* Effective with claims received on or after July 1, 1987, or as otherwise specified, the periodic interim payment (PIP) method is available for the following:

* * * * *

(vi) Effective for payments made on or after July 1, 2004, inpatient CAH services furnished by a CAH as specified in § 413.70. Payment on a PIP basis is described in § 413.70(d).

* * * * *

(4) [Reserved]

* * * * *

■ 4. Section 413.70 is amended by—

- A. Revising the heading of paragraph (a) and paragraph (a)(1).
- B. Adding a new paragraph (a)(4).
- C. Revising paragraph (b)(2)(i).
- D. Revising paragraph (b)(2)(iii).
- E. Revising the heading of paragraph (b)(3) and the contents of paragraphs (b)(3)(i) and (b)(3)(ii).
- F. Revising paragraph (b)(4).
- G. Adding a new paragraph (d).
- H. Adding a new paragraph (e).

The revisions and additions read as follows:

§ 413.70 Payment for services of a CAH.

(a) *Payment for inpatient services furnished by a CAH (other than services of distinct part units).* (1) Effective for cost reporting periods beginning on or after January 1, 2004, payment for inpatient services of a CAH, other than services of a distinct part unit of the CAH, is 101 percent of the reasonable costs of the CAH in providing CAH services to its inpatients, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in this part and in Part 415 of this chapter, except that the following payment principles are excluded when determining payment for CAH inpatient services:

- (i) Lesser of cost or charges;
- (ii) Ceilings on hospital operating costs;
- (iii) Reasonable compensation equivalent (RCE) limits for physician services to providers; and
- (iv) The payment window provisions for preadmission services, specified in § 412.2(c)(5) of this subchapter and § 413.40(c)(2).

* * * * *

(4) Payment for inpatient services of distinct part psychiatric or

rehabilitation units is described in paragraph (e) of this section.

(b) *Payment for outpatient services furnished by CAH.*

* * * * *

(2) *Reasonable costs for facility services.* (i) Effective for cost reporting periods beginning on or after January 1, 2004, payment for outpatient services of a CAH is 101 percent of the reasonable costs of the CAH in providing CAH services to its outpatients, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in this part and in Part 415 of this chapter, except that the following payment principles are excluded when determining payment for CAH outpatient services:

- (A) Lesser of cost or charges; and
- (B) RCE limits.

(iii) Payment for outpatient clinical diagnostic laboratory tests is not subject to the Medicare Part B deductible and coinsurance amounts. Payment to a CAH for clinical diagnostic laboratory tests will be made at 101 percent of reasonable cost under this section only if the individuals are outpatients of the CAH, as defined in § 410.2 of this chapter, and are physically present in the CAH, at the time the specimens are collected. Clinical diagnostic laboratory tests performed for persons who are not physically present when the specimens are collected will be made in accordance with the provisions of sections 1833(a)(1)(D) and 1833(a)(2)(D) of the Social Security Act.

* * * * *

(3) *Election to be paid 101 percent of reasonable costs for facility services plus fee schedule for professional services.*

(i) A CAH may elect to be paid for outpatient services in any cost reporting period beginning on or after July 1, 2004 under the method described in paragraphs (b)(3)(ii) and (b)(3)(iii) of this section.

(A) The election must be made in writing, made on an annual basis, and delivered to the fiscal intermediary servicing the CAH at least 30 days before the start of the cost reporting period for which the election is made.

(B) An election of this payment method, once made for a cost reporting period, remains in effect for all of that period and, effective for cost reporting periods beginning on or after July 1, 2004, applies to all services furnished to outpatients during that period by a physician or other practitioner who has reassigned his or her rights to bill for those services to the CAH in accordance with 42 CFR part 424, Subpart F of this

chapter. If a physician or other practitioner does not reassign his or her billing rights to the CAH in accordance with 42 CFR part 424, payment for the physician's or practitioner's services to CAH outpatients will be made on a fee schedule or other applicable basis as specified in Subpart B of part 414 of this subchapter.

(C) In the case of a CAH that made an election under this section before November 1, 2003, for a cost reporting period beginning before December 1, 2003, the rules in paragraph (b)(3)(i)(B) of this section are applicable to cost reporting periods beginning on or after July 1, 2001.

(D) An election made under paragraph (b)(3)(i)(B) or paragraph (b)(3)(i)(C) of this section is effective only for a period for which it was made and does not apply to an election that was withdrawn or revoked prior to the start of the cost reporting period for which it was made.

(ii) If the CAH elects payment under this method, payment to the CAH for each outpatient visit will be the sum of the following:

(A) For facility services not including any services for which payment may be made under paragraph (b)(3)(ii)(B) of this section, 101 percent of the reasonable costs of the services as determined under paragraph (b)(2)(i) of this section; and

(B) For professional services that are furnished by a physician or other practitioner who has reassigned his or her rights to bill for those services to the CAH in accordance with Part 424, Subpart F of this chapter, and that would otherwise be payable to the physician or other practitioner if the rights to bill for them had not been reassigned, 115 percent of the amounts that otherwise would be paid for the service if the CAH had not elected payment under this method.

* * * * *

(4) *Costs of certain emergency room on-call providers.* (i) Effective for cost reporting periods beginning on or after October 1, 2001, the reasonable costs of outpatient CAH services under paragraph (b) of this section may include amounts for reasonable compensation and related costs for an emergency room physician who is on call but who is not present on the premises of the CAH involved, is not otherwise furnishing physicians' services, and is not on call at any other provider or facility. Effective for costs incurred for services furnished on or after January 1, 2005, the payment amount of 101 percent of the reasonable costs of outpatient CAH services may also include amounts for reasonable

compensation and related costs for the following emergency room providers who are on call but who are not present on the premises of the CAH involved, are not otherwise furnishing physicians' services, and are not on call at any other provider or facility: physician assistants, nurse practitioners, and clinical nurse specialists.

(ii) For purposes of this paragraph (b)(4)—

(A) "Amounts for reasonable compensation and related costs" means all allowable costs of compensating emergency room physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on call to the extent that the costs are found to be reasonable under the rules specified in paragraph (b)(2) of this section and the applicable sections of Part 413. Costs of compensating these specified medical emergency room staff are allowable only if the costs are incurred under written contracts that require the physician, physician assistant, nurse practitioner, or clinical nurse specialist to come to the CAH when the physician's or other practitioner's presence is medically required.

(B) Effective for costs incurred on or after January 1, 2005, an "emergency room physician, physician assistant, nurse practitioner, or clinical nurse specialist who is on call" means a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care who is immediately available by telephone or radio contact, and is available onsite within the timeframes specified in § 485.618(d) of this chapter.

* * * * *

(d) *Periodic interim payments.* Subject to the provisions of § 413.64(h), a CAH receiving payments under this section may elect to receive periodic interim payments (PIP) for Part A inpatient CAH services, effective for payments made on or after July 1, 2004. Payment is made biweekly under the PIP method unless the CAH requests a longer fixed interval (not to exceed one month) between payments. The biweekly interim payment amount is based on the total estimated Medicare payment (after estimated beneficiary deductibles and coinsurance) for the cost reporting period. Each payment is made 2 weeks after the end of a biweekly period of service, as described in § 413.64(h)(6). These PIP provisions are further described in § 413.64(h)(6). Under certain circumstances that are described in § 413.64(g), a CAH that is not receiving PIP may request an accelerated payment.

(e) *Payment for services of distinct part psychiatric and rehabilitation units of CAHs.* Payment for inpatient services of distinct part psychiatric units of CAHs is made in accordance with regulations governing IPPS-excluded psychiatric units of hospitals at § 413.40. Payment for inpatient services of distinct part rehabilitation units of CAHs is made in accordance with regulations governing the IRF PPS at Subpart P (§§ 412.600 through 412.632) of Part 412 of this subchapter.

§ 413.80 [Redesignated as § 413.89]

■ 5. Section 413.80 is redesignated as § 413.89.

§ 413.85 [Amended]

■ 6. In § 413.85—

■ A. Under paragraph (b)(2), the cross-reference “§ 413.86” is removed and the cross-reference “§§ 413.75 through 413.83” is added in its place.

■ B. Under paragraph (c)(3), under the definition “Redistribution of costs,” the cross-reference “§ 413.86” is removed and “§ 413.75 through 413.83” is added in its place.

§ 413.86 [Removed] and Subpart F [Amended]

■ 7. Section 413.86 is removed and §§ 413.75 through 413.83 are added under Subpart F to read as follows:

Subpart F—Specific Categories of Costs

Sec.

413.75 Direct GME payments: General requirements.

413.76 Direct GME payments: Calculation of payments for GME costs.

413.77 Direct GME payments: Determination of per resident amounts.

413.78 Direct GME payments: Determination of the total number of FTE residents.

413.79 Direct GME payments: Determination of the weighted number of FTE residents.

413.80 Direct GME payments: Determination of weighting factors for foreign medical graduates.

413.81 Direct GME payments: Application of community support and redistribution of costs in determining FTE resident counts.

413.82 Direct GME payments: Special rules for States that formerly had a waiver from Medicare reimbursement principles.

413.83 Direct GME payments: Adjustment of a hospital's target amount or prospective payment hospital-specific rate.

Subpart F—Specific Categories of Costs

§ 413.75 Direct GME payments: General requirements.

(a) *Statutory basis and scope*— (1) *Basis.* This section and §§ 413.76

through 413.83 implement section 1886(h) of the Act by establishing the methodology for Medicare payment of the cost of direct graduate medical educational activities.

(2) *Scope.* This section and §§ 413.76 through 413.83 apply to Medicare payments to hospitals and hospital-based providers for the costs of approved residency programs in medicine, osteopathy, dentistry, and podiatry for cost reporting periods beginning on or after July 1, 1985.

(b) *Definitions.* For purposes of this section and §§ 413.76 through 413.83, the following definitions apply:

“*All or substantially all of the costs for the training program in the nonhospital setting*” means the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct graduate medical education (GME).

Approved geriatric program means a fellowship program of one or more years in length that is approved by one of the national organizations listed in § 415.152 of this chapter under that respective organization's criteria for geriatric fellowship programs.

Approved medical residency program means a program that meets one of the following criteria:

(1) Is approved by one of the national organizations listed in § 415.152 of this chapter.

(2) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(i) The Directory of Graduate Medical Education Programs published by the American Medical Association, and available from American Medical Association, Department of Directories and Publications, 515 North State Street, Chicago, Illinois 60610; or

(ii) The Annual Report and Reference Handbook published by the American Board of Medical Specialties, and available from American Board of Medical Specialties, One Rotary Center, Suite 805, Evanston, Illinois 60201.

(3) Is approved by the Accreditation Council for Graduate Medical Education (ACGME) as a fellowship program in geriatric medicine.

(4) Is a program that would be accredited except for the accrediting agency's reliance upon an accreditation standard that requires an entity to perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether the standard provides exceptions or exemptions.

Base period means a cost reporting period that began on or after October 1, 1983 but before October 1, 1984.

Community support means funding that is provided by the community and generally includes all non-Medicare sources of funding (other than payments made for furnishing services to individual patients), including State and local government appropriations.

Community support does not include grants, gifts, and endowments of the kind that are not to be offset in accordance with section 1134 of the Act.

CPI-U stands for the Consumer Price Index for All Urban Consumers as compiled by the Bureau of Labor Statistics.

Foreign medical graduate means a resident who is not a graduate of a medical, osteopathy, dental, or podiatry school, respectively, accredited or approved as meeting the standards necessary for accreditation by one of the following organizations:

(1) The Liaison Committee on Medical Education of the American Medical Association.

(2) The American Osteopathic Association.

(3) The Commission on Dental Accreditation.

(4) The Council on Podiatric Medical Education.

FMGEMS stands for the Foreign Medical Graduate Examination in the Medical Sciences (Part I and Part II).

FTE stands for full-time equivalent.

GME stands for graduate medical education.

Medicare GME affiliated group means—

(1) Two or more hospitals that are located in the same urban or rural area (as those terms are defined in § 412.62(f) of this subchapter) or in a contiguous area and meet the rotation requirements in § 413.79(g)(2).

(2) Two or more hospitals that are not located in the same or in a contiguous urban or rural area, but meet the rotation requirement in § 413.79(g)(2), and are jointly listed—

(i) As the sponsor, primary clinical site, or major participating institution for one or more programs as these terms are used in the most current publication of the *Graduate Medical Education Directory*; or

(ii) As the sponsor or is listed under “affiliations and outside rotations” for one or more programs in operation in *Opportunities, Directory of Osteopathic Postdoctoral Education Programs*.

(3) Two or more hospitals that are under common ownership and, effective for all Medicare GME affiliation agreements beginning July 1, 2003, meet the rotation requirement in § 413.79(g)(2).

Medicare GME affiliation agreement means a written, signed, and dated agreement by responsible representatives of each respective hospital in a Medicare GME affiliated group, as defined in this section, that specifies—

(1) The term of the Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year;

(2) Each participating hospital's direct and indirect GME FTE caps in effect prior to the Medicare GME affiliation;

(3) The total adjustment to each hospital's FTE caps in each year that the Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect FTE caps that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect FTE caps of at least the same amount;

(4) The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's FTE caps (in accordance with paragraph (3) of this definition); and

(5) The names of the participating hospitals and their Medicare provider numbers.

Medicare patient load means, with respect to a hospital's cost reporting period, the total number of hospital inpatient days during the cost reporting period that are attributable to patients for whom payment is made under Medicare Part A divided by total hospital inpatient days. In calculating inpatient days, inpatient days in any distinct part of the hospital furnishing a hospital level of care are included and nursery days are excluded.

Primary care resident is a resident enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine or osteopathic general practice.

Redistribution of costs occurs when a hospital counts FTE residents in medical residency programs and the costs of the program had previously been incurred by an educational institution.

Resident means an intern, resident, or fellow who participates in an approved medical residency program, including

programs in osteopathy, dentistry, and podiatry, as required in order to become certified by the appropriate specialty board.

Rural track FTE limitation means the maximum number of residents (as specified in § 413.79(l)) training in a rural track residency program that an urban hospital may include in its FTE count and that is in addition to the number of FTE residents already included in the hospital's FTE cap.

Rural track or integrated rural track means an approved medical residency training program established by an urban hospital in which residents train for a portion of the program at the urban hospital and then rotate for a portion of the program to a rural hospital(s) or a rural nonhospital site(s).

Shared rotational arrangement means a residency training program under which a resident(s) participates in training at two or more hospitals in that program.

(c) *Payment for GME costs—General rule.* Beginning with cost reporting periods starting on or after July 1, 1985, hospitals, including hospital-based providers, are paid for the costs of approved GME programs as described in §§ 413.76 through 413.83.

(d) *Documentation requirements.* To include a resident in the FTE count for a particular cost reporting period, the hospital must furnish the following information. The information must be certified by an official of the hospital and, if different, an official responsible for administering the residency program.

(1) The name and social security number of the resident.

(2) The type of residency program in which the individual participates and the number of years the resident has completed in all types of residency programs.

(3) The dates the resident is assigned to the hospital and any hospital-based providers.

(4) The dates the resident is assigned to other hospitals, or other freestanding providers, and any nonprovider setting during the cost reporting period, if any.

(5) The name of the medical, osteopathic, dental, or podiatric school from which the resident graduated and the date of graduation.

(6) If the resident is an FMG, documentation concerning whether the resident has satisfied the requirements of this section.

(7) The name of the employer paying the resident's salary.

§ 413.76 Direct GME payments: Calculation of payments for GME costs.

A hospital's Medicare payment for the costs of an approved residency program is calculated as follows:

(a) *Step one.* The hospital's updated per resident amount (as determined under § 413.77) is multiplied by the actual number of FTE residents (as determined under § 413.79). This result is the aggregate approved amount for the cost reporting period.

(b) *Step two.* The product derived in step one is multiplied by the hospital's Medicare patient load.

(c) *Step three.* For portions of cost reporting periods occurring on or after January 1, 1998, the product derived in step one is multiplied by the proportion of the hospital's inpatient days attributable to individuals who are enrolled under a risk-sharing contract with an eligible organization under section 1876 of the Act and who are entitled to Medicare Part A or with a Medicare+Choice organization under Title XVIII, Part C of the Act. This amount is multiplied by an applicable payment percentage equal to—

- (1) 20 percent for 1998;
- (2) 40 percent for 1999;
- (3) 60 percent in 2000;
- (4) 80 percent in 2001; and
- (5) 100 percent in 2002 and subsequent years.

(d) *Step four.* Effective for portions of cost reporting periods occurring on or after January 1, 2000, the product derived from step three is reduced by a percentage equal to the ratio of the Medicare+Choice nursing and allied health payment "pool" for the current calendar year as described at § 413.87(f), to the projected total Medicare+Choice direct GME payments made to all hospitals for the current calendar year.

(e) *Step five.* (1) For portions of cost reporting periods beginning on or after January 1, 1998 and before January 1, 2000, add the results of steps two and three.

(2) Effective for portions of cost reporting periods beginning on or after January 1, 2000, add the results of steps two and four.

(f) *Step six.* The product derived in step two is apportioned between Part A and Part B of Medicare based on the ratio of Medicare's share of reasonable costs excluding GME costs attributable to each part as determined through the Medicare cost report.

§ 413.77 Direct GME payments: Determination of per resident amounts.

(a) *Per resident amount for the base period—*(1) Except as provided in paragraph (d) of this section, the intermediary determines a base-period

per resident amount for each hospital as follows:

(i) Determine the allowable GME costs for the cost reporting period beginning on or after October 1, 1983 but before October 1, 1984. In determining these costs, GME costs allocated to the nursery cost center, research and other nonreimbursable cost centers, and hospital-based providers that are not participating in Medicare are excluded and GME costs allocated to distinct-part hospital units and hospital-based providers that participate in Medicare are included.

(ii) Divide the costs calculated in paragraph (a)(1)(i) of this section by the average number of FTE residents working in all areas of the hospital complex (including those areas whose costs were excluded under paragraph (a)(1)(i) of this section) for its cost reporting period beginning on or after October 1, 1983 but before October 1, 1984.

(2) In determining the base-period per resident amount under paragraph (a)(1) of this section, the intermediary—

(i) Verifies the hospital's base-period GME costs and the hospital's average number of FTE residents;

(ii) Excludes from the base-period GME costs any nonallowable or misclassified costs, including those previously allowed under § 412.113(b)(3) of this chapter; and

(iii) Upon a hospital's request, includes GME costs that were misclassified as operating costs during the hospital's prospective payment base year and were not allowable under § 412.113(b)(3) of this chapter during the GME base period. These costs may be included only if the hospital requests an adjustment of its prospective payment hospital-specific rate or target amount as described in § 413.82(a) of this chapter.

(3) If the hospital's cost report for its GME base period is no longer subject to reopening under § 405.1885 of this chapter, the intermediary may modify the hospital's base-period costs solely for purposes of computing the per resident amount.

(4) If the intermediary modifies a hospital's base-period GME costs as described in paragraph (a)(2)(ii) of this section, the hospital may request an adjustment of its prospective payment hospital-specific rate or target amount as described in § 413.82(a) of this chapter.

(5) The intermediary notifies each hospital that either had direct GME costs or received indirect education payment in its cost reporting period beginning on or after October 1, 1984, and before October 1, 1985, of its base-period average per resident amount. A

hospital may appeal this amount within 180 days of the date of that notice.

(b) *Per resident amount for cost reporting periods beginning on or after July 1, 1985, and before July 1, 1986.* For cost reporting periods beginning on or after July 1, 1985, and before July 1, 1986, a hospital's base-period per resident amount is adjusted as follows:

(1) If a hospital's base period began on or after October 1, 1983, and before July 1, 1984, the amount is adjusted by the percentage change in the CPI-U that occurred between the hospital's base period and the first cost reporting period to which the provisions of this section apply. The adjusted amount is then increased by one percent.

(2) If a hospital's base period began on or after July 1, 1984 and before October 1, 1984, the amount is increased by one percent.

(c) *Per resident amount for cost reporting periods beginning on or after July 1, 1986.* Subject to the provisions of paragraph (d) of this section, for cost reporting periods beginning on or after July 1, 1986, a hospital's base-period per resident amount is adjusted as follows:

(1) Except as provided in paragraph (c)(2) of this section, each hospital's per resident amount for the previous cost reporting is adjusted by the projected change in the CPI-U for the 12-month cost reporting period. This adjustment is subject to revision during the settlement of the cost report to reflect actual changes in the CPI-U that occurred during the cost reporting period.

(2) For cost reporting periods beginning on or after October 1, 1993 through September 30, 1995, each hospital's per resident amount for the previous cost reporting period will not be adjusted for any resident FTEs who are not either a primary care resident or an obstetrics and gynecology resident.

(d) *Per resident amount for cost reporting periods beginning on or after October 1, 2000 and ending on or before September 30, 2013.* For cost reporting periods beginning on or after October 1, 2000 and ending on or before September 30, 2013, a hospital's per resident amount for each fiscal year is adjusted in accordance with the following provisions:

(1) *General provisions.* For purposes of this § 413.77—

(i) *Weighted average per resident amount.* The weighted average per resident amount is established as follows:

(A) Using data from hospitals' cost reporting periods ending during FY 1997, CMS calculates each hospital's single per resident amount by adding each hospital's primary care and nonprimary care per resident amounts,

weighted by its respective FTEs, and dividing by the sum of the FTEs for primary care and nonprimary care residents.

(B) Each hospital's single per resident amount calculated under paragraph (d)(1)(i)(A) of this section is standardized by the 1999 geographic adjustment factor for the physician fee schedule area (as determined under § 414.26 of this chapter) in which the hospital is located.

(C) CMS calculates an average of all hospitals' standardized per resident amounts that are determined under paragraph (d)(1)(i)(B) of this section. The resulting amount is the weighted average per resident amount.

(ii) *Primary care/obstetrics and gynecology and nonprimary care per resident amounts.* A hospital's per resident amount is an amount inclusive of any CPI-U adjustments that the hospital may have received since the hospital's base year, including any CPI-U adjustments the hospital may have received because the hospital trains primary care/obstetrics and gynecology residents and nonprimary care residents as specified under paragraph (c)(2) of this section.

(2) *Adjustment beginning in FY 2001 and ending in FY 2013.* For cost reporting periods beginning on or after October 1, 2000, and ending on or before September 30, 2013, a hospital's per resident amount is adjusted in accordance with paragraphs (d)(2)(i) through (d)(2)(iv) of this section, in that order:

(i) *Updating the weighted average per resident amount for inflation.* The weighted average per resident amount (as determined under paragraph (d)(1)(i) of this section) is updated by the estimated percentage increase in the CPI-U during the period beginning with the month that represents the midpoint of the cost reporting periods ending during FY 1997 (that is, October 1, 1996) and ending with the midpoint of the hospital's cost reporting period that begins in FY 2001.

(ii) *Adjusting for locality.* The updated weighted average per resident amount determined under paragraph (d)(2)(i) of this section (the national average per resident amount) is adjusted for the locality of each hospital by multiplying the national average per resident amount by the 1999 geographic adjustment factor for the physician fee schedule area in which each hospital is located, established in accordance with § 414.26 of this chapter.

(iii) *Determining necessary revisions to the per resident amount.* The locality-adjusted national average per resident amount, as calculated in accordance

with paragraph (d)(2)(ii) of this section, is compared to the hospital's per resident amount and is revised, if appropriate, according to the following three categories:

(A) *Floor.* (1) For cost reporting periods beginning on or after October 1, 2000, and before October 1, 2001, if the hospital's per resident amount would otherwise be less than 70 percent of the locality-adjusted national average per resident amount for FY 2001 (as determined under paragraph (d)(2)(ii) of this section), the per resident amount is equal to 70 percent of the locality-adjusted national average per resident amount for FY 2001.

(2) For cost reporting periods beginning on or after October 1, 2001, and before October 1, 2002, if the hospital's per resident amount would otherwise be less than 85 percent of the locality-adjusted national average per resident amount for FY 2002 (as determined under paragraph (d)(2)(ii) of this section), the per resident amount is equal to 85 percent of the locality-adjusted national average per resident amount for FY 2002.

(3) For subsequent cost reporting periods beginning on or after October 1, 2002, the hospital's per resident amount is updated using the methodology specified under paragraph (c)(1) of this section.

(B) *Ceiling.* If the hospital's per resident amount is greater than 140 percent of the locality-adjusted national average per resident amount, the per resident amount is adjusted as follows for FY 2001 through FY 2013:

(1) *FY 2001.* For cost reporting periods beginning on or after October 1, 2000 and on or before September 30, 2001, if the hospital's FY 2000 per resident amount exceeds 140 percent of the FY 2001 locality-adjusted national average per resident amount (as calculated under paragraph (d)(2)(ii) of this section), subject to the provision stated in paragraph (d)(2)(iii)(B)(5) of this section, the hospital's per resident amount is frozen at the FY 2000 per resident amount and is not updated for FY 2001 by the CPI-U factor.

(2) *FY 2002.* For cost reporting periods beginning on or after October 1, 2001, and on or before September 30, 2002, if the hospital's FY 2001 per resident amount exceeds 140 percent of the FY 2002 locality-adjusted national average per resident amount, subject to the provision stated in paragraph (d)(2)(iii)(B)(5) of this section, the hospital's per resident amount is frozen at the FY 2001 per resident amount and is not updated for FY 2002 by the CPI-U factor.

(3) *FY 2003.* For cost reporting periods beginning on or after October 1, 2002, and on or before September 30, 2003, if the hospital's per resident amount for the previous cost reporting period is greater than 140 percent of the locality-adjusted national average per resident amount for that same previous cost reporting period (for example, for cost reporting periods beginning in FY 2003, compare the hospital's per resident amount from the FY 2002 cost report to the hospital's locality-adjusted national average per resident amount from FY 2002), subject to the provision stated in paragraph (d)(2)(iii)(B)(5) of this section, the hospital's per resident amount is adjusted using the methodology specified in paragraph (c)(1) of this section, except that the CPI-U applied for a 12-month period is reduced (but not below zero) by 2 percentage points.

(4) *FY 2004 through FY 2013.* For cost reporting periods beginning on or after October 1, 2003, and on or before September 30, 2013, if the hospital's preceding year per resident amount exceeds 140 percent of the current year's locality-adjusted national average per resident amount (as calculated under paragraph (d)(2)(ii) of this section), subject to the provision stated in paragraph (d)(2)(iii)(B)(5) of this section, the hospital-specific per resident amount is frozen for the current year at the preceding year's hospital-specific per resident amount and is not updated by the CPI-U factor.

(5) *General rule for hospitals that exceed the ceiling.* For cost reporting periods beginning on or after October 1, 2000, and on or before September 30, 2013, if a hospital's per resident amount exceeds 140 percent of the hospital's locality-adjusted national average per resident amount and it is adjusted under any of the criteria under paragraphs (d)(2)(iii)(B)(1) through (d)(2)(iii)(B)(3) of this section, the current year per resident amount cannot be reduced below 140 percent of the locality-adjusted national average per resident amount.

(C) *Per resident amounts greater than or equal to the floor and less than or equal to the ceiling.* For cost reporting periods beginning on or after October 1, 2000 and on or before September 30, 2013, if a hospital's per resident amount is greater than or equal to 70 percent and less than or equal to 140 percent of the hospital's locality-adjusted national average per resident amount for each respective fiscal year, the hospital's per resident amount is updated using the methodology specified in paragraph (c)(1) of this section.

(e) *Exceptions—*(1) *Base period for certain hospitals.* If a hospital did not have any approved medical residency training programs or did not participate in Medicare during the base period, but either condition changes in a cost reporting period beginning on or after July 1, 1985, the intermediary establishes a per resident amount for the hospital using the information from the first cost reporting period during which the hospital participates in Medicare and the residents are on duty during the first month of that period. Any GME program costs incurred by the hospital before that cost reporting period are reimbursed on a reasonable cost basis. The per resident amount is based on the lower of the amount specified in paragraph (e)(1)(i) or in paragraph (e)(1)(ii) of this section, subject to the provisions of paragraph (e)(1)(iii) of this section.

(i) The hospital's actual costs, incurred in connection with the GME program for the hospital's first cost reporting period in which residents were on duty during the first month of the cost reporting period.

(ii) Except as specified in paragraph (e)(1)(iii) of this section—

(A) For base periods that begin before October 1, 2002, the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area, as that term is used in the prospective payment system under Part 412 of this chapter.

(B) For base periods beginning on or after October 1, 2002, the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

(iii) If, under paragraph (e)(1)(ii)(A) or paragraph (e)(1)(ii)(B) of this section, there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in § 412.62(f)(1)(i) of this chapter.

(2) *Short or long base-period cost reporting periods.* If a hospital's base-period cost reporting period reflects GME costs for a period that is shorter than 50 weeks or longer than 54 weeks, the intermediary converts the allowable costs for the base period into a daily

figure. The daily figure is then multiplied by 365 or 366, as appropriate, to derive the approved per resident amount for a 12-month base-period cost reporting period. If a hospital has two cost reporting periods beginning in the base period, the later period serves as the base-period cost reporting period.

(3) *Short or long cost reporting periods beginning on or after July 1, 1985.* If a hospital's cost reporting period is shorter than 50 weeks or longer than 54 weeks, the hospital's intermediary should contact CMS Central Office to receive a special CPI-U adjustment factor.

(f) *Residency match.* Effective for cost reporting periods beginning on or after October 1, 2004, with respect to a resident who matches simultaneously for a first year of training in a primary care specialty, and for an additional year(s) of training in a nonprimary care specialty, the per resident amount that is used to determine direct GME payment with respect to that resident is the nonprimary care per resident amount for the first year of training in the primary care specialty and for the duration of the resident's training in the nonprimary care specialty.

(g) *Special use of locality-adjusted national average per resident amount.* Effective for portions of cost reporting periods beginning on or after July 1, 2005, for a hospital that counts additional residents as a result of an increase in its FTE resident cap under § 413.79(c)(4) direct GME payments attributable to those additional FTE residents are calculated using the locality-adjusted national average per resident amount, as determined under paragraph (d)(2)(ii) of this section. The hospital will receive direct GME payments based on the sum of the following two direct GME calculations:

(1) A calculation using the per resident amount(s) as determined under paragraph (d) of this section and the hospital's number of FTE residents that is not attributable to an FTE resident cap increase under § 413.79(c)(4); and

(2) A calculation using the locality-adjusted national average per resident amount, as determined under paragraph (d)(2)(ii) of this section, inflated to the hospital's current cost reporting period, and the hospital's number of FTE residents that is attributable to the increase in the hospital's FTE resident cap under § 413.79(c)(4).

§ 413.78 Direct GME payments: Determination of the total number of FTE residents.

Subject to the weighting factors in §§ 413.79 and 413.80, and subject to the

provisions of § 413.81, the count of FTE residents is determined as follows:

(a) Residents in an approved program working in all areas of the hospital complex may be counted.

(b) No individual may be counted as more than one FTE. A hospital cannot claim the time spent by residents training at another hospital. Except as provided in paragraphs (c), (d), and (e) of this section, if a resident spends time in more than one hospital or in a nonprovider setting, the resident counts as partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of allowable time worked compared to the total time necessary to fill a full-time internship or residency slot.

(c) On or after July 1, 1987, and for portions of cost reporting periods occurring before January 1, 1999, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs is not excluded in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time in patient care activities.

(2) There is a written agreement between the hospital and the outside entity that states that the resident's compensation for training time spent outside of the hospital setting is to be paid by the hospital.

(d) For portions of cost reporting periods occurring on or after January 1, 1999, and before October 1, 2004, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time in patient care activities.

(2) The written agreement between the hospital and the nonhospital site must indicate that the hospital will incur the cost of the resident's salary and fringe benefits while the resident is training in the nonhospital site and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities.

(3) The hospital must incur all or substantially all of the costs for the training program in the nonhospital

setting in accordance with the definition in § 413.75(b).

(4) The hospital is subject to the principles of community support and redistribution of costs as specified in § 413.81.

(e) For portions of cost reporting periods occurring on or after October 1, 2004, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time in patient care activities.

(2) The hospital must incur all or substantially all of the costs of the training program in a nonhospital setting(s) (in accordance with the definition under § 413.75(b)).

(3) The hospital must comply with one of the following:

(i) The hospital must pay all or substantially all of the costs of the training program in a nonhospital setting(s) attributable to training that occurs during a month by the end of the third month following the month in which the training in the nonhospital site occurred; or

(ii) There is a written agreement between the hospital and the nonhospital site that states that the hospital will incur the cost of the resident's salary and fringe benefits while the resident is training in the nonhospital site and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities.

(4) The hospital is subject to the principles of community support and redistribution of costs as specified in § 413.81.

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

Subject to the provisions in § 413.80, CMS determines a hospital's number of FTE residents by applying a weighting factor to each resident and then summing the resulting numbers that represent each resident. The weighting factor is determined as follows:

(a) *Initial residency period.* Generally, for purposes of this section, effective July 1, 1995, an initial residency period is defined as the minimum number of years required for board eligibility.

(1) Prior to July 1, 1995, the initial residency period equals the minimum

number of years required for board eligibility in a specialty or subspecialty plus 1 year. An initial residency period may not exceed 5 years in order to be counted toward determining FTE status except in the case of a resident in an approved geriatric program whose initial residency period may last up to 2 additional years.

(2) Effective October 1, 2003, for a resident who trains in an approved geriatric program that requires the residents to complete 2 years of training to initially become board eligible in the geriatric specialty, the 2 years spent in the geriatrics program are treated as part of the resident's initial residency period.

(3) Effective July 1, 2000, for residency programs that began before, on, or after November 29, 1999, the period of board eligibility and the initial residency period for a resident in an approved child neurology program is the period of board eligibility for pediatrics plus 2 years.

(4) Effective August 10, 1993, residents or fellows in an approved preventive medicine residency or fellowship program also may be counted as a full FTE resident for up to 2 additional years beyond the initial residency period limitations.

(5) For combined residency programs, an initial residency period is defined as the time required for individual certification in the longer of the programs. If the resident is enrolled in a combined medical residency training program in which all of the individual programs (that are combined) are for training primary care residents (as defined in § 413.75(b)) or obstetrics and gynecology residents, the initial residency period is the time required for individual certification in the longer of the programs plus 1 year.

(6) For residency programs other than those specified in paragraphs (a)(2) through (a)(4) of this section, the initial residency period is the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training, as specified in the most recently published edition of the Graduate Medical Education Directory.

(7) For residency programs in osteopathy, dentistry, and podiatry, the minimum requirement for certification in a specialty or subspecialty is the minimum number of years of formal training necessary to satisfy the requirements of the appropriate approving body listed in § 415.152 of this chapter.

(8) For residency programs in geriatric medicine, accredited by the appropriate approving body listed in § 415.152 of

this chapter, these programs are considered approved programs on the later of—

(i) The starting date of the program within a hospital; or

(ii) The hospital's cost reporting periods beginning on or after July 1, 1985.

(9) The time spent in residency programs that do not lead to certification in a specialty or subspecialty, but that otherwise meet the definition of approved programs, as described in § 413.75(b), is counted toward the initial residency period limitation.

(10) Effective for cost reporting periods beginning on or after October 1, 2004, if a hospital can document that a resident simultaneously matched for one year of training in a particular specialty program, and for a subsequent year(s) of training in a different specialty program, the resident's initial residency period will be determined based on the period of board eligibility associated with the program for which the resident matched for the subsequent year(s) of training.

(b) *Weighting factor*—(1) If the resident is in an initial residency period, the weighting factor is one.

(2) If the resident is not in an initial residency period, the weighting factor is 1.00 during the period beginning on or after July 1, 1985 and before July 1, 1986, .75 during the period beginning on or after July 1, 1986 and before July 1, 1987, and .50 thereafter without regard to the hospital's cost reporting period.

(c) *Unweighted FTE counts.*

(1) *Definitions.* As used in this paragraph (c):

(i) *Otherwise applicable resident cap* refers to a hospital's FTE resident cap that is determined for a particular cost reporting period under paragraph (c)(2) of this section.

(ii) *Reference resident level* refers to a hospital's resident level in the applicable reference period specified under paragraph (c)(3)(ii) of this section.

(iii) *Resident level* refers to the number of unweighted allopathic and osteopathic FTE residents who are training in a hospital in a particular cost reporting period.

(2) *Determination of the FTE resident cap.* Subject to the provisions of paragraphs (c)(3) and (c)(4) of this section and § 413.81, for purposes of determining direct GME payment—

(i) For cost reporting periods beginning on or after October 1, 1997, a hospital's resident level may not exceed the hospital's unweighted FTE count (or, effective for cost reporting periods beginning on or after April 1, 2000, 130

percent of the unweighted FTE count for a hospital located in a rural area) for these residents for the most recent cost reporting period ending on or before December 31, 1996.

(ii) If a hospital's number of FTE residents in a cost reporting period beginning on or after October 1, 1997, and before October 1, 2001, exceeds the limit described in this section, the hospital's total weighted FTE count (before application of the limit) will be reduced in the same proportion that the number of FTE residents for that cost reporting period exceeds the number of FTE residents for the most recent cost reporting period ending on or before December 31, 1996.

(iii) If the hospital's number of FTE residents in a cost reporting period beginning on or after October 1, 2001 exceeds the limit described in this section, the hospital's weighted FTE count (before application of the limit) for primary care and obstetrics and gynecology residents and nonprimary care residents, respectively, will be reduced in the same proportion that the number of FTE residents for that cost reporting period exceeds the number of FTE residents for the most recent cost reporting period ending on or before December 31, 1996.

(iv) Hospitals that are part of the same Medicare GME affiliated group (as described under § 413.75(b)) may elect to apply the limit on an aggregate basis as described under paragraph (f) of this section.

(v) The fiscal intermediary may make appropriate modifications to apply the provisions of this paragraph (c) of this section based on the equivalent of a 12-month cost reporting period.

(3) *Determination of the reduction to the FTE resident cap due to unused FTE resident slots.* If a hospital's reference resident level is less than its otherwise applicable FTE resident cap as determined under paragraph (c)(2) of this section or paragraph (e) of this section in the reference cost reporting period (as described under paragraph (c)(3)(ii) of this section), for portions of cost reporting periods beginning on or after July 1, 2005, the hospital's otherwise applicable FTE resident cap is reduced by 75 percent of the difference between the otherwise applicable FTE resident cap and the reference resident level. Under this provision—

(i) *Exemption for certain rural hospitals.* A rural hospital, as defined at § 412.62(f)(iii), with less than 250 beds (as determined at § 412.105(b)) in its most recent cost reporting period ending on or before September 30, 2002, is exempt from any reduction to the otherwise applicable FTE resident cap

limit under paragraph (c)(3) of this section.

(ii) *Reference cost reporting periods.*

(A) To determine a hospital's reference resident level, CMS uses one of the following periods:

(1) A hospital's most recent cost reporting period ending on or before September 30, 2002, for which a cost report has been settled or if the cost report has not been settled, the as-submitted cost report (subject to audit); or

(2) A hospital's cost reporting period that includes July 1, 2003 if the hospital submits a timely request to CMS to increase its resident level due to an expansion of an existing program and that expansion is not reflected on the hospital's most recent settled cost report. An expansion of an existing program means that, except for expansions due to newly approved programs under paragraph (c)(3)(ii)(A)(3) of this section, the number of unweighted allopathic and osteopathic FTE residents in any cost reporting period after the hospital's most recent settled cost report, up to and including the hospital's cost report that includes July 1, 2003, is greater than the number of unweighted allopathic and osteopathic FTE residents in programs that were existing at that hospital during the hospital's most recent settled cost report.

(3) A hospital may submit a timely request that CMS adjust the resident level for purposes of determining any reduction under paragraph (c)(3) of this section for the following purposes:

(i) In the hospital's reference cost reporting period under paragraph (c)(3)(ii)(A)(1) of this section, to include the number of FTE residents for which a new program was accredited by the appropriate allopathic or osteopathic accrediting body (listed under § 415.152 of this chapter) before January 1, 2002, if the program was not in operation during the reference cost reporting period under paragraph (c)(3)(ii)(A)(1); or

(ii) In the hospital's reference cost reporting period under paragraph (c)(3)(ii)(A)(2) of this section, to include the number of FTE residents for which a new program was accredited by the appropriate allopathic or osteopathic accrediting body (listed under § 415.152 of this chapter) before January 1, 2002, if the program was not in operation during the cost reporting period that includes July 1, 2003, and if the hospital also qualifies to use its cost report under paragraph (c)(3)(ii)(A)(2) of this section due to an expansion of an existing program.

(B) If the cost report that is used to determine a hospital's otherwise applicable FTE resident cap in the reference period is not equal to 12 months, the fiscal intermediary may make appropriate modifications to apply the provisions of paragraph (c)(3)(i)(A) of this section based on the equivalent of a 12-month cost reporting period.

(iii) If the new program described in paragraph (c)(3)(ii)(A)(3)(i) or paragraph (c)(3)(ii)(A)(ii) was accredited for a range of residents, the hospital may request that its reference resident level in its applicable reference cost reporting period under paragraph (c)(3)(ii)(A)(1) or (c)(3)(ii)(A)(2) of this section be adjusted to reflect the maximum number of accredited slots applicable to that hospital.

(iv) *Consideration of Medicare GME affiliated group agreements.* For hospitals that are members of the same affiliated group for the program year July 1, 2003 through June 30, 2004, in determining whether a hospital's otherwise applicable resident FTE resident cap is reduced under paragraph (c)(3) of this section, CMS treats these hospitals as a group. Using information from the hospitals' cost reports that include July 1, 2003, if the hospitals' aggregate FTE resident counts are equal to or greater than the aggregate otherwise applicable FTE resident cap for the affiliated group, then no reductions are made under paragraph (c)(3) of this section to the hospitals' otherwise applicable FTE resident caps. If the hospitals' aggregate FTE resident count is below the aggregate otherwise applicable FTE resident cap, then CMS determines on a hospital-specific basis whether the individual hospital's FTE resident count is less than its otherwise applicable resident cap (as adjusted by affiliation agreement(s)) in the hospital's cost report that includes July 1, 2003. If the hospital's FTE resident count is in excess of its otherwise applicable FTE resident cap, the hospital will not have its otherwise applicable FTE resident cap reduced under paragraph (c)(3) of this section. Hospitals in the affiliated group that have FTE resident counts below their individual otherwise applicable FTE resident caps are subject to a pro rata reduction in their otherwise applicable FTE resident caps that is equal, in total, to 75 percent of the difference between the aggregate FTE cap and the aggregate FTE count for the affiliated group. The pro rata reduction to the individual hospital's otherwise applicable resident cap is calculated by dividing the difference between the hospital's individual otherwise applicable FTE resident cap and the

hospital's FTE resident count by the total amount by which all of the hospitals' individual FTE resident counts are below their otherwise applicable FTE resident caps, multiplying the quotient by the difference between the aggregate FTE resident cap and the aggregate FTE resident counts for the affiliated group, and multiplying that result by 75 percent.

(4) *Determination of an increase in otherwise applicable resident cap.* For portions of cost reporting periods beginning on or after July 1, 2005, a hospital may receive an increase in its otherwise applicable FTE resident cap up to an additional 25 FTEs (as determined by CMS) if the hospital meets the requirements and qualifying criteria of section 1886(h)(7) of the Act and implementing instructions issued by CMS and if the hospital submits an application to CMS within the timeframe specified by CMS.

(5) *Special rules for hospitals that participate in demonstration projects or voluntary resident reduction plans.*

(i) If a hospital was participating in a demonstration project under section 402 of Public Law 90-248 or the voluntary reduction plan under § 413.88 for a greater period of time than the time period that elapsed since it withdrew from participation (or if it completed its participation) in the demonstration program or the voluntary reduction plan, for purposes of determining a possible reduction to the FTE resident caps under paragraph (c)(3) of this section, CMS compares the higher of the hospital's base number of residents (after subtracting any dental and podiatric FTE residents) or the hospital's reference resident level to the hospital's otherwise applicable resident cap determined under paragraph (c)(2) of this section.

(ii) If a hospital participated in the demonstration project or the voluntary resident reduction plan for a period of time that is less than the time that elapsed since it withdraw from participation in the demonstration project or the voluntary reduction plan, the special rules in paragraph (c)(5)(i) do not apply, and the hospital is subject to the procedures applicable to all other hospitals for determining possible reductions to the FTE resident caps under paragraph (c)(3) of this section.

(iii) CMS will not redistribute residency positions that are attributable to a hospital's participation in a demonstration project or a voluntary resident reduction plan to other hospitals that seek to increase their FTE resident caps under paragraph (c)(4) of this section.

(d) *Weighted FTE counts.* Subject to the provisions of § 413.81, for purposes of determining direct GME payment—

(1) For the hospital's first cost reporting period beginning on or after October 1, 1997, the hospital's weighted FTE count is equal to the average of the weighted FTE count for the payment year cost reporting period and the preceding cost reporting period.

(2) For cost reporting periods beginning on or after October 1, 1998, and before October 1, 2001, the hospital's weighted FTE count is equal to the average of the weighted FTE count for the payment year cost reporting period and the preceding two cost reporting periods.

(3) For cost reporting periods beginning on or after October 1, 2001, the hospital's weighted FTE count for primary care and obstetrics and gynecology residents is equal to the average of the weighted primary care and obstetrics and gynecology counts for the payment year cost reporting period and the preceding two cost reporting periods, and the hospital's weighted FTE count for nonprimary care residents is equal to the average of the weighted nonprimary care FTE counts for the payment year cost reporting period and the preceding two cost reporting periods.

(4) The fiscal intermediary may make appropriate modifications to apply the provisions of this paragraph (d) based on the equivalent of 12-month cost reporting periods.

(5) If a hospital qualifies for an adjustment to the limit established under paragraph (c)(2) of this section for new medical residency programs created under paragraph (e) of this section, the count of the residents participating in new medical residency training programs above the number included in the hospital's FTE count for the cost reporting period ending during calendar year 1996 is added after applying the averaging rules in this paragraph (d), for a period of years. Residents participating in new medical residency training programs are included in the hospital's FTE count before applying the averaging rules after the period of years has expired. For purposes of this paragraph (d), for each new program started, the period of years equals the minimum accredited length for each new program. The period of years begins when the first resident begins training in each new program.

(6) Subject to the provisions of paragraph (h) of this section, FTE residents that are displaced by the closure of either another hospital or another hospital's program are added to the FTE count after applying the

averaging rules in this paragraph (d), for the receiving hospital for the duration of the time that the displaced residents are training at the receiving hospital.

(7) Subject to the provisions under paragraph (k) of this section, effective for cost reporting periods beginning on or after April 1, 2000, FTE residents in a rural track program at an urban hospital are included in the urban hospital's rolling average calculation described in this paragraph (d).

(e) *New medical residency training programs.* If a hospital establishes a new medical residency training program as defined in paragraph (l) of this section on or after January 1, 1995, the hospital's FTE cap described under paragraph (c) of this section may be adjusted as follows:

(1) If a hospital had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it establishes a new medical residency training program on or after January 1, 1995, the hospital's unweighted FTE resident cap under paragraph (c) of this section may be adjusted based on the product of the highest number of residents in any program year during the third year of the first program's existence for all new residency training programs and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program. The adjustment to the cap may not exceed the number of accredited slots available to the hospital for the new program.

(i) If the residents are spending an entire program year (or years) at one hospital and the remainder of the program at another hospital, the adjustment to each respective hospital's cap is equal to the product of the highest number of residents in any program year during the third year of the first program's existence and the number of years the residents are training at each respective hospital.

(ii) Prior to the implementation of the hospital's adjustment to its FTE cap beginning with the fourth year of the hospital's residency program(s), the hospital's cap may be adjusted during each of the first 3 years of the hospital's new residency program using the actual number of residents participating in the new program. The adjustment may not exceed the number of accredited slots available to the hospital for each program year.

(iii) Except for rural hospitals, the cap will not be adjusted for new programs established more than 3 years after the first program begins training residents.

(iv) An urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is not permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap.

(v) A rural hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap.

(2) If a hospital had allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, the hospital's unweighted FTE cap may be adjusted for new medical residency training programs established on or after January 1, 1995 and on or before August 5, 1997. The adjustment to the hospital's FTE resident limit for the new program is based on the product of the highest number of residents in any program year during the third year of the newly established program and the number of years in which residents are expected to complete each program based on the minimum accredited length for the type of program.

(i) If the residents are spending an entire program year (or years) at one hospital and the remainder of the program at another hospital, the adjustment to each respective hospital's cap is equal to the product of the highest number of residents in any program year during the third year of the first program's existence and the number of years the residents are training at each respective hospital.

(ii) Prior to the implementation of the hospital's adjustment to its FTE cap beginning with the fourth year of the hospital's residency program, the hospital's cap may be adjusted during each of the first 3 years of the hospital's new residency program, using the actual number of residents in the new programs. The adjustment may not exceed the number of accredited slots available to the hospital for each program year.

(3) If a hospital with allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, is located in a rural area (or other hospitals located in rural areas that added residents under paragraph (e)(1) of this section), the hospital's unweighted FTE limit may be adjusted in the same manner described in paragraph (e)(2) of this section to reflect the increase for residents in the new medical residency training programs established after August 5, 1997. For these hospitals, the limit will be adjusted for additional new programs

but not for expansions of existing or previously existing programs.

(4) A hospital seeking an adjustment to the limit on its unweighted resident count policy must provide documentation to its fiscal intermediary justifying the adjustment.

(f) *Medicare GME affiliated group.* A hospital may receive a temporary adjustment to its FTE cap, which is subject to the averaging rules under paragraph (e)(3) of this section, to reflect residents added or subtracted because the hospital is participating in a Medicare GME affiliated group (as defined under § 413.75(b)). Under this provision—

(1) Each hospital in the Medicare GME affiliated group must submit the Medicare GME affiliation agreement, as defined under § 413.75(b) of this section, to the CMS fiscal intermediary servicing the hospital and send a copy to CMS's Central Office no later than July 1 of the residency program year during which the Medicare GME affiliation agreement will be in effect.

(2) Each hospital in the Medicare GME affiliated group must have a shared rotational arrangement, as defined in § 413.75(b), with at least one other hospital within the Medicare GME affiliated group, and all of the hospitals within the Medicare GME affiliated group must be connected by a series of such shared rotational arrangements.

(3) During the shared rotational arrangements under a Medicare GME affiliation agreement, as defined in § 413.75(b), more than one of the hospitals in the Medicare GME affiliated group must count the proportionate amount of the time spent by the resident(s) in its FTE resident counts. No resident may be counted in the aggregate as more than one FTE.

(4) The net effect of the adjustments (positive or negative) on the Medicare GME affiliated hospitals' aggregate FTE cap for each Medicare GME affiliation agreement must not exceed zero.

(5) If the Medicare GME affiliation agreement terminates for any reason, the FTE cap of each hospital in the Medicare GME affiliated group will revert to the individual hospital's pre-affiliation FTE cap that is determined under the provisions of paragraph (c) of this section.

(g) *Newly constructed hospitals.* A hospital that began construction of its facility prior to August 5, 1997, and sponsored new medical residency training programs on or after January 1, 1995, and on or before August 5, 1997, that either received initial accreditation by the appropriate accrediting body or temporarily trained residents at another hospital(s) until the facility was

completed, may receive an adjustment to its FTE cap.

(1) The newly constructed hospital's FTE cap is equal to the lesser of—

(i) The product of the highest number of residents in any program year during the third year of the newly established program and the number of years in which residents are expected to complete the programs based on the minimum accredited length for each type of program; or

(ii) The number of accredited slots available to the hospital for each year of the programs.

(2) If the new medical residency training programs sponsored by the newly constructed hospital have been in existence for 3 years or more by the time the residents begin training at the newly constructed hospital, the newly constructed hospital's cap will be based on the number of residents training in the third year of the programs begun at the temporary training site.

(3) If the new medical residency training programs sponsored by the newly constructed hospital have been in existence for less than 3 years by the time the residents begin training at the newly constructed hospital, the newly constructed hospital's cap will be based on the number of residents training at the newly constructed hospital in the third year of the programs (including the years at the temporary training site).

(4) A hospital that qualifies for an adjustment to its FTE cap under this paragraph (g) may be part of an affiliated group for purposes of establishing an aggregate FTE cap.

(5) The provisions of this paragraph (g) are applicable during portions of cost reporting periods occurring on or after October 1, 1999.

(h) *Closure of hospital or hospital residency program.*

(1) *Definitions.* For purposes of this section—

(i) *Closure of a hospital* means the hospital terminates its Medicare agreement under the provisions of § 489.52 of this chapter.

(ii) *Closure of a hospital residency training program* means the hospital ceases to offer training for residents in a particular approved medical residency training program.

(2) *Closure of a hospital.* A hospital may receive a temporary adjustment to its FTE cap to reflect residents added because of another hospital's closure if the hospital meets the following criteria:

(i) The hospital is training additional residents from a hospital that closed on or after July 1, 1996.

(ii) No later than 60 days after the hospital begins to train the residents, the hospital submits a request to its

fiscal intermediary for a temporary adjustment to its FTE cap, documents that the hospital is eligible for this temporary adjustment by identifying the residents who have come from the closed hospital and have caused the hospital to exceed its cap, and specifies the length of time the adjustment is needed.

(3) *Closure of a hospital's residency training program.* If a hospital that closes its residency training program voluntarily agrees to temporarily reduce its FTE cap according to the criteria specified in paragraph (h)(3)(ii) of this section, another hospital(s) may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of the residency training program if the criteria specified in paragraph (h)(3)(i) of this section are met.

(i) *Receiving hospital(s).* A hospital may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of another hospital's residency training program if—

(A) The hospital is training additional residents from the residency training program of a hospital that closed a program; and

(B) No later than 60 days after the hospital begins to train the residents, the hospital submits to its fiscal intermediary a request for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary adjustment by identifying the residents who have come from another hospital's closed program and have caused the hospital to exceed its cap, specifies the length of time the adjustment is needed, and submits to its fiscal intermediary a copy of the FTE reduction statement by the hospital that closed its program, as specified in paragraph (h)(3)(ii)(B) of this section.

(ii) *Hospital that closed its program(s).* A hospital that agrees to train residents who have been displaced by the closure of another hospital's program may receive a temporary FTE cap adjustment only if the hospital with the closed program—

(A) Temporarily reduces its FTE cap based on the FTE residents in each program year training in the program at the time of the program's closure. This yearly reduction in the FTE cap will be determined based on the number of those residents who would have been training in the program during that year had the program not closed; and

(B) No later than 60 days after the residents who were in the closed program begin training at another hospital, submit to its fiscal intermediary a statement signed and

dated by its representative that specifies that it agrees to the temporary reduction in its FTE cap to allow the hospital training the displaced residents to obtain a temporary adjustment to its cap; identifies the residents who were in training at the time of the program's closure; identifies the hospitals to which the residents are transferring once the program closes; and specifies the reduction for the applicable program years.

(i) *Additional FTEs for residents on maternity or disability leave or other approved leave of absence.* Effective for cost reporting periods beginning on or after November 29, 1999, a hospital may receive an adjustment to its FTE cap of up to three additional resident FTEs, if the hospital meets the following criteria:

(1) The additional residents are residents of a primary care program that would have been counted by the hospital as residents for purposes of the hospital's FTE cap but for the fact that the additional residents were on maternity or disability leave or a similar approved leave of absence during the hospital's most recent cost reporting period ending on or before December 31, 1996;

(2) The leave of absence was approved by the residency program director to allow the residents to be absent from the program and return to the program after the leave of absence; and

(3) No later than 6 months after August 1, 2000, the hospital submits to the fiscal intermediary a request for an adjustment to its FTE cap, and provides contemporaneous documentation of the approval of the leave of absence by the residency director, specific to each additional resident that is to be counted for purposes of the adjustment.

(j) *Residents previously trained at VA hospitals.* For cost reporting periods beginning on or after October 1, 1997, a non-Veterans Affairs (VA) hospital may receive a temporary adjustment to its FTE cap to reflect residents who had previously trained at a VA hospital and were subsequently transferred to the non-VA hospital, if that hospital meets the following criteria:

(1) The transferred residents had been training previously at a VA hospital in a program that would have lost its accreditation by the ACGME if the residents continued to train at the VA hospital;

(2) The residents were transferred to the hospital from the VA hospital on or after January 1, 1997, and before July 31, 1998; and

(3) The hospital submits a request to its fiscal intermediary for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary

adjustment by identifying the residents who have come from the VA hospital, and specifies the length of time those residents will be trained at the hospital.

(k) *Residents training in rural track programs.* Subject to the provisions of § 413.81, an urban hospital that establishes a new residency program, or has an existing residency program, with a rural track (or an integrated rural track) may include in its FTE count residents in those rural tracks, in addition to the residents subject to its FTE cap specified under paragraph (c) of this section. An urban hospital with a rural track residency program may count residents in those rural tracks up to a rural track FTE limitation if the hospital complies with the conditions specified in paragraphs (k)(2) through (k)(6) of this section.

(1) If an urban hospital rotates residents to a separately accredited rural track program at a rural hospital(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count for the time the rural track residents spend at the urban hospital. The urban hospital may include in its FTE count those residents in the rural track training at the urban hospital, not to exceed its rural track FTE limitation, determined as follows:

(i) For the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital.

(ii) Beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the third year of the rural track's existence are training in the rural track at the urban hospital or the rural hospital(s) and are designated at the beginning of their training to be rotated to the rural hospital(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2002, or for more than one-half of the duration of the program effective for cost reporting periods beginning on or after October 1, 2003, and the number of years those residents are training at the urban hospital.

(2) If an urban hospital rotates residents to a separately accredited rural track program at a rural nonhospital

site(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track FTE limitation, determined as follows:

(i) For the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonhospital site(s).

(ii) Beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(A) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at—

(1) The urban hospital and are designated at the beginning of their training to be rotated to a rural nonhospital site(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000 and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(2) The rural nonhospital site(s); and

(B) The number of years in which the residents are expected to complete each program based on the minimum accredited length for the type of program.

(3) If an urban hospital rotates residents in the rural track program to a rural hospital(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the rural hospital may not include those residents in its FTE count (if the rural track is not a new program under paragraph (e)(3) of this section, or if the rural hospital's FTE count exceeds that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation.

(4) If an urban hospital rotates residents in the rural track program to a rural nonhospital site(s) for less than

two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000 and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

(i) For the first 3 years of the rural track's existence, the rural track FTE limitation for the urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the rural nonhospital site(s).

(ii) Beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(A) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at the rural nonhospital site(s) or are designated at the beginning of their training to be rotated to the rural nonhospital site(s) for a period that is less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2002, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(B) The length of time in which the residents are being training at the rural nonhospital site(s) only.

(5) All urban hospitals that wish to count FTE residents in rural tracks, not to exceed their respective rural track FTE limitation, must also comply with all of the following conditions:

(i) An urban hospital may not include in its rural track FTE limitation or (assuming the urban hospital's FTE count exceeds its FTE cap) FTE count residents who are training in a rural track residency program that were already included as part of the hospital's FTE cap.

(ii) The hospital must base its count of residents in a rural track on written contemporaneous documentation that each resident enrolled in a rural track program at the hospital intends to rotate for a portion of the residency program to a rural area.

(iii) All residents that are included by the hospital as part of its rural track FTE count (not to exceed its rural track FTE limitation) must train in the rural area. However, where a resident begins to

train in the rural track program at the urban hospital but leaves the program before completing the total required portion of training in the rural area, the urban hospital may count the time the resident trained in the urban hospital if another resident fills the vacated FTE slot and completes the training in the rural portion of the rural track program. An urban hospital may not receive GME payment for the time the resident trained at the urban hospital if another resident fills the vacated FTE slot and first begins to train at the urban hospital.

(6) If CMS finds that residents who are included by the urban hospital as part of its FTE count did not actually complete the training in the rural area, CMS will reopen the urban hospital's cost report within the 3-year reopening period as specified in § 405.1885 of this chapter and adjust the hospital's Medicare GME payments (and, where applicable, the hospital's rural track FTE limitation).

(l) For purposes of this section, a new medical residency training program means a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995.

§ 413.80 Direct GME payments: Determination of weighting factors for foreign medical graduates.

(a) The weighting factor for a foreign medical graduate is determined under the provisions of § 413.79 if the foreign medical graduate—

(1) Has passed FMGEMS; or

(2) Before July 1, 1986, received certification from, or passed an examination of, the Educational Committee for Foreign Medical Graduates.

(b) Before July 1, 1986, the weighting factor for a foreign medical graduate is 1.0 times the weight determined under the provisions of § 413.79. On or after July 1, 1986, and before July 1, 1987, the weighting factor for a graduate of a foreign medical school who was in a residency program both before and after July 1, 1986 but who does not meet the requirements set forth in paragraph (a) of this section is .50 times the weight determined under the provisions of § 413.79.

(c) On or after July 1, 1987, these foreign medical graduates are not counted in determining the number of FTE residents.

(d) During the cost reporting period in which a foreign medical graduate passes FMGEMS, the weighting factor for that resident is determined under the provisions of § 413.79 for the part of the

cost reporting period beginning with the month the resident passes the test.

(e) On or after September 1, 1989, the National Board of Medical Examiners Examination, Parts I and II, may be substituted for FMGEMS for purposes of the determination made under paragraphs (a) and (d) of this section.

(f) On or after June 1, 1992, the United States Medical Licensing Examination may be substituted for the FMGEMS for purposes of the determination made under paragraphs (a) and (d) of this section. On or after July 1, 1993, only the results of steps I and II of the United States Medical Licensing Examination will be accepted for purposes of making this determination.

§ 413.81 Direct GME payments: Application of community support and redistribution of costs in determining FTE resident counts.

(a) For purposes of determining direct GME payments, the following principles apply:

(1) *Community support.* If the community has undertaken to bear the costs of medical education through community support, the costs are not considered GME costs to the hospital for purposes of Medicare payment.

(2) *Redistribution of costs.* The costs of training residents that constitute a redistribution of costs from an educational institution to the hospital are not considered GME costs to the hospital for purposes of Medicare payment.

(b) *Application.* A hospital must continuously incur costs of direct GME of residents training in a particular program at a training site since the date the residents first began training in that program in order for the hospital to count the FTE residents in accordance with the provisions of §§ 413.78, 413.79 (c) through (e), and 413.79(k). This rule also applies to providers that are paid for direct GME in accordance with § 405.2468 of this chapter, § 422.270 of this subchapter, and § 413.70.

(c)(1) *Effective date.* Subject to the provisions of paragraph (c)(2) of this section, payments made in accordance with determinations made under the provisions of paragraphs (a) and (b) of this section will be effective for portions of cost reporting periods occurring on or after October 1, 2003.

(2) *Applicability for certain hospitals.* With respect to an FTE resident who begins training in a residency program on or before October 1, 2003, and with respect to whom there has been a redistribution of costs or community support determined under the provisions of paragraphs (a) and (b) of this section, the hospital may continue

to count the FTE resident until the resident has completed training in that program, or until 3 years after the date the resident began training in that program, whichever comes first.

§ 413.82 Direct GME payments: Special rules for States that formerly had a waiver from Medicare reimbursement principles.

(a) Effective for cost reporting periods beginning on or after January 1, 1986, hospitals in States that, prior to becoming subject to the prospective payment system, had a waiver for the operation of a State reimbursement control system under section 1886(c) of the Act, section 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1 or section 222(a) of the Social Security Amendment of 1972 (42 U.S.C. 1395b-1 (note)) are permitted to change the order in which they allocate administrative and general costs to the order specified in the instructions for the Medicare cost report.

(b) For hospitals making this election, the base-period costs for the purpose of determining the per resident amount are adjusted to take into account the change in the order by which they allocate administrative and general costs to interns and residents in approved program cost centers.

(c) Per resident amounts are determined for the base period and updated as described in § 413.77. For cost reporting periods beginning on or after January 1, 1986, payment is made based on the methodology described in § 413.76.

§ 413.83 Direct GME payments: Adjustment of a hospital's target amount or prospective payment hospital-specific rate.

(a) *Misclassified operating costs*—(1) *General rule.* If a hospital has its base-period GME costs reduced under § 413.77(a) of this section because those costs included misclassified operating costs, the hospital may request that the intermediary review the classification of the affected costs in its rate-of-increase ceiling or prospective payment base year for purposes of adjusting the hospital's target amount or hospital-specific rate. For those cost reports that are not subject to reopening under § 405.1885 of this chapter, the hospital's reopening request must explicitly state that the review is limited to this one issue.

(2) *Request for review.* The hospital must request review of the classification of its rate-of-increase ceiling or prospective payment base year costs no later than 180 days after the date of the notice by the intermediary of the hospital's base-period average per resident amount. A hospital's request

for review must include sufficient documentation to demonstrate to the intermediary that adjustment of the hospital's hospital-specific rate or target amount is warranted.

(3) *Effect of intermediary's review.* If the intermediary, upon review of the hospital's costs, determines that the hospital's hospital-specific rate or target amount should be adjusted, the adjustment of the hospital-specific rate or the target amount is effective for the hospital's cost reporting periods subject to the prospective payment system or the rate-of-increase ceiling that are still subject to reopening under § 405.1885 of this chapter.

(b) *Misclassification of GME costs*—(1) *General rule.* If costs that should have been classified as GME costs were treated as operating costs during both the GME base period and the rate-of-increase ceiling base year or prospective payment base year and the hospital wishes to receive benefit for the appropriate classification of these costs as GME costs in the GME base period, the hospital must request that the intermediary review the classification of the affected costs in the rate-of-increase ceiling or prospective payment base year for purposes of adjusting the hospital's target amount or hospital-specific rate. For those cost reports that are not subject to reopening under § 405.1885 of this chapter, the hospital's reopening request must explicitly state that the review is limited to this one issue.

(2) *Request for review.* The hospital must request review of the classification of its costs no later than 180 days after the date of the intermediary's notice of the hospital's base-period average per resident amount. A hospital's request for review must include sufficient documentation to demonstrate to the intermediary that modification of the adjustment of the hospital's hospital-specific rate or target amount is warranted.

(3) *Effect of intermediary's review.* If the intermediary, upon review of the hospital's costs, determines that the hospital's hospital-specific rate or target amount should be adjusted, the adjustment of the hospital-specific rate and the adjustment of the target amount is effective for the hospital's cost reporting periods subject to the prospective payment system or the rate-of-increase ceiling that are still subject to reopening under § 405.1885 of this chapter.

§ 413.87 [Amended]

- 8. In § 413.87—
- A. Under paragraph (e), the cross-reference “§ 413.86(d)(4)” is removed

and the cross-reference “413.76(d)” is added in its place.

- B. Under paragraph (f)(1)(i), the cross-reference “413.86(d)(3)” is removed and the cross-reference “413.76(c)” is added in its place.

§ 413.88 [Amended]

- 9. In § 413.88—
- A. Under paragraph (b)(1), the cross-reference “413.86(b)” is removed and the cross-reference “§ 413.75(b)” is added in its place.
- B. Under paragraph (b)(2), the cross-reference “§ 413.86(b)” is removed and the cross-reference “§ 413.75(b)” is added in its place.
- C. Under paragraph (d)(7), the reference “413.86(b)” is removed and the cross-reference “§ 413.75(b)” is added in its place.
- D. Under paragraphs (g)(1)(i)(A) and (B), the cross-reference “§ 413.86(g)” is removed and the cross-reference “§ 413.79” is added in its place, wherever it appears.
- E. Under paragraph (h)(1)(i), the cross-reference “§ 413.86(d)” (2 times) is removed and the cross-reference “§ 413.76” (2 times) is added in its place.
- 10. Section 413.114 is amended by revising the last sentence of paragraph (a)(2) to read as follows:

§ 413.114 Payment for posthospital SNF care furnished by a swing-bed hospital.

(a) * * *

(2) *Services furnished in cost reporting periods beginning on and after July 1, 2002.* * * * Posthospital SNF care furnished in general routine inpatient beds in CAHs is paid based on reasonable cost for cost reporting periods beginning on and after July 1, 2002 and before January 1, 2004, and is paid based on 101 percent of reasonable cost for cost reporting periods beginning on and after January 1, 2004, in accordance with the provisions of subparts A through G of this part (other than paragraphs (c) and (d) of this section).

* * * * *

- 11. Section 413.302 is amended by revising the definition of “Urban area” to read as follows:

§ 413.302 Definitions.

For purposes of this subpart—

* * * * *

Urban area means—

(1) Prior to October 1, 2004, a Metropolitan Statistical Area (MSA), or New England County Metropolitan Area (NECMA), as defined by the Office of Management and Budget, or a New England county deemed to be an urban area as listed in § 412.62(f)(1)(ii)(B) of this chapter.

(2) Effective October 1, 2004, a Metropolitan Statistical Area (MSA), as defined by the Office of Management and Budget, or a New England county deemed to be an urban area as specified under § 412.64.

■ D. Part 418 is amended as follows:

PART 418—HOSPICE CARE

■ 1. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 418.100 is amended as follows:

- A. Revising paragraph (d)(1).
- B. Revising paragraph (d)(4).
- C. Adding a new paragraph (d)(5).

The revision and addition read as follows:

§ 418.100 Condition of participation: Hospices that provide inpatient care directly.

* * * * *

(d) *Standard: Fire protection.* (1) Except as otherwise provided in this section—

(i) The hospice must meet the provisions applicable to nursing homes of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101 ® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to a hospice.

* * * * *

(4) Beginning March 13, 2006, a hospice must be in compliance with Chapter 9.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospices.

* * * * *

■ E. Part 460 is amended as follows:

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 1. The authority citation for part 460 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395).

Subpart E—PACE Administrative Requirements

- 2. Section 460.72 is amended by—
 - A. Revising paragraph (b)(1).
 - B. Revising paragraph (b)(3).
 - C. Adding paragraph (b)(4).

The revision and addition read as follows:

§ 460.72 Physical environment.

* * * * *

(b) *Fire safety.* (1) *General rule.* Except as otherwise provided in this section—

(i) A PACE center must meet the applicable provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association that apply to the type of setting in which the center is located. The Director of the Office of the Federal Register has approved the NFPA 101 ® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to PACE centers.

* * * * *

(3) Beginning March 13, 2006, a PACE center must be in compliance with Chapter 9.2.9, Emergency Lighting.

(4) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to PACE centers.

* * * * *

■ F. The title of Part 480 under Subchapter F is revised to read as follows:

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE OF QUALITY IMPROVEMENT ORGANIZATION INFORMATION

■ G. Part 480 is amended as follows:

■ 1. The authority citation for Part 480 continues to read:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 480.106 is amended by adding a new paragraph (c) to read as follows:

§ 480.106 Exceptions to QIO notice requirements.

* * * * *

(c) *Other.* The notification requirements in § 480.105(a) and (b)(2) do not apply if:

- (1) The institution or practitioner has requested, in writing, that the QIO make the disclosure;
- (2) The institution or practitioner has provided, in writing, consent for the disclosure; or
- (3) The information is public information as defined in § 480.101(b) and specified under § 480.120.

■ 3. Section 480.133 is amended by revising paragraph (a)(2)(iii) to read as follows:

§ 480.133 Disclosure of information about practitioners, reviewers and institutions.

(a) * * *

(2) *Disclosure to others.* * * *

(iii) A QIO may disclose to any person, agency, or organization information on a particular practitioner or reviewer at the written request of or with the written consent of that practitioner or reviewer. The recipient of the information has the same redisclosure rights and responsibilities as the requesting or consenting practitioner or reviewer as provided under this Subpart B.

* * * * *

■ 4. Section 480.140 is amended by redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively, and adding a new paragraph (d) to read as follows:

§ 480.140 Disclosure of quality review study information.

* * * * *

(d) A QIO may disclose quality review study information with identifiers of

particular practitioners or institutions, or both, at the written request of, or with the written consent of, the identified practitioner(s) or institution(s).

(1) The consent or request must specify the information that is to be disclosed and the intended recipient of the information.

(2) The recipient of the information has the same redisclosure rights and responsibilities as the requesting or

consenting practitioner or institution as provided under this Subpart B.

* * * * *

■ 5. Cross-Reference Changes

§§ 480.101, 480.104, 480.105, 480.106, 480.120, 480.121, 480.130, 480.132, 480.133, 480.136, 480.137, 480.138, 480.141, 480.142 [Amended]

■ In the table below, for each section indicated in the left column, remove the

cross-reference indicated in the middle column from wherever it appears in the section, and add the cross-reference in the right column:

BILLING CODE 4120-01-P

Section	Remove	Add
480.101(b), under the definition "Patient representative"	§476.132(c)(3)	§480.132(c)(3)
480.104(a)(1)	§476.105	§480.105
480.104(a)(2)	§476.106	§480.106
480.104(a)(2)	§476.107	§480.107
480.104(d)	§476.120(a)(6)	§480.120(a)(6)
480.105(a)	§476.106	§480.106
480.105(b)(1)	§476.132	§480.132
480.105(b)(2)	§§476.137 and 476.138	§§480.137 and 480.138
480.105(b)(2)	§476.106	§480.106
480.106(a)	§476.105	§480.105
480.106(b)	§476.105	§480.105
480.120, introductory text	§§476.104 and 476.105	§§480.104 and 480.105
480.120(a)(5)	§476.139	§480.139
480.121	§476.105	§480.105
480.121	§476.120	§480.120
480.130	§§476.139(a) and 476.140	§§480.139(a) and 480.140
480.132(b)(2)	§476.139(a)	§480.139(a)
480.132(b)(3)	§476.140	§480.140
480.133(a)(2)(ii)	§§476.137 and 476.138	§§480.137 and 480.138
480.133(b)(2)	§476.139(a)	§480.139(a)
480.133(b)(3)	§476.140	§480.140
480.136(a), introductory text	§§476.139(a) and 476.140	§§480.139(a) and 480.140
480.137(a), introductory text	§§476.139(a) and 476.140	§§480.139(a) and 480.140
480.138(b)(2)	§§476.139(a) and 476.140	§§480.139(a) and 480.140
480.141	§§476.104 and 476.105	§§480.104 and 480.105
480.142(b)	§476.137	§480.137

BILLING CODE 4120-01-C

■ H. Part 482 is amended as follows:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302 and 1395hh).

■ 2. Section 482.41 is amended by—
revising paragraph (b).

§ 482.41 **Conditions of participation: Physical environment.**

* * * * *

(b) *Standard: Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101®

2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospitals.

(2) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

(4) Beginning March 13, 2006, a hospital must be in compliance with Chapter 19.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospitals.

(6) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

(7) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

(8) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

* * * * *

■ 3. Section 482.43 is amended by adding new paragraphs (c)(6), (c)(7), and (c)(8) to read as follows:

§ 482.43 Conditions of participation: Discharge planning.

* * * * *

(c) * * *

(6) The hospital must include in the discharge plan a list of HHAs or SNFs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and posthospital extended care services through individuals and entities that have a contract with the managed care organizations.

(iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the individual acting on the patient's behalf.

(7) The hospital, as part of the discharge planning process, must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of posthospital care services and must, when possible, respect patient and family preferences when they are expressed. The hospital must not specify or otherwise limit the qualified providers that are available to the patient.

(8) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of Part 420, Subpart C, of this chapter.

* * * * *

■ I. Part 483 is amended as follows:

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 483.70 is amended by revising paragraph (a) to read as follows.

§ 483.70 Physical environment.

* * * * *

(a) *Life safety from fire.*

(1) Except as otherwise provided in this section—

(i) The facility must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the **Federal Register** to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to long-term care facilities.

(2) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

(3) The provisions of the Life safety Code do not apply in a State where CMS finds, in accordance with applicable provisions of sections 1819(d)(2)(B)(ii) and 1919(d)(2)(B)(ii) of the Act, that a fire and safety code imposed by State law adequately protects patients, residents and personnel in long term care facilities.

(4) Beginning March 13, 2006, a long-term care facility must be in compliance with Chapter 19.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to long-term care facilities.

* * * * *