DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412 and 413

[CMS–1470–P]

RIN 0938–AL89

Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital costs to implement changes arising from our continuing experience with these systems. In addition, in the Addendum to this proposed rule, we are describing proposed 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 would be applicable to discharges occurring on or after October 1, 2003. We also are setting forth proposed rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the IPPS.

Among other changes that we are proposing are changes to the policies governing postacute care transfers, payments to hospitals for the direct and indirect costs of graduate medical education, determination of hospital beds and patient days for payment adjustment purposes, and payments to critical access hospitals (CAHs).

DATES: Comments will be considered if received at the appropriate address, as provided below, no later than 5 p.m. on July 18, 2003.

ADDRESSES: Mail written comments (an original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1470–P, P.O. Box 8010, Baltimore, MD 21244–1850.

If you prefer, you may deliver, by hand or courier, your written comments (an original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–14–03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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For information on viewing public comments see the beginning of the **SUPPLEMENTARY INFORMATION** section.

For comments that relate to information collection requirements, mail a copy of comments to the following addresses:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Security and Standards Group, Office of Regulations Development and Issuances, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Attn: Julie Brown, CMS–1470–P; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

FOR FURTHER INFORMATION CONTACT:

Stephen Phillips, (410) 786–4548, Operating Prospective Payment, Diagnosis-Related Groups (DRGs), Wage Index, New Medical Services and Technology, Patient Transfers, Counting Beds and Patient Days, and Hospital Geographic Reclassifications Issues;

Tzvi Hefter, (410) 786–4487, Capital Prospective Payment, Excluded Hospitals, Nursing and Allied Health Education, Graduate Medical Education, and Critical Access Hospital Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room C5–12–08 of the Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. Please call (410) 786–7197 to schedule an appointment to view public comments.

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Acronyms

AHIMA American Health Information Management Association
AHA American Hospital Association
CAH Critical access hospital
CBSAs Core Based Statistical Areas
CC Complication or comorbidity
CMS Centers for Medicare & Medicaid Services
CMSA Consolidated Metropolitan Statistical Areas
COBRA Consolidated Omnibus Reconciliation Act of 1985, Pub. L. 99–272
CPI Consumer Price Index
CRNA Certified registered nurse anesthetist
DRG Diagnosis-related group
DSH Disproportionate share hospital
FDA Food and Drug Administration
FQHC Federally qualified health center
FTE Full-time eguivalent
FY Federal fiscal year
GME Graduate medical education
HIPC Health Information Policy Council
HIPAA Health Insurance Portability and Accountability Act, Pub. L. 104–191
HHA Home health agency
ICD–9–CM International Classification of Diseases, Ninth Revision, and Clinical Modification
ICD–10–PCS International Classification of Diseases Tenth Edition, and Procedure Coding System
IME Indirect medical education
IPPS Acute care hospital inpatient prospective payment system
IRF Inpatient Rehabilitation Facility
LDRP Labor, delivery room, and postpartum
LTC–DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
MCE Medicare Code Editor
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
MPFS Medicare Physician Fee Schedule
MSA Metropolitan Statistical Area
NECMA New England County Metropolitan Areas
NCHS National Center for Health Statistics
NCHVS National Committee on Health and Vital Statistics
O.R. Operating room
PPS Prospective payment system
PRA Per resident amount
ProPAC Prospective Payment Assessment Commission
PRRB Provider Reimbursement Review Board
RCE Reasonable compensation equivalent
RHC Rural health center
RRC Rural referral center
SCH Sole community hospital
SNF Skilled nursing facility
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248
UHDDS Uniform Hospital Discharge Data Set

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 that have been approved for special add-on payments. To qualify, a new technology must demonstrate that it is a substantial clinical improvement over technologies 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 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, 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. Inpatient Rehabilitation Facilities. 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 on a full prospective payment system basis effective for cost reporting periods beginning on or after October 1, 2002 (66 FR 41316, August 7, 2001 and 67 FR 49982, August 1, 2002). 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 Pub. L. 106–113 and section 307(b)(1) of Pub. L. 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 fully Federal prospective rates 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 under the fully Federal prospective payment rate (the August 30, 2002 LTCH PPS final rule (67 FR 55954)). LTCHs may elect to be paid based on full PPS payments 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. Psychiatric Hospitals and Units. Sections 124(a) and (c) of Pub. L. 106–113 provide for the development of a per diem PPS for payment for inpatient hospital services furnished in psychiatric hospitals and units 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 maintain budget neutrality. We are in the process of developing a proposed rule, to be followed by a final rule, to implement the PPS for psychiatric hospitals and units.

3. Critical Access Hospitals

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

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.

B. Major Contents of This Proposed Rule

In this proposed rule, we are setting forth proposed changes to the Medicare IPPS for operating costs and for capital-related costs in FY 2004. We also are proposing changes relating to payments for GME costs, payments to CAHs, and payments to providers classified as psychiatric hospitals and units that continue to be excluded from the IPPS and paid on a reasonable cost basis. The proposed changes would be effective for discharges occurring on or after October 1, 2003.

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

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

As required by section 1886(d)(4)(C) of the Act, we adjust the DRG classifications and relative weights annually. Based on analyses of Medicare claims data, we are proposing to establish a number of new DRGs and make changes to the designation of diagnosis and procedure codes under other existing DRGs. Our proposed changes for FY 2004 are set forth in section II. of this preamble.

Among the proposed changes discussed are:

- Expanding the number of DRGs that are split on the basis of the presence or absence of complications or comorbidities (CCs). The DRGs we are proposing to split are: DRG 4 (Spinal Procedures), DRG 5 (Extracranial Vascular Procedures), DRG 231 (Local Excision and Removal of Internal Fixation Devices Except Hip and Femur) and DRG 400 (Lymphoma and Leukemia With Major O.R. Procedure).
- Creating two new DRGs to differentiate current DRG 514 (Cardiac Defibrillator Implant With Cardiac Catheterization) on the basis of whether the patient does or does not experience any of the following symptoms: acute myocardial infarction, heart failure, or shock.
- Changing the DRG assignments of certain congenital anomalies that currently result in patients being assigned to newborn DRGs even when the patient is actually an adult. We also are adding to the list of major problems in newborns that affect DRG assignment.
- Modifying DRG 492 (Chemotherapy With Acute Leukemia as Secondary Diagnosis) to include in this DRG cases receiving high-dose Interleukin-2 (IL–2)

chemotherapy for patients with advanced renal cell cancer and advanced melanoma.

We also are presenting our analysis of applicants for add-on payments for high-cost new medical technologies.

2. Proposed Changes to the Hospital Wage Index

In section III. of this preamble, we discuss proposed revisions to the wage index and the annual update of the wage data. Specific issues addressed in this section include the following:

- The proposed FY 2004 wage index update, using wage data from cost reporting periods that began during FY 2000.
- Proposed exclusion of the wage data for rural health centers (RHCs) and Federally qualified health centers (FQHCs) from the calculation of the FY 2004 wage index.
- Proposed exclusion of paid hours associated with military and jury duty leave from the wage index calculation, and request for comments on possible exclusion of paid lunch or meal break hours.
- Proposed revisions to the wage index based on hospital redesignations and reclassifications.
- Proposed amendments to the timetable for reviewing and verifying the wage data that will be in effect for the FY 2005 wage index.

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

In section IV. of this preamble, we discuss several provisions of the regulations in 42 CFR parts 412 and 413 and set forth certain proposed changes concerning the following:

- Proposed expansion of the current postacute transfer policy to 19 additional DRGs.
- Proposed clarification of our policies that would be applied to counting hospital beds and patient days, in particular with regard to the treatment of swing-beds and observation beds, for purposes of the IME and DSH adjustments.
- Proposed changes in our policy relating to nursing and allied health education payments to wholly owned subsidiary educational institutions of hospitals.
- Proposed clarification of policy relating to application of redistribution of costs and community support funds in determining a hospital's resident training costs.
- Proposed change in the amount of rural training time required for an urban hospital to qualify for an increase in the rural track FTE limitation.
- Proposed inclusion of FTE residents training in rural tracks in a hospital's rolling average calculation.

4. PPS for Capital-Related Costs

In section V., of this preamble, we discuss the payment requirements for capital-related costs. We are not proposing any changes to the policies on payments to hospitals for capital-related costs.

5. Proposed Changes for Hospitals and Hospital Units Excluded from the IPPS

In section VI., of this preamble, we discuss the following proposals concerning excluded hospitals and hospital units and CAHs:

- Revisions relating to the operation of excluded ''grandfathered'' hospitals-within-hospitals in effect on September 30, 1999.
- Clarification of the classification criteria for LTCHs.
- Clarification of the policy on payments for laboratory services provided by a CAH to patients outside a CAH.

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

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

7. Impact Analysis

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

8. Proposed Recommendation of Update Factor for Hospital Inpatient Operating Costs

As required by sections 1886(e)(4) and (e)(5) of the Act, Appendix B provides our recommendation of the appropriate percentage change for FY 2004 for the following:

- Large urban area and other area average standardized amounts (and hospital-specific rates applicable to SCHs and MDHs) for hospital inpatient services paid under the IPPS for operating costs.
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by hospitals and hospital units excluded from the IPPS.

9. 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. This annual report makes recommendations concerning hospital inpatient payment policies. In section VII., of this preamble, we discuss the MedPAC recommendations and any actions we are proposing to take with regard to them (when an action is recommended). For further information relating specifically to the MedPAC March 1 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.*

II. Proposed 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 proposed changes to the DRG classification system and the proposed recalibration of the DRG weights for discharges occurring on or after October 1, 2003 are discussed below.

B. DRG Reclassification

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 2003, cases are assigned to one of 510 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 the 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
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 2003, there are eight DRGs to which cases are directly assigned on the basis of ICD–9-CM procedure codes. These are the DRGs for heart, liver, bone marrow, lung transplants, simultaneous pancreas/kidney, and pancreas transplants (DRGs 103, 480, 481, 495, 512, and 513, respectively) and the two DRGs for tracheostomies (DRGs 482 and 483). Cases are assigned to these DRGs before classification to an MDC.

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 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, such as extracorporeal shock wave lithotripsy for patients with a principal diagnosis of urinary stones.

Patients' 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). These screens are designed to identify cases that require further review before classification into a DRG.

After screening through the MCE and any further development of the claims, 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, a payment is calculated by the PRICER software. The PRICER calculates the payments for each case covered by the IPPS based on the DRG relative weight and factors associated with each hospital, such as IME and DSH adjustments.

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 the use of particular data to be feasible, 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 data submitted. Generally, however, a significant sample of the data should be submitted by mid-October for consideration in conjunction with the next year's proposed rule, so that we can 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 the 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.

The changes we are proposing to the DRG classification system for FY 2004 GROUPER version 21.0 and to the methodology to recalibrate the DRG weights are set forth below. Unless otherwise noted, our DRG analysis is based on data from the December 2002 update of the FY 2002 MedPAR file, which contains hospital bills received

through December 31, 2002, for discharges in FY 2002.

2. Review of DRGs for CC Split

In an effort to improve the clinical and cost cohesiveness of the DRG classification system, we have evaluated whether additional DRGs should be split based on the presence or absence of a CC. There are currently 116 paired CC split DRGs. We last performed a systematic evaluation and considered changes to the DRGs to recognize the within-DRG cost differences based on the presence or absence of CCs in 1994 (May 27, 1994 IPPS proposed rule, 59 FR 27715). In 1994, we described a refined DRG system based on a list of secondary diagnoses that have a major effect on the resources used by hospitals in treating patients across DRGs. We analyzed how the presence of the secondary diagnosis affected resource use compared to other secondary diagnoses, and classified these secondary diagnoses as non-CC, CC, or major CC. After finalizing the classification of secondary diagnoses, we evaluated which collapsed DRGs should be split on the basis of the presence 8 of a major CC, other CC, or both.[1] However, this refined system was not implemented because we did not believe it would be prudent policy to make changes for which we could not predict the effect on the case-mix (the average DRG relative weight for all cases) and, thus, payments (60 FR 29209). We were concerned that we would be unable to fulfill the requirement of section 1886(d)(4)(C)(iii) of the Act that aggregate payments may not be affected by DRG reclassification and recalibration of weighting factors. That is, our experience has been that hospitals respond to major changes to the DRGs by changing their coding practices in ways that increase total payments (for example, by beginning to include ICM–9–CM codes that previously did not affect payment for a case). Because changes in coding behavior do not represent a real increase in the severity of the overall mix of cases, total payments should not increase. The only way to ensure this behavioral response does not lead to higher total payments is to make an offsetting adjustment to the system in advance of the fiscal year when the changes are effective.

Section 301(e) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 Public Law 106–554 authorized the Secretary to make such a prospective adjustment to the average standardized amounts for discharges occurring on or after October 1, 2001, to ensure the total payment impacts of changes to the DRGs do not result in any more or less total spending than would otherwise occur without the changes (budget neutrality).

Pending a decision whether to replace ICD–9–CM with another classification system, we are not proposing to proceed with implementing a refined DRG system at this time. The refined DRG system discussed in the 1994 **Federal Register** involved a complete and thorough assessment of all of the ICD–9–CM diagnosis codes in order to establish an illness severity level associated with each code. Rather than undertaking the time-consuming process of establishing illness severity levels for all ICD–9–CM codes at this time, we believe the more prudent course would be to delay this evaluation pending the potential replacement of ICD–9–CM. For example, the National Committee on Health and Vital Statistics (NCHVS) is considering making a recommendation to the Secretary on whether to recommend the adoption of ICD–10–CM and the ICD–10–Procedure Coding System (PCS) as the national uniform standard coding system for inpatient reporting.

In the meantime, we have undertaken an effort to identify groups of DRGs where a CC-split appears most justified. Our analysis identified existing DRGs that meet the following criteria: a reduction in variance in charges within the DRG of at least 4 percent; fewer than 75 percent of all patients in the current DRG would be assigned to the with-CC DRG; and the overall payment impact (higher payments for cases in the with-CC DRG offset by lower payments for cases in the without-CC DRG) is at least $40 million.

The following four DRGs meet these criteria: DRG 4 (Spinal Procedures) and DRG 5 (Extracranial Vascular Procedures) in MDC 1 (Diseases and Disorders of the Nervous System); DRG 231 (Local Excision and Removal of Internal Fixation Devices Except Hip and Femur) in MDC 8 (Diseases and Disorders of the Musculoskeletal and Connective Tissue); and DRG 400 (Lymphoma and Leukemia with Major O.R. Procedure) in MDC 17 (Myeloproliferative Diseases and Disorders and Poorly Differentiated Neoplasms).

The following data indicate that the presence or absence of a CC was found to have a significant impact on patient charges and average length of stays in these four DRGs.

DRG	Number of cases	Average charges	Average length of stay
DRG 4 (Current)	4,488	$35,074	7.3
With CC	2,514	46,071	10.0
Without CC	1,974	21,070	3.9
DRG 5 (Current)	64,942	18,613	2.9
With CC	29,296	23,213	4.1
Without CC	35,646	14,833	2.0
DRG 231 (Current)	8,971	20,147	4.9
With CC	4,565	25,948	6.9
Without CC	4,406	14,136	2.9
DRg 400 (Current)	4,275	39,953	9.0
With CC	2,990	49,044	11.2
Without CC	1,285	18,799	4.0

Therefore, we are proposing to establish the following new DRGs: proposed DRG 531 (Spinal Procedures With CC) and proposed DRG 532 (Spinal Procedures Without CC) in MDC 1; proposed DRG 533 (Extracranial Vascular Procedures With CC) and proposed DRG 534 (Extracranial Vascular Procedures Without CC) in

[1] The complete description of the analysis was published in the *Health Care Financing Review* (Edwards, N., Honemann, D., Burley, D., Navarro, M., ''Refinement of the Medicare Diagnosis-Related Groups to Incorporate a Measure of Severity,'' *Health Care Financing Review,* Winter 1994, Vol. 16, No. 2, p. 45).

MDC 1; proposed DRG 537 (Local Excision and Removal of Internal Fixation Devices Except Hip and Femur With CC) and proposed DRG 538 (Local Excision and Removal of Internal Fixation Devices Except Hip and Femur Without CC) in MDC 8; and proposed DRG 539 (Lymphoma and Leukemia With Major O.R. Procedure With CC) and DRG 540 (Lymphoma and Leukemia With Major O.R. Procedure Without CC) in MDC 17. We are proposing that DRGs 4, 5, 231, and 400 would become invalid.

3. MDC 1 (Diseases and Disorders of the Nervous System)

a. Revisions of DRGs 1 and 2. In the FY 2003 IPPS final rule, we split DRGs 1 and 2 (Craniotomy Age >17 With and Without CC, respectively) based on the presence or absence of a CC (67 FR 49986). We have received several proposals related to devices or procedures that are used in a small subset of cases from these DRGs. These proposals argue that the current payment for these devices or procedures under DRGs 1 and 2 is inadequate.[2]

Therefore, we undertook an analysis of the charges of various procedures and diagnoses within DRGs 1 and 2 to assess whether further changes to these DRGs may be warranted. Currently, the average charges for cases assigned to DRGs 1 and 2 are approximately $55,000 and $30,000, respectively. We are proposing to create two separate new DRGs for: Cases with an intracranial vascular procedure and a principal diagnosis of an intracranial hemorrhage; and craniotomy cases with a ventricular shunt procedure (absent another procedure). The former set of cases are much more expensive than those presently in DRGs 1 and 2; the latter set of cases are much less expensive.

(1) Intracranial Vascular Procedures

Our analysis indicated that patients with an intracranial vascular procedure and a principal diagnosis of an intracranial hemorrhage were significantly more costly than other cases in DRGs 1 and 2. These patients have an acute condition with a high severity of illness and risk of mortality. There were 917 cases in DRGs 1 and 2 with an intracranial vascular procedure and a principal diagnosis of hemorrhage with average charges of approximately $113,884, which are much higher than the average charges of DRGs 1 and 2 noted above.

We also found 890 cases that had an intracranial vascular procedure without a principal diagnosis of hemorrhage (for example, nonruptured aneurysms). These cases are generally less acutely ill than those involving ruptured aneurysms, and have a lower risk of mortality. Among these 890 cases, the average charges were approximately $52,756, which are much more similar to the average charges for all cases in DRGs 1 and 2.

Based on this analysis, we are proposing to create new DRG 528 (Intracranial Vascular Procedure With a Principal Diagnosis of Hemorrhage) for patients with an intracranial vascular procedure and an intracranial hemorrhage. We are proposing that cases involving intracranial vascular procedures without a principal diagnosis of hemorrhage would remain in DRGs 1 and 2.

Proposed new DRG 528 would have the following principal diagnoses:

- 094.87, Syphilitic ruptured cerebral aneurysm
- 430, Subarachnoid hemorrhage
- 431, Intracerebral hemorrhage
- 432.0, Nontraumatic extradural hemorrhage
- 432.1, Subdural hemorrhage
- 432.9, Unspecified intracranial hemorrhage

And operating room procedures:

- 02.13, Ligation of meningeal vessel
- 38.01, Incision of vessel, intracranial vessels
- 38.11, Endarterectomy, intracranial vessels
- 38.31, Resection of vessel with anastomosis, intracranial vessels
- 38.41, Resection of vessel with replacement, intracranial vessels
- 38.51, Ligation and stripping of varicose veins, intracranial vessels
- 38.61, Other excision of vessels, intracranial vessels
- 38.81, Other surgical occlusion of vessels, intracranial vessels
- 39.28, Extracranial-intracranial (EC–IC) vascular bypass
- 39.51, Clipping of aneurysm
- 39.52, Other repair of aneursym
- 39.53, Repair of arteriovenous fistula
- 39.72, Endovascular repair or occlusion of head and neck vessels
- 39.79, Other endovascular repair of aneurysm of other vessels

(2) Ventricular Shunt Procedures

We also found that craniotomy patients who had a ventricular shunt procedure (absent another procedure) were significantly less costly than other craniotomy patients in DRGs 1 and 2. Ventricular shunts are normally performed for draining intracranial fluid. A ventricular shunt is a less extensive procedure than the other intracranial procedures in DRGs 1 and 2. As a result, if a ventricular shunt is the only intracranial procedure performed, these cases will typically be less costly.

There were 4,373 cases in which only ventricular shunt procedures were performed. These cases had average charges of approximately $27,188. However, the presence or absence of a CC had a significant impact on patient charges and lengths of stay. There were 2,533 cases with CC, with average charges of approximately $33,907 and an average length of stay of 8.2 days. In contrast, there were 1,840 cases without CC, with average charges of approximately $17,939 and an average length of stay of 3.7 days.

Therefore, we are proposing to create two new DRGs, splitting on CC, for patients with only a vascular shunt procedure: proposed new DRG 529 (Ventricular Shunt Procedures With CC) and proposed new DRG 530 (Ventricular Shunt Procedures Without CC).

Proposed new DRG 529 would consist of any principal diagnosis in MDC 5, with the presence of a CC and one of the following operating room procedures:

- 02.31, Ventricular shunt to structure in head and neck
- 02.32, Ventricular shunt to circulatory system
- 02.33, Ventricular shunt to thoracic cavity
- 02.34, Ventricular shunt to abdominal cavity and organs
- 02.35, Ventricular shunt to urinary system
- 02.39, Other operations to establish drainage of ventricle
- 02.42, Replacement of ventricular shunt
- 02.43, Removal of ventricular shunt

Proposed new DRG 530 would consist of any principal diagnosis in MDC 5 with one of the operating room procedures listed above for the proposed new DRG 529, but without the presence of a CC.

b. DRG 23 (Nontraumatic Stupor and Coma). In DRG 23 (Nontraumatic Stupor and Coma), there are currently six principal diagnoses identified by the following ICD–9-CM diagnosis codes: 348.4, Compression of the brain; 348.5, Cerebral edema; 780.01, Coma; 780.02, Transient alteration of awareness; 780.03, Persistent vegetative state; and 780.09, Other alteration of consciousness. Code 780.02 is often used to describe the diagnosis of psychiatric patients rather than the diagnosis of patients with severe

[2] We also examined the issue of treating brain tumors through the implantation of chemotherapy wafers. This analysis is discussed later in this preamble under section II.E.2.b. relative to the application for new technology add-on payments for the GLIADEL® Wafer.

neurological disorders. The treatment plan for a patient with ''transient alteration of awareness'' is clinically very different from the treatment plan for a coma patient. Furthermore, many patients with this diagnosis are treated in psychiatric facilities rather than in acute care hospitals.

Although there are neurological patients who present with the complaint of ''transient alteration of awareness,'' the cause of this alteration of consciousness is commonly identified, and the principal diagnosis for the hospital admission is the etiology of the alteration of consciousness rather than the symptom itself. For the few remaining neurological patients for whom the cause is not identified and for whom code 780.02 is assigned as the principal diagnosis, we still believe that the care of these patients is different than the care of patients with coma or cerebral edema.

Because we believe the patients with a principal diagnosis of ''transient alteration of consciousness'' are more clinically related to the patients in DRG 429 (Organic Disturbances and Mental Retardation) in MDC 19 (Mental Diseases and Disorders), we are proposing that patients who are assigned a principal diagnosis of code 780.02 will be assigned to DRG 429 instead of DRG 23. DRG 429 also contains similar diagnoses, such as code 293.81, Organic delusional syndrome and code 293.82, Organic hallucinosis syndrome. We note that the charges for the patient cases in DRGs 23 and 429 are very similar ($11,559 and $11,713, respectively), so the proposed movement of code 780.02 from DRG 23 to DRG 429 would have minimal payment impact. Moving this diagnosis code would also consolidate diagnoses treated frequently in psychiatric hospitals in those DRGs that are likely to be a part of the upcoming proposed Medicare psychiatric facility PPS.

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

a. DRG 478 (Other Vascular Procedures With CC) and DRG 479 (Other Vascular Procedures Without CC)

Code 37.64 (Removal of heart assist system) in DRGs 478 and 479 describes the operative, as opposed to bedside, removal of a heart assist system. Based on comments we received suggesting that code 37.64 was inappropriately assigned to DRGs 478 and 479, we reviewed the MedPAR data for both DRGs 478 and 479 and DRG 110 (Major Cardiovascular Procedures With CC) and DRG 111 (Major Cardiovascular Procedures Without CC) to assess the appropriate assignment of code 37.64.

We found that there were only 17 cases of code 37.64 in DRGs 478 and 479, with an average length of stay of 14.1 days and average charges of $105,153. There were a total of 90,591 cases in DRGs 478 and 479 that did not contain code 37.64. These cases had an average length of stay of 6.6 days and average charges of $31,879. In DRGs 110 and 111, we found an average length of stay of 8.1 days, with average charges of $54,653.

We are proposing to remove code 37.64 from DRGs 478 and 479 and reassign it to DRGs 110 and 111. The surgical removal of a heart assist system is a major cardiovascular procedure and, therefore, more appropriately assigned to DRGs 110 and 111. Accordingly, we believe this DRG assignment for this procedure is more clinically and financially appropriate.

b. DRGs 514 (Cardiac Defibrillator Implant With Cardiac Catheterization) and 515 (Cardiac Defibrillator Implant Without Cardiac Catheterization)

(1) Cardiac Defibrillator Implant With Cardiac Catheterization With Acute Myocardial Infarction

We received a recommendation that we modify DRG 514 (Cardiac Defibrillator Implant With Cardiac Catheterization) and DRG 515 (Cardiac Defibrillator Implant Without Cardiac Catheterization) so that these DRGs are split based on the presence or absence of acute myocardial infarction, heart failure, or shock. We note that the increased cost of treating cardiac patients with acute myocardial infarction, heart failure, or shock is recognized in the payment logic for pacemaker implants (DRG 115 (Permanent Cardiac Pacemaker Implant With Acute Myocardial Infarction, Heart Failure or Shock, or AICD Lead or Generator) and DRG 116 (Other Permanent Cardiac Pacemaker Implant)).

We examined FY 2002 MedPAR data regarding the number of cases and the average charges for DRGs 514 and 515. The results of our examination are summarized in the following table.

DRG	Number of cases	Average charges	With AMI, heart failure, or shock count	Average charges
514	16,743	$97,133	3,623	$120,852
515	4,674	76,537	935	84,140

A cardiac catheterization is 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.

We found that the average charges for patients with cardiac catheterizations who also had acute myocardial infarction, heart failure, or shock were $120,852, compared to the average charges for all DRG 514 cases of $97,133. Therefore, we are proposing to split DRG 514 and create a new DRG for patients receiving a cardiac defibrillator implant with cardiac catheterization and with acute myocardial infarction, heart failure, or shock.

Patients without cardiac catheterization generally have had the need for the defibrillator established on an outpatient basis prior to admission. We found 935 cases with acute myocardial infarction, heart failure, or shock, with average charges of $84,140. The average charges for all cases in DRG 515 were $76,537. Because of the relatively small number of patients and the less-than-10-percent charge difference for patients in DRG 515 who have acute myocardial infarction, heart failure, or shock, we are not proposing to create a separate DRG for patients with a cardiac defibrillator implant without cardiac catheterization with acute myocardial infarction, heart failure, or shock.

Specifically, we are proposing to create two new DRGs that would replace the current DRG 514. The two new DRGs would have the same procedures currently listed for DRG 514, but would be split based on the presence or absence of acute myocardial infarction, heart failure, or shock. The proposed new DRGs would be DRG 535 (Cardiac

Defibrillator Implant With Cardiac Catheterization and With Acute Myocardial Infarction, Heart Failure, or Shock) and DRG 536 (Cardiac Defibrillator Implant With Cardiac Catheterization and Without Acute Myocardial Infarction, Heart Failure, or Shock). Proposed new DRG 536 would exclude the following principal diagnosis codes from MDC 5 associated with acute myocardial infarction, heart failure, or shock.

- 398.91, Rheumatic heart failure
- 402.01, Malignant hypertensive heart disease with heart failure
- 402.11, Benign hypertensive heart disease with heart failure
- 402.91, Hypertensive heart disease not otherwise specified 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, Hypertensive heart and renal disease not otherwise specified with heart failure
- 404.93, Hypertensive heart and renal disease not otherwise specified with heart failure and renal failure
- 410.01, AMI anterolateral, initial
- 410.11, AMI anterior wall, initial
- 410.21, AMI inferolateral, initial
- 410.31, AMI inferopost, initial
- 410.41, AMI inferior wall, initial
- 410.51, AMI lateral not elsewhere classified, initial
- 410.61, True posterior infarction, initial
- 410.71, Subendocardial infarction, initial
- 410.81, AMI not elsewhere classified, initial
- 410.91, AMI not otherwise specified, initial
- 428.0, Congestive heart failure, not otherwise specified
- 428.1, Left heart failure
- 428.20, Systolic heart failure, not otherwise specified
- 428.21, Acute systolic heart failure
- 428.22, Chronic systolic heart failure
- 428.23, Acute on chronic systolic heart failure
- 428.30, Diastolic heart failure, not otherwise specified
- 428.31, Acute diastolic heart failure
- 428.32, Chronic diastolic heart failure
- 428.33, Acute on chronic diastolic heart failure
- 428.40, Combined systolic and diastolic heart failure not otherwise specified
- 428.41, Acquired combined systolic and diastolic heart failure
- 428.42, Chronic combined systolic and diastolic heart failure
- 428.43, Acute on chronic combined systolic and diastolic heart failure
- 428.9, Heart failure, not otherwise specified
- 785.50, Shock, not otherwise specified
- 785.51, Cardiogenic shock

(2) Cardiac Resynchronization Therapy (CRT)

We received a comment from a provider who pointed out that we did not include the following combination of codes under the list of procedure combinations that would lead to an assignment of DRG 514 or DRG 515:

- 39.75, Implantation of automatic cardioverter/defibrillator lead(s) only
- 00.54, Implantation or replacement of cardiac resynchronization defibrillator, pulse generator device only [CRT–D]

The commenter pointed out that cases are assigned to DRGS 514 and 515 when a total cardiodefibrillator or CRT–D system is implanted. In addition, cases are assigned to DRGs 514 and 515 when implantation of a variety of combinations of defibrillator leads and device combinations are reported. The commenter indicated that total defibrillator and CRT–D system may be replaced with completely new systems or all new devices and leads, and added that it is also possible to replace a generator, a lead, or a combination of generators and up to three leads.

When the CRT–D generator (code 00.54) and one of the cardioverter/defibrillator leads are replaced, the case currently is assigned to DRG 115 (Permanent Cardiac Pacemaker Implant with AMI, Heart Failure, or Shock or AICD Lead or Generator Procedure). The commenter recommended that we include the combination of codes 39.75 and 00.54 as a combination that would result in assignment to DRG 514 or DRG 515, as do other combinations of generators and leads. Our medical advisors agree with this recommendation. As discussed previously, we are proposing to delete DRG 514 and replace it with proposed new DRGs 535 and 536. Therefore, we are proposing to add codes 39.75 and 00.54 to the list of procedure combinations that would result in assignment to DRG 515 or new proposed DRGs 535 and 536.

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

We received a comment that two codes for cervical fusion of the spine are not included within DRG 519 (Cervical Spinal Fusion With CC) and DRG 520 (Cervical Spinal Fusion Without CC). The two cervical fusion codes are:

- 81.01, Atlas-axis spinal fusion
- 81.31, Refusion of atlas-axis

The atlas-axis includes the first two vertebrae of the cervical spine (C1 and C2). These two cervical fusion codes are currently assigned to DRG 497 (Spinal Fusion Except Cervical With CC) and DRG 498 (Spinal Fusion Except Cervical Without CC). Because codes 81.01 and 81.31 involve the cervical spine, we are proposing to remove these codes from DRGs 497 and 498 and reassign them to DRGs 519 and 520.

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

a. Nonneonate Diagnoses. As indicated earlier, ICD–9–CM diagnosis codes are assigned to MDCs based on 25 groupings corresponding to a single organ system or etiology and, in general, are associated with a particular medical specialty. MDC 15 is comprised of diagnoses that relate to newborns and other neonates with conditions originating in the perinatal period. Some of the codes included in MDC 15 consist of conditions that originate in the neonatal period but can persist throughout life. These conditions are referred to as congenital anomalies. When an older (not neonate) population is treated for a congenital anomaly, DRG assignment problems can arise. For instance, if a patient is over 65 years old and is admitted with a congenital anomaly, it is not appropriate to assign the patient to a newborn DRG. This situation occurs when a congenital anomaly code is classified within MDC 15.

We have received a recommendation to move the following congenital anomaly codes from MDC 15 and reassign them to other appropriate MDCs based on the body system being treated:

- 758.9, Chromosome anomaly, not otherwise specified
- 759.4, Conjoined twins
- 759.7, Multiple congenital anomalies, not elsewhere classified
- 759.81, Prader-Willi syndrome
- 759.83, Fragile X syndrome
- 759.89, Specified congenital anomalies, not elsewhere classified
- 759.9, Congenital anomaly, not otherwise specified

- 779.7, Periventricular leukomalacia
- 795.2, Abnormal chromosomal analysis

Each of the congenital anomaly diagnosis codes recommended for reassignment represents a condition that is frequently addressed beyond the neonatal period. In addition, the assignment of these congenital anomaly codes as principal diagnosis currently results in assignment to MDC 15.

We have evaluated the recommendation and agree that each of the identified codes represents a condition that is frequently addressed beyond the neonate period and should therefore be removed from the list of principal diagnoses that result in assignment to MDC 15. Therefore, we are proposing to change the MDC and DRG assignments of the congenital anomaly codes as specified in the following table. The table shows the principal diagnosis code for the congenital anomaly and the proposed MDC and DRG to which the code would be assigned.

Principal diagnosis code in MDC 15	Code title	Proposed MDC assignment	Proposed DRG assignment
758.9	Chromosome anomaly, not otherwise specified.	23	467 (Other Factors Influencing Health Status).
759.4	Conjoined twins	6	188, 189, and 190 (Other Digestive System Diagnoses, Age >17 with CC, Age >17 without CC, and Age 0–17, respectively).
759.7	Multiple congenital anomalies, not elsewhere classified.	8	256 (Other Musculoskeletal System and Connective Tissue Diagnoses).
759.81	Prader-Willi syndrome	8	256 (Other Musculoskeletal System and Connective Tissue Diagnoses).
759.83	Fragile X syndrome	19	429 (Organic Disturbances and Mental Retardation).
759.89	Specified congenital anomalies, not elsewhere classified.	8	256 (Other Musculoskeletal System and Connective Tissue Diagnoses).
759.9	Congenital anomaly, not otherwise specified.	23	467 (Other Factors Influencing Health Status).
779.7	Periventricular leukomalacia	1	34 and 35 (Other Disorders of Nervous System with CC, and without CC, respectively).
795.2	Abnormal chromosomal analysis	23	467 (Other Factors Influencing Health Status).

b. Heart Failure Codes for Newborns and Neonates. Under MDC 15, cases of newborns and neonates with major problems may be assigned to DRG 387 (Prematurity With Major Problems) or DRG 389 (Full-Term Neonate With Major Problems). Existing DRG 387 has three components: (1) Principal or secondary diagnosis of prematurity; (2) principal or secondary diagnosis of major problem (these are the diagnoses that define MDC 15); or (3) secondary diagnosis of major problem (these are diagnoses that do not define MDC 15, so they will only be secondary diagnosis codes for patients assigned to MDC 15). To be assigned to DRG 389, the neonate must have one of the principal or secondary diagnoses listed under the DRG.

We have received correspondence suggesting that the following diagnosis codes for heart failure, which are currently in MDC 5, be added to the list of major problems for neonates under MDC 15.

Diagnosis code	Title
428.20	Systolic heart failure, not otherwise specified.
428.21	Acute systolic heart failure.
428.22	Chronic systolic heart failure.
428.23	Acute on chronic systolic heart failure.
428.30	Diastolic heart failure, not otherwise specified.
428.31	Acute diastolic heart failure.
428.32	Chronic diastolic heart failure.
428.33	Acute on chronic diastolic heart failure.
428.40	Systolic/diastolic heart failure, not otherwise specified.
428.41	Acute systolic/diastolic heart failure.
428.42	Chronic systolic/diastolic heart failure.
428.43	Acute on chronic systolic/diastolic heart failure.

These heart failure-related diagnosis codes were new codes as of October 1, 2002. They were an expansion of the previous 4-digit codes for heart failure and provided additional detail about the specific type of heart failure. The other codes for heart failure that existed prior to October 1, 2002, are classified as major problems within MDC 15 and are currently assigned to DRGs 387 and DRG 389.

We agree that diagnosis codes 428.20 through 428.43 listed in the chart above should be included as principal diagnosis of major problem codes within MDC 15 and, therefore, are proposing to add them to DRG 387 and 389.

7. MDC 17 (Myeloproliferative Diseases and Disorders and Poorly Differentiated Neoplasms)

High-dose Interleukin-2 (IL–2) Chemotherapy is a hospital inpatient-based regimen requiring administration by experienced oncology professionals. It is used for the treatment of patients with advanced renal cell cancer and advanced melanoma. Unlike traditional cytotoxic chemotherapies that attack cancer cells themselves, Interleukin-2 is designed to enhance the body's defenses by mimicking the way natural IL–2 activates the immune system and stimulates the growth and activity of cancer-killing cells. The IL–2 product on the market was approved for use by the Food and Drug Administration (FDA) in 1992.

High-dose IL–2 therapy is performed only in very specialized treatment settings, such as an intensive care unit or a bone marrow transplant unit. This therapy requires oversight by oncology health care professionals experienced in the administration and management of patients undergoing this intensive treatment because of the severity of the side effects. Unlike most cancer

therapies, high-dose IL–2 therapy is associated with predictable toxicities that require extensive monitoring. Often patients require one-on-one nursing or physician care for extended portions of their stay.

High-dose IL–2 therapy is significantly different from conventional chemotherapy in terms of the resources required to administer it. Conventional chemotherapy may be given to patients either on an outpatient basis or through a series of short (that is, 1 to 3 day) inpatient stays.

High-dose IL–2 therapy is given during two separate hospital admissions. For the first cycle, the IL–2 is administered every 8 hours over 5 days. Patients are then discharged to rest at home for several days and then are admitted for the second cycle of therapy, in which the same regimen and dosing is repeated. The two cycles complete the first course of high-dose IL–2 therapy. This regimen may be repeated at 8 to 12 weeks if the patient is responding. The maximum number of courses for any one patient is predicted to be five courses.

Not all patients with end-stage renal cell carcinoma or end-stage melanoma are appropriate candidates for high-dose IL–2 chemotherapy. It is estimated that there are between 15,000 and 20,000 patients in the United States who have one of these two types of cancer. However, only 20 percent of those patients will be appropriate candidates for the rigors of the treatment regimen. It is further estimated that, annually, approximately 1,300 of these patients will be Medicare beneficiaries. However, allegedly due to the level of payment for the DRGs to which these cases are currently assigned, we have been informed by industry sources that only between 100 and 200 Medicare patients receive the treatment each year. According to these industry sources, several treatment centers have had to discontinue their high-dose IL–2 therapy programs for end-stage renal cell carcinoma or end-stage melanoma because of the low Medicare payment.

According to industry sources, the wholesale cost of IL–2 is approximately $700 per vial. Dosages range between 15 and 20 vials per treatment, or between $10,500 and $14,000 per patient, per cycle, for the cost of the IL–2 drug alone. There is no ICD–9–CM procedure code that currently identifies patients receiving this therapy. Therefore, it is not possible to identify directly these cases in the MedPAR data. Currently, this therapy is coded using the more general ICD–9–CM code 99.28 (Injection or infusion of biologic response modifier). When we addressed this issue previously in the August 1, 2000 IPPS final rule (65 FR 47067) by examining cases for which procedure code 99.28 was present, our analysis was inconclusive due to the wide range of cases identified (1,179 cases across in 136 DRGs). However, recent data collected by the industry on 30 Medicare beneficiaries who received high-dose IL–2 therapy during FY 2002 show average charges for these cases of approximately $54,000.

Depending on the principal diagnosis reported, patients receiving high-dose IL–2 therapy may be assigned to one of the following five DRGs: DRG 272 (Major Skin Disorder With CC) and DRG 273 (Major Skin Disorder Without CC) in MDC 9; DRG 318 (Kidney and Urinary Tract Neoplasms With CC) and DRG 319 (Kidney and Urinary Tract Neoplasms Without CC) in MDC 11; and DRG 410 (Chemotherapy Without Leukemia as Secondary Diagnosis) in MDC 17. The following table illustrates the average charges for patients in these DRGs.

DRG	Average charges
272	$14,997
273	9,128
318	16,892
319	9,583
410	16,103

Because of the need to identify the subset of patients receiving this type of treatment, the ICD–9–CM Coordination and Maintenance Committee determined, based on its consideration at the December 6, 2002 public meeting, that a new code for high-dose IL–2 therapy was warranted. Therefore, a new code has been created in the 00 Chapter of ICD–9–CM (Procedures and Interventions, Not Elsewhere Classified), in category 00.1 (Pharmaceuticals) at 00.15 (High-dose infusion Interleukin-2 (IL–2)), effective October 1, 2003.

We believe patients receiving high-dose IL–2 therapy are clinically similar to other cases currently assigned to DRG 492 (Chemotherapy With Acute Leukemia as Secondary Diagnosis) in MDC 17. The average charge for patients currently assigned to DRG 492 is $55,581. Currently, DRG 492 requires one of the following two principal diagnoses:

- V58.1, Encounter for chemotherapy
- V67.2, Followup examination following chemotherapy
- And one of the following secondary diagnoses:
- 204.00, Acute lymphoid leukemia without mention of remission
- 204.01, Acute lymphoid leukemia with remission
- 205.00, Acute myeloid leukemia without mention of remission
- 205.01, Acute myeloid leukemia with remission
- 206.00, Acute monocytic leukemia without mention of remission
- 206.01, Acute monocytic leukemia with remission
- 207.00, Acute erythremia and erythroleukemia without mention of remission
- 207.01, Acute erythremia and erythroleukemia with remission
- 208.00, Acute leukemia of unspecified cell type without mention of remission
- 208.01, Acute leukemia of unspecified cell type without mention of remission

We are proposing to modify DRG 492 by adding new procedure code 00.15 to the logic. Assignment to this DRG would require the same two V-code principal diagnosis codes as listed above (V58.1 and V67.2), but would require either one of the leukemia codes listed as a secondary diagnosis, or would require the procedure code 00.15. In addition, we are proposing to change the title of DRG 492 to ''Chemotherapy With Acute Leukemia or With Use of High Dose Chemotherapy Agent''.

We will monitor cases with procedure code 00.15 as these data become available, and consider potential further refinements to DRG 492 as necessary.

8. MDC 23 (Factors Influencing Health Status and Other Contacts With Health Services)

a. Implantable Devices. We received a comment regarding three ICD–9–CM diagnosis codes that are currently assigned to MDC 23: V53.01 (Fitting and adjustment of cerebral ventricular (communicating) shunt); V53.02 (Neuropacemaker (brain) (peripheral nerve) (spinal cord)); and V53.09 (Fitting and adjustment of other devices related to nervous system and special senses). The commenter suggested that we move these three codes from MDC 23 to MDC 1 (Diseases and Disorders of the Nervous System) because these codes are used as the principal diagnosis for admissions involving removal, replacement, and reprogramming of devices such as cerebral ventricular shunts, neurostimulators, intrathecal infusion pumps and thalamic stimulators.

Currently, if these diagnosis codes are reported alone without an O.R. procedure, the case would be assigned to DRG 467 (Other Factors Influencing Health Status). However, if an O.R. procedure is reported with the principal

diagnosis of V53.01, V53.02, or V53.09, the case would be assigned to DRG 461 (O.R. Procedure with Diagnoses of Other Contact with Health Services).

In our analysis of the MedPAR data, we found 30 cases assigned to DRG 467 and 179 cases assigned to DRG 461 with one of these codes as principal diagnosis. We found that the procedures reported with one of these diagnosis codes were procedures in MDC 1. The most frequent procedure was 86.06 (Insertion of totally implantable infusion pump).

Because the procedures that are routinely used with these codes are in MDC 1, it would be appropriate to assign these diagnosis codes to MDC 1. As the commenter also stated, this assignment would be consistent with how fitting and adjustments of devices are handled within other MDCs, such as in MDC 5 (Disease and Disorders of the Circulatory System) and MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). Diagnosis codes V53.31 (Cardiac pacemaker), V53.32 (Automatic implantable cardiac defibrillator), and V53.39 (Other cardiac device) are used for fitting and adjustment of cardiac devices and are assigned to MDC 5. Diagnosis code V53.6 (Urinary devices) is used for fitting and adjustment of urinary devices and is assigned to MDC 11.

Therefore, we are proposing to move V53.01, V53.02, and V53.09 from MDC 23 to MDC 1 when an O.R. procedure is performed. If no O.R. procedure is performed, these diagnosis codes would be assigned to DRG 34 (Other Disorders of Nervous System With CC) or DRG 35 (Other Disorders of Nervous System Without CC). If an O.R. procedure is performed on a patient assigned with one of these codes as the principal diagnosis, the case would be assigned to the DRG in MDC 1 to which the O.R. procedure is assigned.

b. Malignancy Codes. We received correspondence that indicated that when we recognized code V10.48 (History of malignancy, epididymis) as a new code for FY 2002, we did not include the code as a history of malignancy code in DRG 465 (Aftercare with History of Malignancy as Secondary Diagnosis). All other history of malignancy codes were included in DRG 465.

We agree that code V10.48 should have been included in the list of history of malignancy codes within DRG 465 and, therefore, are proposing to add it to the list of secondary diagnoses in DRG 465.

9. Medicare Code Editor (MCE) Change

As explained under section II.B.1. of this preamble, the MCE is a software program that detects and reports errors in the coding of Medicare claims data.

We received a request to examine the MCE edit ''Adult Diagnosis—Age Greater than 14'' because currently the edit rejects claims for patients under age 15 who are being treated for gall bladder disease. We reviewed this issue with our pediatric consultants and determined that, although incidence is rare, gallbladder disease does occur in patients under age 15. Therefore, we are proposing to modify the MCE by removing the following codes from the edit ''Adult Diagnosis—Age Greater Than 14'':

- 574.00, Calculus of gallbladder with acute cholecystitis without mention of obstruction
- 574.01, Calculus of gallbladder with acute cholecystitis with obstruction
- 574.10, Calculus of gallbladder with other cholecystitis without mention of obstruction
- 574.11, Calculus of gallbladder with other cholecystitis with obstruction
- 574.20, Calculus of gallbladder without mention of cholecystitis without mention of obstruction
- 574.21, Calculus of gallbladder without mention of cholecystitis with obstruction
- 574.30, Calculus of bile duct with acute cholecystitis without mention of obstruction
- 574.31, Calculus of bile duct with acute cholecystitis with obstruction
- 574.40, Calculus of bile duct with other cholecystitis without mention of obstruction
- 574.41, Calculus of bile duct with other cholecystitis with obstruction
- 574.50, Calculus of bile duct without mention of cholecystitis without mention of obstruction
- 574.51, Calculus of bile duct without mention of cholecystitis with obstruction
- 574.60, Calculus of gallbladder and bile duct with acute cholecystitis without mention of obstruction
- 574.61, Calculus of gallbladder and bile duct with acute cholecystitis with obstruction)
- 574.70, Calculus of gallbladder and bile duct with other cholecystitis without mention of obstruction
- 574.71, Calculus of gallbladder and bile duct with other cholecystitis with obstruction
- 574.80, Calculus of gallbladder and bile duct with acute and chronic cholecystitis without mention of obstruction
- 574.81, Calculus of gallbladder and bile duct with acute and chronic cholecystitis with obstruction
- 574.90, Calculus of gallbladder and bile duct without cholecystitis without mention of obstruction
- 574.90, Calculus of gallbladder and bile duct without cholecystitis with obstruction
- 575.0, Acute cholecystitis
- 575.10, Cholecystitis, not otherwise specified
- 575.11, Chronic cholecystitis
- 575.12, Acute and chronic cholecystitis
- 575.2, Obstruction of gallbladder
- 575.3, Hydrops of gallbladder
- 576.0, Postcholecystectomy syndrome
- 577.1, Chronic pancreatitis

10. 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, we are proposing modifications of the surgical hierarchy as set forth below.

At this time, we are proposing to revise the surgical hierarchy for the pre-MDC DRGs, MDC 1 (Diseases and Disorders of the Nervous System), MDC 5 (Diseases and Disorders of the Circulatory System), MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue), and MDC 17 (Myeloproliferative Disease and Disorders, Poorly Differentiated Neoplasms for Lymphoma and Leukemia) as follows:

- In the pre-MDC DRGs, we are proposing to reorder DRG 513 (Pancreas Transplant) above DRG 512 (Simultaneous Pancreas/Kidney Transplant).
- In MDC 1, we are proposing to reorder DRG 3 (Craniotomy Age 0–17) above DRG 528 (Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage); DRG 528 above DRGs 1 and 2 (Craniotomy Age >17 With and Without CC, respectively); DRGs 1 and 2 above DRGs 529 and 530 (Ventricular Shunt Procedures With and Without CC, respectively); DRGs 529 and 530 above DRGs 531 and 532 (Spinal Procedures With and Without CC, respectively); DRGs 531 and 532 above DRGs 533 and 534 (Extracranial Procedures With and Without CC, respectively); and DRGs 533 and 534 above DRG 6 (Carpal Tunnel Release).
- In MDC 5, we are proposing to reorder DRG 535 (Cardiac Defibrillator Implant With Cardiac Catheterization With AMI, Heart Failure, or Shock) above DRG 536 (Cardiac Defibrillator Implant With Cardiac Catheterization Without AMI, Heart Failure, or Shock), and DRG 536 above DRG 515 (Cardiac Defibrillator Implant Without Cardiac Catheterization).
- In MDC 8, we are proposing to reorder DRGs 537 and 538 (Local Excision and Removal of Internal Fixation Devices Except Hip and Femur With and Without CC, respectively) above DRG 230 (Local Excision and Removal of Internal Fixation Devices of Hip and Femur).
- In MDC 17, we are proposing to reorder DRGs 539 and 540 (Lymphoma and Leukemia With Major O.R. Procedure With and Without CC, respectively) above DRGs 401 and 402 (Lymphoma and Non-Acute Leukemia With Other O.R. Procedures With and Without CC, respectively).

11. 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. Thus, we created the CC Exclusions List. We made these changes for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative coding 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 standard 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 standard list of CCs, either by adding new CCs or deleting CCs already on the list. At this time, we are not proposing to delete any of the diagnosis codes on the CC list.

In the May 19, 1987 proposed notice (52 FR 18877) concerning changes to the DRG classification system, 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 (as subsequently corrected in the September 1, 1987 final notice (52 FR 33154)).
- 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. The FY 1988 revisions were intended only as a first step toward refinement of the CC list in that the criteria used for eliminating certain diagnoses from consideration as CCs were intended to identify only the most obvious diagnoses that should not be considered CCs of another diagnosis. For that reason, and in light of comments and questions on the CC list, 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. (See the September 30, 1988 final rule (53 FR 38485) for the revision made for the discharges 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; and the August 1, 2002 final rule (67 FR 49998) for the FY 2003 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.

We are proposing 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, 2003. (See section II.B.13. of this preamble for a discussion of ICD–9–CM changes.) These proposed changes are being made in accordance with the principles established when we created the CC Exclusions List in 1987.

Tables 6G and 6H in the Addendum to this proposed rule contain the revisions to the CC Exclusions List that would be effective for discharges occurring on or after October 1, 2003. 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, 2003, the indented diagnoses would 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, 2003, the indented diagnoses would 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 Department of Commerce. It is available in hard copy for $133.00 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 2216l; 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, 2000, 2002, and 2003) and those in Tables 6G and 6H of the final rule for FY 2004 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, 2003. (Note: There was no CC Exclusions List in FY 2001 because we did not make changes to the ICD–9-CM codes for FY 2001.)

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 20.0, is available for $225.00, which includes $15.00 for shipping and handling. Version 21.0 of this manual, which includes the final FY 2003 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.

12. 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
- 60.99, 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. 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 477, and some procedures from DRG 477 to 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 procedures codes from DRG 468 and placed them in more clinically coherent DRGs.

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 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 necessary changes in procedures under DRG 477. Therefore, we are not proposing to move any procedures from DRG 477 to one of the surgical DRGs.

However, we have identified a necessary proposed change under DRG 468 relating to code 50.29 (Other destruction of lesion of liver). We were contacted by a hospital about the fact that code 50.29 is not currently included in MDC 6 (Diseases and Disorders of the Digestive System). The hospital pointed out that it is not uncommon for patients to have procedures performed on the liver when they are admitted for a condition that is classified in MDC 6. For example, DRGs 170 and 171 (Other Digestive System O.R. Procedures With and Without CC, respectively) in MDC 6 currently include liver procedures such as biopsy of the liver. The hospital disagreed with the assignment of code 50.29 to DRG 468 when performed on a patient with a principal diagnosis in MDC 6. We believe that the commenter is correct and are proposing to assign code 50.29 to DRGs 170 and 171 in MDC 6.

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 DRGs to another of these DRGs based on average charges and 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 moving 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 our review this year, we are not proposing to move any procedures from DRG 468 to DRGs 476 or 477, from DRG 476 to DRGs 468 or 477, or from DRG 477 to DRGs 468 or 476.

c. Adding Diagnosis or Procedure Codes to MDCs. Based on our review this year, we are not proposing to add any diagnosis codes to MDCs.

However, we have identified several procedures that we propose to move from DRG 468 and add to DRGs 476 and 477 because the procedures are nonextensive:

- 38.21, Biopsy of blood vessel
- 77.42, Biopsy of scapula, clavicle and thorax [ribs and sternum]
- 77.43, Biopsy of radius and ulna
- 77.44, Biopsy of carpals and metacarpals
- 77.45, Biopsy of femur
- 77.46, Biopsy of patella
- 77.47, Biopsy of tibia and fibula
- 77.48, Biopsy of tarsals and metatarsals
- 77.49, Biopsy of other bones
- 92.27, Implantation or insertion of radioactive elements

13. 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 that is 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 ICD–9–CM Manual contains the list of valid diagnosis and procedure codes. (The ICD–9–CM Manual is available from the Government Printing Office on CD–ROM for $23.00 by calling (202) 512–1800.) 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 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 2004 at a public meeting held on December 6, 2002, and finalized the coding changes after consideration of comments received at the meetings and in writing by January 10, 2003. Those coding changes are announced later in this section of the preamble. Copies of the Committee procedure minutes of the 2002 meetings can be obtained from the CMS home page at: *http://www.cms.gov/paymentsystems/icd9/.* The diagnosis minutes 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.

The first of the 2003 public meetings was held on April 3, 2003. 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 all proposals discussed and approved at the April meeting as part of the code revisions effective the following October. Because this proposed rule is being published after the April meeting, we are able to include all new codes that were approved subsequent to that meeting in Table 6F of the Addendum to this proposed rule, including the DRG assignments.

For a report of procedure topics discussed at the April 2003 meeting, see the Summary Report at: *http://www.cms.hhs.gov/paymentsystems/icd9/.* For a report of the diagnosis topics discussed at the April 2003 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 Mangement, 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: *pbrooks@cms.hhs.gov.*

The ICD–9–CM code changes that have been approved will become effective October 1, 2003. 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 proposed 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 this proposed rule, we are only soliciting comments on the proposed DRG 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 GROUPER beginning with discharges occurring on or after October 1, 2003. Table 6D contains 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 a revised procedure code title for FY 2003.

The Department of Health and Human Services has been actively working on the development of new coding systems to replace the ICD–9–CM. For example, the ICD–10–CM (for diagnoses) and the ICD–10–PCS (for procedures) were developed to replace ICD–9–CM. These efforts have become increasingly important because of the many problems with the ICD–9–CM, which was implemented 24 years ago.

Implementing ICD–10–PCS as a national standard was discussed at the December 6, 2002, ICD–9–CM Coordination and Maintenance Committee meeting. A complete report of the meeting, including examples of letters supporting and opposing ICD–10–PCS, can be found at the CMS web site: *www.cms.hhs.gov/paymentsystems/icd9/.* Also, the Secretary has asked the NCVHS to recommend whether or not the country should replace ICD–9–CM as a national coding standard with ICD–10–CM and ICD–10–PCS. A complete report on the activities of this committee can be found at: *http://www.ncvhs.hhs.gov.*

14. Other Issues

In addition to the specific topics discussed in section II.B.1. through 13. of this proposed rule, we considered a number of other DRG-related issues. Below is a summary of the issues that were addressed.

a. Cochlear Implants. Cochlear implants were first covered by Medicare in 1986 and were assigned to DRG 49 (Major Head and Neck Procedures) in MDC 3 (Diseases and Disorders of the Ear, Nose, Mouth, and Throat). This is the highest weighted surgical DRG in MDC 3. However, commenters have contended that this DRG is clinically and economically inappropriate and have requested a specific DRG for cochlear implants. The commenters contend that, like heart assist systems (we created a new DRG last year, DRG 525 (Heart Assist System Implant) in MDC 5), cochlear implants are low incidence procedures with disproportionately high costs compared to other procedures within DRG 49.

As we stated in the FY 2003 final rule in our discussion regarding the creation of DRG 525 (67 FR 49989), we found 185 heart assist system cases in DRG 104 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization) and 90 cases in DRG 105 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization). The average charges for these cases were approximately $36,000 and $85,000, higher than the average charges for cases in DRGS 104 and 105, respectively, but they represented only a small fraction of all cases in these DRGs (1.3 percent and 0.5 percent, respectively). Therefore, despite the drastically higher average charges for heart assist systems, the relative volume was insufficient to affect the DRG weight to any great degree.

In our analysis of the FY 2002 MedPAR file, we found 134 cochlear implant cases out of 1,637 cases assigned to DRG 49, which represent more than 8 percent of the total cases in DRG 49. Compared to the situation with the heart assist system implant cases in DRGs 104 and 105, cochlear implants do have a greater effect on the relative weight for DRG 49. Also, while average charges for cochlear implant cases are significantly more than other cases in DRG 49 (average charges for cochlear implant cases were $51,549 compared to $25,052 for noncochlear implant cases), this difference is much less than the $36,000 and $85,000 differences for heart assist systems cited above.

Although we are concerned about the disparity between the average costs and payments for cochlear implant patients, we also have concerns about establishing a separate DRG for these cases. Doing so could create an incentive for some of these procedures to be shifted from outpatient settings, where most are currently performed. Even among current cochlear implant cases, our analysis found the average length of stay for Medicare patients receiving this procedure in the inpatient setting was just over 1 day, indicating minimal inpatient care is necessary for these cases. It is unclear whether a shift toward more inpatient stays would be appropriate.

We also are concerned whether the volume of cochlear implant cases across all hospitals performing this procedure warrants establishing a new DRG. The DRG relative weights reflect an average cost per case, with the costs of some procedures above the DRG mean costs and some below the mean. It is expected that hospitals will offset losses for certain procedures with payment gains for other procedures, while responding to incentives to maintain efficient operations. An excessive proliferation of new DRGs for specific technologies would fundamentally alter this averaging concept.

Accordingly, for the reasons cited above, we are not proposing to change the DRG assignment of cochlear implants at this time. However, we encourage public comments as to whether a new DRG for cochlear implants (or some other solution) is warranted.

b. Burn Patients on Mechanical Ventilation. Concerns have 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 DRG 482 (Tracheostomy for Face, Mouth, and Neck Diagnoses) or DRG 483 (Tracheostomy with Mechanical Ventilation 96 + Hours, 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 consecutive hours or more) for the first time in the DRG assignment (67 FR 49996). 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). We stated that we would give future consideration to further modifying DRGs 482 and 483 based on the presence of code 96.72. We anticipate that cases of patients receiving 96 or more hours of continuous mechanical ventilation are more expensive than other tracheostomy patients. Once code 96.72 is reported more frequently, we will be better able to assess the need for future revisions to DRGs 482 and 483.

To assess the payment for burn patients on mechanical ventilation when the hospital did not perform the tracheostomy, we analyzed data on cases reporting both code 96.72 and diagnosis code V44.0 (Tracheostomy status). We had hoped that these cases would show patients on long-term ventilation who were admitted to the hospital with a tracheostomy in place. Our data did not include any cases reported in any of the burn DRGs with codes 96.72 and V44.0. We then analyzed data on the frequency of cases reporting code 96.72 along with diagnosis code V46.1 (Respirator dependence). We found only 5 of these cases in the burn DRGs. With so few cases reporting code 96.72, it is difficult for us to determine the effect of long-term ventilation on reimbursement for burn cases.

All hospitals, including those that treat burn patients, are encouraged to increase the reporting of code 96.72 for patients who are on continuous mechanical ventilation for 96 or more hours. With better data, we would be able to determine how best to make any future DRG modification for all patients on long-term mechanical ventilation.

c. Multiple Level Spinal Fusion. 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. The commenter noted that the ICD–9–CM Coordination and Maintenance Committee discussed adding a new series of codes to identify multiple levels of spinal fusions at its December 6, 2002 meeting.

The following codes were approved by the Committee, effective for October 1, 2003, and are listed in Table 6B in the Addendum to this proposed rule:

- 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

The commenter conducted an analysis to support redefining the spinal fusion DRGs using these new ICD–9–CM codes. Using the CMS FY 2001 Standard Analytical File data for physicians and hospitals as the basis for its analysis, the commenter linked a 5-percent sample of hospital spinal fusion cases with the corresponding physician claims. Because there were no ICD–9–CM codes to identify multiple level fusions in 2001, multiple level fusions were identified using Current Procedural Terminology (CPT) codes on the physician claims.

The analysis found that increasing the levels fused from 1 to 2 levels to 3 or more levels increased the mean standardized charges by 38 percent for lumbar/thoracic fusions, and by 47 percent for cervical fusions. The commenter then recommended redefining the spinal fusion DRGs to differentiate between 1 to 2 level spinal fusions and multilevel spinal 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); and DRG 519 (Cervical Spinal Fusion With CC) and DRG 520 (Cervical Spinal Fusion Without CC). The difference in charges associated with the current CC-split is only slightly greater than the difference attributable to the number of levels fused as found by the commenter's analysis. Therefore, at this time, we are not proposing to redefine these DRGs to differentiate on the basis of the number of levels fused.

We note that adopting the commenter's recommendation would necessitate adjusting the DRG relative weights using non-MedPAR data, because Medicare claims data with the new ICD–9–CM codes will not be available until the FY 2003 MedPAR file. Although we considered this possibility, we believe the more prudent course, given that the current DRG structure actually appears to differentiate appropriately among these cases, is to wait until sufficient data with the new multilevel spinal fusion codes are available before making a final determination on whether multilevel spinal fusions should be incorporated into the DRG structure.

d. Heart Assist System Implant. During the comment period for the FY 2003 IPPS proposed rule on which the FY 2003 IPPS final rule was based, we received a suggestion that we develop a new heart transplant DRG entitled ''Heart Transplant with Left Ventricular Assist Device (LVAD).'' The commenter stated that, because a great number of LVAD cases remain inpatients until heart transplant occurs, there is a disparity in costs between heart transplant patients who receive LVADs during the stay and those who do not. Cases in which heart transplantation occurs during the hospitalization are assigned to DRG 103 (Heart Transplant). Therefore, the costs of LVAD cases are included in the DRG relative weight for DRG 103. However, we noted that we would continue to monitor these types of cases.

When we reviewed the FY 2002 MedPAR data, we identified only 21 cases in DRG 103 that listed a procedure code that would indicate the use of an LVAD. We do not believe this is a sufficient number of cases to support creation of an additional DRG. Therefore, we are not proposing a change to the structure of either DRG 103 or DRG 525 at this time.

e. *Drug-Eluting Stents.* In the August 1, 2002 final rule, we created two new temporary DRGs to reflect cases involving the insertion of a drug-eluting coronary artery stent as signified by the presence of code 36.07 (Insertion of drug-eluting coronary artery stent): DRG 526 (Percutaneous Cardiovascular Procedure With Drug-Eluting Stent With AMI); and DRG 527 (Percutaneous Cardiovascular Procedure With Drug-Eluting Stent Without AMI). We expect that when claims data are available that reflect the use of these stents, we will combine drug-eluting stent cases with other cases in DRGs 516 and 517.

In the absence of MedPAR data reflecting the use of drug-eluting stents, it was necessary to undertake several calculations to establish the FY 2003 DRG relative weights for these two new DRGs. First, based on prices where drug-eluting stents are currently being used and the average price of currently available stents, we calculated a price differential of approximately $1,200. Assuming average hospital charge markups for this technology (based on weighted average cost-to-charge ratios), the anticipated charge differential

between nondrug-eluting and drug-eluting stents would be approximately $2,664 per stent. However, we recognize that some cases involve more than one stent. Using an average of 1.5 stents per procedure, we estimate that the net incremental charge for cases that would receive drug-eluting stents is $3,996.

In order to determine accurately the DRG relative weights for these two new DRGs relative to all other DRGs, we also must estimate the volume of cases likely to occur. We used the manufacturer's estimate that as many as 43 percent of current stent patients will receive drug-eluting stents during FY 2003 to calculate the FY 2003 DRG relative weights, although we prorated this percentage since the new DRGs did not become active until April 1, 2003. Even though the DRG will become active on April 1, 2003, we expect that hospitals did not use this technology before FDA approval. (We intend to identify and review any cases with the code 36.07 that occurred prior to FDA approval.) Therefore, no payments are expected to have been made under these DRGs for cases occurring before FDA approval.

In determining the FY 2004 proposed DRG relative weights for DRGs 526 and 527, we assumed that 43 percent of coronary stent cases (those with code 36.06 (Insertion of nondrug-eluting coronary artery stent)) from DRGs 516 and 517 would be reassigned to new DRGs 526 and 527 (with code 36.07), and the charges of these cases would be increased $3,996 per case, to approximate the higher charges associated with the drug-eluting stents in DRGs 526 and 527. The relative weights for DRGs 516 and 517 are calculated based on the charges of the cases estimated to remain in these two DRGs.

We are proposing to maintain DRGs 526 and 527 for FY 2004, and to adopt the same methodology to establish the relative weights as we used for FY 2003. The FDA issued a decision on April 24, 2003 approving drug-eluting stents. For the final rule, we will use the best available data at that time to establish the FY 2004 relative weights for DRGs 526 and 527.

f. *Artificial Anal Sphincter.* The ICD–9–CM Coordination and Maintenance Committee created two new codes to describe procedures involving an artificial anal sphincter for use for discharges occurring on or after October 1, 2002. One code (49.75, Implantation or revision of artificial anal sphincter) is used to identify cases involving implantation or revision of an artificial anal sphincter. The second code (49.76, Removal of artificial anal sphincter) is used to identify cases involving the removal of the device. In Table 6B of the August 1, 2002 IPPS final rule (67 FR 50242), we assigned both codes to one of four MDCs based on principal diagnosis, and to one of six DRGs within those MDCs as follows: MDC 6, DRG 157 (Anal and Stomal Procedures With CC) and DRG 158 (Anal and Stomal Procedures Without CC); MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast), DRG 267 (Perianal and Pilonidal Procedures); MDC 21 (Injuries, Poisonings, and Toxic Effect of Drugs), DRG 442 (Other O.R. Procedures for Injuries With CC) and DRG 443 (Other O.R. Procedures for Injuries Without CC); and MDC 24 (Multiple Significant Trauma), DRG 486 (Other O.R. Procedures for Multiple Significant Trauma).

We have received a request that we review these DRG assignments. According to the requester, the artificial anal sphincter procedures are expensive and the payment does not adequately cover a hospital's costs in the most likely occurring DRGs 157 and 158. The requester submitted data showing cases involving artificial anal sphincters with average charges of $44,000, and suggested that we assign codes 49.75 and 49.76 in MDC 6 to DRG 170 (Other Digestive System O.R. Procedures With CC) and DRG 171) (Other Digestive System O.R. Procedures Without CC) because DRG 170 and DRG 171 are higher weighted than DRGs 157 and 158.

At this time, we are not proposing to assign these cases to DRGs 170 and 171. Although we recognize the data submitted by the commenter appear to show this procedure is associated with above average costs in the DRGs to which these cases are assigned, we believe the current assignment is the most clinically appropriate at this time. As noted above, the procedure codes to identify the implantation, revision, or removal of these devices were effective beginning on October 1, 2002. Therefore, we propose to monitor the costs of these cases using actual Medicare cases with these codes included from the FY 2003 MedPAR that will be used for the FY 2004 DRG relative weights.

C. Recalibration of DRG Weights

We are proposing to use the same basic methodology for the FY 2004 recalibration as we did for FY 2003 (August 1, 2002 IPPS final rule (67 FR 50008). That is, we are proposing to recalibrate the DRG weights based on charge data for Medicare discharges using the most current charge information available (the FY 2002 MedPAR file).

The MedPAR file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. FY 2002 MedPAR data include discharges occurring between October 1, 2001 and September 30, 2002, based on bills received by CMS through December 31, 2002, from all hospitals subject to the IPPS and short-term acute care hospitals in Maryland (which is under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2002 MedPAR file includes data for approximately 11,404,829 Medicare discharges. Discharges for Medicare beneficiaries enrolled in a Medicare+Choice managed care plan are excluded from this analysis. The data include hospitals that subsequently became CAHs, although no data are included for hospitals after the point they are certified as CAHs.

The proposed methodology used to calculate the DRG relative weights from the FY 2002 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.
- 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, transfer cases paid 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 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 2000 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.

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 proposed DRG weights for FY 2004. Using the FY 2002 MedPAR data set, there are 42 DRGs that contain fewer than 10 cases. We computed the weights for these low-volume DRGs by adjusting the proposed FY 2003 weights of these DRGs by the percentage change in the average weight of the cases in the other DRGs.

The proposed new weights are normalized by an adjustment factor (1.45510) 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.

As noted below in section IV.A.2., we are proposing to expand the transfer policy applicable to postacute care transfers from 10 DRGs currently to an additional 19 DRGs, beginning in FY 2004. Because we count a transfer case as a fraction of a case as described above in the recalibration process, any expansion of the postacute care transfer policy to 19 additional DRGs would affect the proposed relative weights for those DRGs. Therefore, we calculated the proposed FY 2004 normalization factor comparing the case-mix using the proposed FY 2004 DRG relative weights in which we treated postacute care transfer cases in the 19 DRGs proposed to be added to the postacute transfer policy for FY 2004 as a fraction of a case with the case-mix using the FY 2003 DRG relative weights without treating cases in these 19 additional DRGs as transfer cases.

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 proposed rule, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

D. Proposed LTC–DRG Reclassifications and Relative Weights for LTCHs for FY 2004

1. Background

In the March 7, 2003 LTCH PPS proposed rule (68 FR 11234), we proposed to change 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, since 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 proposed rule, we proposed that the annual update of the long-term care diagnosis-related group (LTC–DRG) classifications and relative weights would continue to remain linked to the annual reclassification and recalibration of the CMS–DRGs 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), Pub. L. 104–191, under 45 CFR Parts 160 and 162. Therefore, the manual and electronic versions of the GROUPER 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 March 7, 2003 LTCH PPS proposed rule (68 FR 11234), we proposed to 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.

As we explained in the March 7, 2003 LTCH PPS proposed rule (68 FR 11234), the FY 2004 DRGs and relative weights used under the IPPS had not yet been proposed, and we were unable to propose updated LTC–DRGs and relative weights at that time. Therefore, since the LTC–DRG classifications and relative weights would continue to be based on the annual updates to the IPPS DRGs, we proposed that proposed revisions to the LTC–DRG classifications and relative weights would be presented for public comment in the IPPS proposed rule and finalized in the IPPS final rule, to be effective October 1, 2003 through September 30, 2004.

For FY 2003, version 20.0 of the DRG GROUPER is being utilized under both the IPPS and the LTCH PPS. The LTC–DRG classifications and relative weights are shown in Table 3 of the Addendum to the August 30, 2002 for FY 2003 final rule (67 FR 56076–56084) and in Table 3 of the Addendum to the March 7, 2003 LTCH PPS proposed rule (68 FR 11285 through 11292). Below we discuss the proposed LTC–DRGs and relative weights for FY 2004 based on the proposed changes to the hospital IPPS DRGs (GROUPER version 21.0) discussed in section II. of this preamble.

2. Proposed Changes in the LTC–DRG Classifications

a. Background. Section 123 of Pub. L. 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 Pub. Law 106–554 modified the requirements of section 123 of Pub. L. 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 Pub. L. 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, in this proposed rule, we are proposing to use the proposed IPPS version 21.0 GROUPER for FY 2004 to process LTCH PPS claims. The proposed changes to the IPPS DRG classification system for FY 2004 (Grouper 21.0) are discussed in section II.B. of this preamble.

Under the LTCH PPS, we determine relative weights for each of the IPPS DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs. In a departure from the IPPS, as we discussed in the August 30, 2002 final rule (67 FR 55985), we use low volume LTC–DRGs (less than 25 LTCH cases) in determining the LTC–DRG weights, since LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. In order to deal with the large number of low volume LTC–DRGs (DRGs with fewer than 25 cases), we group those low volume LTC–DRGs into 5 quintiles based on average charge per discharge. (A listing of the composition of low volume quintiles for the FY 2003 LTC–DRGs (based on FY 2001 MedPAR data) appears in the August 30, 2002 final rule at 67 FR 55986–55988). We also adjusted for cases in which the stay at the LTCH is five-sixths of the geometric average length of stay; that is, short-stay outlier cases (§ 412.529). (A detailed discussion of the application of the Lewin Group model that was used to develop the LTC–DRGs appears in the August 30, 2002 final rule at 67 FR 55978).

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 above in section II.B. of this preamble, the 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 will be paid for the case, it is important that the coding is accurate. As is the case under the IPPS, classifications and terminology used in 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).

As we stated in the August 30, 2002 LTCH PPS final rule (67 FR 55981), 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. (For further information on the use of ICD–9–CM codes under the LTCH PPS, see the August 30, 2002 LTCH PPS final rule (67 FR 55979–55983).)

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 a DRG can be made. (For more information on types of cases selected for further development, see the August 30, 2002 LTCH PPS final rule (67 FR 55979).)

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 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 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 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 Proposed FY 2004 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 55984), one of the primary goals for the implementation of the LTCH IPPS 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 LTC–DRG relative weights 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 a LTC–DRG with a relative weight of 2 will, on average, cost twice as much as cases in a LTC–DRG with a weight of 1.

b. Data. To calculate the proposed LTC–DRG relative weights for FY 2004 in this proposed rule, we obtained total Medicare allowable charges from FY 2002 Medicare hospital bill data from the December 2002 update of the MedPAR file, and we used the proposed Version 21.0 of the CMS GROUPER used under the acute care hospital inpatient IPPS as discussed above in section II.B. of this preamble. Consistent with the methodology under the hospital IPPS, we are proposing to recalculate the FY 2004 LTC–DRG relative weights based on the best available data for the final rule.

As we discussed in further detail in the August 30, 2002 LTCH PPS final rule (67 FR 55984), based on comments regarding the data used in the development of the LTCH prospective payment system, 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 proposed FY 2004 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.

In addition, as we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 55989), a data problem regarding the proposed FY 2003 LTC–DRG relative weight values that were determined using MedPAR (claims) data for FYs 2000 and 2001 was brought to our attention. Following notification of this problem, we researched the commenter's claims and determined that, given the long stays at LTCHs, some providers had submitted multiple bills for payment under the TEFRA reimbursement system for the same stay. Based upon our research, we became aware of the following situation: In certain LTCHs, hospital personnel apparently reported a different principal diagnosis on each bill since, under the TEFRA system, payment was not dependent upon principal diagnosis as it is under a DRG-based system. These claims from the MedPAR file were run through the LTCH GROUPER and used in determining the proposed FY 2003 relative weights for each LTC–DRG.

Since this issue was brought to our attention and we discovered that only data from the final bills were being extracted for the MedPAR file, it was possible that the original MedPAR file was not receiving the correct principal diagnosis. Therefore, in the August 30, 2002 final rule (67 FR 55989), we addressed the problem by identifying all LTCH cases in the FY 2001 MedPAR file for which multiple bills were submitted. For each of these cases, beginning with the first bill and moving forward consecutively through subsequent bills for that stay, we recorded the first unique diagnosis codes up to 10 and the first unique procedure codes up to 10. We then used these codes to appropriately group each LTCH case to a LTC–DRG for FY 2003.

As we noted above, we are proposing to use LTCH claims data from the FY 2002 MedPAR file for the determination of the proposed FY 2004 LTC–DRG relative weights. Since at the time (FY 2002) LTCHs were still reimbursed under the TEFRA reasonable cost-based system, some LTCHs also had submitted multiple bills for Medicare payment for the same stay. Thus, in certain LTCHs, hospital personnel were apparently still reporting a different principal diagnosis on each bill since, under the TEFRA system in FY 2002, payment was not dependent upon principal diagnosis as it is under a DRG-based system. Therefore, we are proposing to follow the same methodology outlined above to determine the appropriate diagnosis and procedure codes for those multiple bill LTCH cases in the FY 2002 MedPAR files, and we are proposing to use these codes to group each LTCH case to a proposed LTC–DRG for FY 2004. 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.

c. Hospital-Specific Relative Value Methodology. As we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 55985), 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. Such 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, as explained in that same final rule (67 FR 55985), we use a hospital-specific relative value method to calculate the proposed LTC–DRG relative weights instead of the methodology used to determine the proposed DRG relative weights under the hospital 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, as we explained in the August 30, 2002 LTCH PPS final rule (67 FR 55985), 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 in the August 30, 2002 LTCH PPS final rule (67 FR 55985), 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.

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 we established in the August 30, 2002 LTCH PPS final rule (67 FR 55985), 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 proposed rule, using LTCH cases from the December 2002 update of the FY 2002 MedPAR file, we identified 163 proposed LTC–DRGs that contained between 1 and 24 cases. This list of proposed LTC–DRGs was then divided into one of the five proposed low volume quintiles, each containing a minimum of 32 proposed LTC–DRGs (163/5 = 32 with 3 proposed LTC–DRGs as the remainder). For FY 2004, we are proposing to make an assignment to a specific low volume quintile by sorting the 163 low volume proposed LTC–DRGs in ascending order by average charge. Since the number of proposed LTC–DRGs with less than 25 LTCH cases is not evenly divisible by five, the average charge of the low volume proposed LTC–DRG was used to determine which proposed low volume quintile received the additional proposed LTC–DRG. After sorting the 163 low volume proposed LTC–DRGs in ascending order, we are proposing that the first fifth (32) of low volume proposed LTC–DRGs with the lowest average charge would be grouped into Quintile 1. Since the average charge of the 33rd proposed LTC–DRG in the sorted list is closer to the previous proposed LTC–DRG's average charge (assigned to proposed Quintile 1) than to the average charge of the 34th proposed LTC–DRG on the sorted list (to be assigned to proposed Quintile 2), we are proposing to place it into proposed Quintile 1. The highest average charge cases would then be grouped into proposed Quintile 5. This process would be repeated through the remaining low volume proposed LTC–DRGs so that 3 proposed low volume quintiles would contain 33 proposed LTC–DRGs and 2 proposed low volume quintiles would contain 32 proposed LTC–DRGs.

In order to determine the proposed relative weights for the proposed LTC–DRGs with low volume for FY 2004, in accordance with the methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55985), we would use the five proposed low volume quintiles described above. The proposed composition of each of the five low volume quintiles shown below in Table 1 would be used in determining the proposed LTC–DRG relative weights for FY 2004. We would determine a proposed relative weight and (geometric) average length of stay for each of the five proposed low volume quintiles using the formula that we are proposing to apply to the regular proposed LTC–DRGs (25 or more cases), as described below in section II.D.4. of this preamble. We are proposing to assign the same proposed relative weight and average length of stay to each of the proposed LTC–DRGs that make up that proposed 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.

TABLE 1.—PROPOSED COMPOSITION OF LOW VOLUME QUINTILES

Proposed LTC–DRG	Description
Proposed Quintile 1	
044	ACUTE MAJOR EYE INFECTIONS
047	OTHER DISORDERS OF THE EYE AGE >17 W/O CC
065	DYSEQUILIBRIUM
066	EPISTAXIS
069	OTITIS MEDIA & URI AGE >17 W/O CC
072	NASAL TRAUMA & DEFORMITY
128	DEEP VEIN THROMBOPHLEBITIS
149	MAJOR SMALL & LARGE BOWEL PROCEDURES W/O CC
178	UNCOMPLICATED PEPTIC ULCER W/O CC
192	PANCREAS, LIVER & SHUNT PROCEDURES W/O CC
262	BREAST BIOPSY & LOCAL EXCISION FOR NON-MALIGNANCY
273	MAJOR SKIN DISORDERS W/O CC
276	NON-MALIGNANT BREAST DISORDERS
305	KIDNEY,URETER & MAJOR BLADDER PROC FOR NON-NEOPL W/O CC
311	TRANSURETHRAL PROCEDURES W/O CC
319	KIDNEY & URINARY TRACT NEOPLASMS W/O CC
328	URETHRAL STRICTURE AGE >17 W CC
339	TESTES PROCEDURES, NON-MALIGNANCY AGE >17
342	CIRCUMCISION AGE >17
348	BENIGN PROSTATIC HYPERTROPHY W CC
349	BENIGN PROSTATIC HYPERTROPHY W/O CC

TABLE 1.—PROPOSED COMPOSITION OF LOW VOLUME QUINTILES—Continued

Proposed LTC–DRG	Description
376	POSTPARTUM & POST ABORTION DIAGNOSES W/O O.R. PROCEDURE
385	NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY
399	RETICULOENDOTHELIAL & IMMUNITY DISORDERS W/O CC
420	FEVER OF UNKNOWN ORIGIN AGE >17 W/O CC
428	DISORDERS OF PERSONALITY & IMPULSE CONTROL
431	CHILDHOOD MENTAL DISORDERS
432	OTHER MENTAL DISORDER DIAGNOSES
455	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W/O CC
465	AFTERCARE W HISTORY OF MALIGNANCY AS SECONDARY DIAGNOSIS
509	FULL THICKNESS BURN W/O SKIN GRFT OR INH INJ W/O CC OR SIG TRAUMA
511	NON-EXTENSIVE BURNS W/O CC OR SIGNIFICANT TRAUMA
540	LYMPHOMA AND LEUKEMIA WITH MAJOR O.R. PROCEDURE WITHOUT CC
Proposed Quintile 2	
021	VIRAL MENINGITIS
022	HYPERTENSIVE ENCEPHALOPATHY
031**	CONCUSSION AGE >17 W CC
046	OTHER DISORDERS OF THE EYE AGE >17 W CC
053	SINUS & MASTOID PROCEDURES AGE >17
084	MAJOR CHEST TRAUMA W/O CC
177	UNCOMPLICATED PEPTIC ULCER W CC
193	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W CC
194*	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W/O CC
200	HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR NON-MALIGNANCY
206	DISORDERS OF LIVER EXCEPT MALIG, CIRR, ALC HEPA W/O CC
208	DISORDERS OF THE BILIARY TRACT W/O CC
211	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W/O CC
232	ARTHROSCOPY
234	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W/O CC
237	SPRAINS, STRAINS, & DISLOCATIONS OF HIP, PELVIS & THIGH
275	MALIGNANT BREAST DISORDERS W/O CC
299	INBORN ERRORS OF METABOLISM
309	MINOR BLADDER PROCEDURES W/O CC
323	URINARY STONES W CC, &/OR ESW LITHOTRIPSY
324	URINARY STONES W/O CC
341	PENIS PROCEDURES
344	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES FOR MALIGNANCY
367	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM W/O CC
414	OTHER MYELOPROLIF DIS OR POORLY DIFF NEOPL DIAG W/O CC
421	VIRAL ILLNESS AGE >17
454	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W CC
473	ACUTE LEUKEMIA W/O MAJOR O.R. PROCEDURE AGE >17
497**	SPINAL FUSION W CC
502	KNEE PROCEDURES W PDX OF INFECTION W/O CC
506	FULL THICKNESS BURN W SKIN GRAFT OR INHAL INJ W CC OR SIG TRAUMA
507*	FULL THICKNESS BURN W SKIN GRFT OR INHAL INJ W/O CC OR SIG TRAUMA
508	FULL THICKNESS BURN W/O SKIN GRFT OR INHAL INJ W CC OR SIG TRAUMA
510	NON-EXTENSIVE BURNS W CC OR SIGNIFICANT TRAUMA
529	VENTRICULAR SHUNT PROCEDURES WITH CC
Proposed Quintile 3	
031*	CONCUSSION AGE >17 W CC
032	CONCUSSION AGE >17 W/O CC
063	OTHER EAR, NOSE, MOUTH & THROAT O.R. PROCEDURES
083	MAJOR CHEST TRAUMA W CC
117	CARDIAC PACEMAKER REVISION EXCEPT DEVICE REPLACEMENT
119	VEIN LIGATION & STRIPPING
158	ANAL & STOMAL PROCEDURES W/O CC
194**	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W/O CC
197	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W CC
218	LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE >17 W CC
223	MAJOR SHOULDER/ELBOW PROC, OR OTHER UPPER EXTREMITY PROC W CC
228	MAJOR THUMB OR JOINT PROC, OR OTH HAND OR WRIST PROC W CC
257	TOTAL MASTECTOMY FOR MALIGNANCY W CC
293	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W/O CC
295	DIABETES AGE 0–35
317	ADMIT FOR RENAL DIALYSIS
345	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROC EXCEPT FOR MALIGNANCY
347***	MALIGNANCY, MALE REPRODUCTIVE SYSTEM, W/O CC
352	OTHER MALE REPRODUCTIVE SYSTEM DIAGNOSES

TABLE 1.—PROPOSED COMPOSITION OF LOW VOLUME QUINTILES—Continued

Proposed LTC–DRG	Description
369	MENSTRUAL & OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS
402	LYMPHOMA & NON- ACUTE LEUKEMIA W OTHER O.R. PROC W/O CC
408	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W OTHER O.R.PROC
410	CHEMOTHERAPY W/O ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS
411	HISTORY OF MALIGNANCY W/O ENDOSCOPY
419	FEVER OF UNKNOWN ORIGIN AGE >17 W CC
443	OTHER O.R. PROCEDURES FOR INJURIES W/O CC
447	ALLERGIC REACTIONS AGE >17
449	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W CC
450	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W/O CC
497*	SPINAL FUSION W CC
498*	SPINAL FUSION W/O CC
503	KNEE PROCEDURES W/O PDX OF INFECTION
505	EXTENSIVE 3RD DEGREE BURNS W/O SKIN GRAFT
507**	FULL THICKNESS BURN W SKIN GRFT OR INHAL INJ W/O CC OR SIG TRAUMA
518	PERCUTANEOUS CARDIVASCULAR PROC W/O CORONARY ARTERY STENT OR AMI
Proposed Quintile 4	
008	PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W/O CC
061	MYRINGOTOMY W TUBE INSERTION AGE >17
095***	PNEUMOTHORAX W/O CC
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG
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
157	ANAL & STOMAL PROCEDURES W CC
161	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W CC
191	PANCREAS, LIVER & SHUNT PROCEDURES W CC
195	CHOLECYSTECTOMY W C.D.E. W CC
210	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W CC
226	SOFT TISSUE PROCEDURES W CC
227	SOFT TISSUE PROCEDURES W/O CC
230	LOCAL EXCISION & REMOVAL OF INT FIX DEVICES OF HIP & FEMUR
268	SKIN, SUBCUTANEOUS TISSUE & BREAST PLASTIC PROCEDURES
306	PROSTATECTOMY W CC
308	MINOR BLADDER PROCEDURES W CC
310	TRANSURETHRAL PROCEDURES W CC
312	URETHRAL PROCEDURES, AGE >17 W CC
360	VAGINA, CERVIX & VULVA PROCEDURES
394	OTHER O.R. PROCEDURES OF THE BLOOD AND BLOOD FORMING ORGANS
427	NEUROSES EXCEPT DEPRESSIVE
479***	OTHER VASCULAR PROCEDURES W/O CC
486	OTHER O.R. PROCEDURES FOR MULTIPLE SIGNIFICANT TRAUMA
493	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W CC
494*	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W/O CC
498**	SPINAL FUSION W/O CC
500	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W/O CC
517	PERCUTANEOUS CARDIVASCULAR PROC W NON-DRUG ELUTING STENT W/O AMI
519	CERVICAL SPINAL FUSION W CC
532	SPINAL PROCEDURES WITHOUT CC
538	LOCAL EXCISION AND REMOVAL OF INTERNAL FIXATION DEVICES EXCEPT HIP AND FEMUR WITHOUT CC
Proposed Quintile 5	
001	CRANIOTOMY AGE >17 W CC
055	MISCELLANEOUS EAR, NOSE, MOUTH & THROAT PROCEDURES
075	MAJOR CHEST PROCEDURES
077	OTHER RESP SYSTEM O.R. PROCEDURES W/O CC
108	OTHER CARDIOTHORACIC PROCEDURES
110	MAJOR CARDIOVASCULAR PROCEDURES W CC
115	PRM CARD PACEM IMPL W AMI,HRT FAIL OR SHK,OR AICD LEAD OR GNRTR P
116	OTH PERM CARD PACEMAK IMPL OR PTCA W CORONARY ARTERY STENT IMPLNT
118	CARDIAC PACEMAKER DEVICE REPLACEMENT
154	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W CC
168	MOUTH PROCEDURES W CC
171***	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W/O CC
201	OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES
209	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF LOWER EXTREMITY
216	BIOPSIES OF MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE
261	BREAST PROC FOR NON-MALIGNANCY EXCEPT BIOPSY & LOCAL EXCISION

TABLE 1.—PROPOSED COMPOSITION OF LOW VOLUME QUINTILES—Continued

Proposed LTC–DRG	Description
266***	SKIN GRAFT &/OR DEBRID EXCEPT FOR SKIN ULCER OR CELLULITIS W/O CC
288	O.R. PROCEDURES FOR OBESITY
304	KIDNEY,URETER & MAJOR BLADDER PROC FOR NON-NEOPL W CC
365	OTHER FEMALE REPRODUCTIVE SYSTEM O.R. PROCEDURES
401	LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W CC
406	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R.PROC W CC
412	HISTORY OF MALIGNANCY W ENDOSCOPY
441	HAND PROCEDURES FOR INJURIES
471	BILATERAL OR MULTIPLE MAJOR JOINT PROCS OF LOWER EXTREMITY
482	TRACHEOSTOMY FOR FACE,MOUTH & NECK DIAGNOSES
488	HIV W EXTENSIVE O.R. PROCEDURE
494**	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W/O CC
499	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W CC
501	KNEE PROCEDURES W PDX OF INFECTION W CC
515	CARDIAC DEFIBRILATOR IMPLANT W/O CARDIAC CATH
534	EXTRACRANIAL VASCULAR PROCEDURES WITHOUT CC
536	CARDIAC DEFIB IMPLANT WITH CARDIAC CATH WITHOUT AMI/HF/SHOCK

* One of the original 163 low volume proposed LTC–DRGs initially assigned to a different proposed low volume quintile; reassigned to this proposed low volume quintile in addressing nonmonotonicity (see step 5 below).

** One of the original 163 low volume proposed LTC–DRGs initially assigned to this proposed low volume quintile; reassigned to a different proposed low volume quintile in addressing nonmonotonicity (see step 5 below).

*** One of the original 163 low volume proposed LTC–DRGs initially assigned to this proposed low volume quintile; removed from the proposed low volume quintiles in addressing nonmonotonicity (see step 5 below).

4. Steps for Determining the Proposed FY 2004 LTC–DRG Relative Weights

As we noted previously, the proposed FY 2004 LTC–DRG relative weights are determined in accordance with the methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55989–55991). In summary, LTCH cases must be grouped in the appropriate proposed LTC–DRG, while taking into account the low volume proposed LTC–DRGs as described above, before the proposed FY 2004 LTC–DRG relative weights can be determined. After grouping the cases in the appropriate proposed LTC–DRG, we are proposing to calculate the proposed relative weights for FY 2004 in this proposed rule by first removing statistical outliers and cases with a length of stay of 7 days or less. Next, we are proposing to adjust the number of cases in each proposed LTC–DRG for the effect of short-stay outlier cases under § 412.529. The short-stay adjusted discharges and corresponding charges would be used to calculate ''relative adjusted weights'' in each proposed LTC–DRG using the hospital-specific relative value method described above.

Below we discuss in detail the steps for calculating the proposed FY 2004 LTC–DRG relative weights, in accordance with the methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55989–55991).

Step 1—Remove statistical outliers. The first step in the calculation of the proposed FY 2004 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 proposed LTC–DRG. These statistical outliers would be removed prior to calculating the proposed 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 proposed relative weights could result in an inaccurate proposed relative weight that does not truly reflect relative resource use among the proposed LTC–DRGs.

Step 2—Remove cases with a length of stay of 7 days or less. The proposed FY 2004 LTC–DRG relative weights should 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, since such 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 proposed FY 2004 LTC–DRG relative weights, the value of many proposed 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 proposed FY 2004 LTC–DRG relative weights, we remove LTCH cases with a length of stay of 7 days or less.

Step 3—Adjust charges for the effects of short-stay outliers. The third step in the calculation of the proposed FY 2004 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 as described in the August 30, 2002 LTCH PPS final rule (67 FR 55977).

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 proposed 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 proposed 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 proposed LTC–DRG.

As we explained in the August 30, 2002 LTCH PPS final rule (67 FR 55990), counting short-stay outlier cases as full discharges with no adjustment in determining the proposed LTC–DRG relative weights would lower the proposed LTC–DRG relative weight for affected proposed LTC–DRGs because the relatively lower charges of the short-

stay outlier cases would bring down the average charge for all cases within a proposed LTC–DRG. This would result in an ''underpayment'' to nonshort-stay outlier cases and an ''overpayment'' to short-stay outlier cases. Therefore, in this proposed rule, in accordance with the methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55990), we adjust for short-stay outlier cases under § 412.529 in this manner since it would result in more appropriate payments for all LTCH cases.

Step 4—Calculate the proposed FY 2004 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 proposed LTC–DRG, the proposed FY 2004 LTC–DRG relative weight is calculated by dividing the average of the adjusted hospital-specific relative charge values (from above) for the proposed LTC–DRG by the overall average hospital-specific relative charge value across all cases for all LTCHs. Using these recalculated proposed LTC–DRG relative weights, each LTCH's average proposed relative weight for all of its cases (case-mix) is calculated by dividing the sum of all the LTCH's proposed 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 proposed LTC–DRG relative weights across all LTCHs. In this proposed 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 proposed FY 2004 LTC–DRG relative weights to account for nonmonotonically increasing relative weights. As explained in section II.B. of this preamble, the proposed FY 2004 CMS DRGs, upon which the proposed FY 2004 LTC–DRGs are based, contain ''pairs'' that are differentiated based on the presence or absence of CCs. The proposed 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 August 30, 2002 LTCH PPS final rule (67 FR 55990), 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 a proposed LTC–DRG means that cases classified into a ''without CC'' proposed 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 proposed LTC–DRGs.

For a case to be assigned to a proposed LTC–DRG with CCs, as we explained in the August 30, 2002 LTCH PPS final rule (67 FR 55990), more coded information is called for (that is, at least one relevant secondary diagnosis), than for a case to be assigned to a proposed 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 a proposed LTC–DRG ''without CCs'' since only one principal diagnosis was coded. Since LTCHs were previously paid under cost-based reimbursement, which is not based on patient diagnoses, LTCHs' coding 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 explained 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 2002 claims data, we also found on occasion that the data suggested that cases classified to the proposed LTC–DRG ''with CCs'' of a ''with CC''/''without CC'' pair would have a lower average charge than the corresponding proposed LTC–DRG ''without CCs'' for FY 2004.

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 proposed rule, in accordance with the methodology established in that same final rule (67 FR 55990–55991), we grouped both the cases ''with CCs'' and ''without CCs'' together for the purpose of calculating the proposed FY 2004 LTC–DRG relative weights. We 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.

As we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 55990), there are three types of ''with CC'' and ''without CC'' pairs that were nonmonotonic, that is, where the ''without CC'' proposed LTC–DRG would have a higher average charge than the ''with CC'' proposed LTC–DRG. For this proposed rule, using the LTCH cases in the December 2002 update of the FY 2002 MedPAR file, we identified two of the types of nonmonotonic LTC–DRG pairs.

The first category of nonmonotonically increasing relative weights for proposed FY 2004 LTC–DRG pairs ''with and without CCs'' contains no pairs of proposed LTC–DRGs in which both the proposed LTC–DRG ''with CCs'' and the proposed LTC–DRG ''without CCs'' had 25 or more LTCH cases and, therefore, would not fall into one of the 5 proposed low volume quintiles. For that type of nonmonotonic LTC–DRG pair, in accordance with the methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55990–55991), we would combine the LTCH cases and compute a new proposed relative weight based on the case-weighted average of the combined LTCH cases of the proposed 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 proposed LTC–DRG. This new proposed relative weight would then be assigned to both of the proposed LTC–DRGs in the pair. However, as there are no pairs that fall into this category, in this proposed rule, we are proposing that, for FY 2004, there would be zero proposed LTC–DRGs in this category.

The second category of nonmonotonically increasing relative weights for proposed LTC–DRG pairs with and without CCs consists of 5 pairs of proposed LTC–DRGs that has fewer than 25 cases, and each proposed LTC–DRG would be grouped to different proposed low volume quintiles in which the ''without CC'' proposed LTC–DRG would be in a higher-weighted proposed low volume quintile than the ''with CC'' proposed LTC–DRG. For those pairs, in accordance with the methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55990–55991), 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 proposed LTC–DRG. Based on the case-weighted average LTCH charge, we determine which proposed low volume quintile the ''combined proposed LTC–DRG'' would be grouped. Both proposed LTC–DRGs in the pair are then grouped into the same proposed low volume quintile, and thus would have the same proposed relative weight. For the FY 2004, in this proposed rule, we are proposing that the following proposed LTC–DRGs would be in this category: Proposed LTC–DRGs 31 and 32 (proposed low volume quintile 3); proposed LTC–DRGs 193 and 194 (proposed low volume quintile 2); proposed LTC–DRGs 493 and 494 (proposed low volume quintile 4); proposed LTC–DRGs 497 and 498 (proposed low volume quintile 3); and proposed LTC–DRGs 506 and 507 (proposed low volume quintile 2).

The third category of nonmonotonically increasing relative weights for proposed LTC–DRG pairs with and without CCs consists of 5 pairs of proposed LTC–DRGs where one of the proposed LTC–DRGs has fewer than 25 LTCH cases and is grouped to a proposed low volume quintile and the other proposed LTC–DRG has 25 or more LTCH cases and has its own proposed LTC–DRG relative weight, and the proposed LTC–DRG ''without CCs'' has the higher proposed relative weight. In accordance with the methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55990 and 55991), we remove the proposed low volume LTC–DRG from the proposed low volume quintile and combine it with the other proposed LTC–DRG for the computation of a new proposed relative weight for each of these proposed LTC–DRGs. This new proposed relative weight is assigned to both proposed LTC–DRGs, so they each have the same proposed relative weight. For FY 2004, in this proposed rule, we are proposing the following proposed LTC–DRGs would be in this category: Proposed LTC–DRGs 94 and 95; proposed LTC–DRGs 170 and 171; proposed LTC–DRGs 265 and 266; proposed LTC–DRGs 346 and 347; and proposed LTC–DRGs 478 and 479.

Step 6—Determine a proposed FY 2004 LTC–DRG relative weight for LTC–DRGs with no LTCH cases. As we stated above, we determine the proposed relative weight for each proposed LTC–DRG using charges reported in the December 2002 update of the FY 2002 MedPAR file. Of the 518 proposed LTC–DRGs for FY 2004, we identified 164 proposed LTC–DRGs for which there were no LTCH cases in the database. That is, based on data from the FY 2002 MedPAR file used in this proposed rule, no patients who would have been classified to those proposed LTC–DRGs were treated in LTCHs during FY 2002 and, therefore, no charge data were reported for those proposed LTC–DRGs. Thus, in the process of determining the proposed LTC–DRG relative weights, we are unable to determine proposed weights for these 164 proposed LTC–DRGs using the methodology described in steps 1 through 5 above. However, since patients with a number of the diagnoses under these proposed LTC–DRGs may be treated at LTCHs beginning in FY 2004, in accordance with the methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55991), we assign proposed relative weights to each of the 164 ''no volume'' proposed LTC–DRGs based on clinical similarity and relative costliness to one of the remaining 354 (518 − 164 = 354) proposed LTC–DRGs for which we are able to determine proposed relative weights, based on FY 2002 claims data.

As there are currently no LTCH cases in these ''no volume'' proposed LTC–DRGs, in accordance with the methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55991), we determine proposed relative weights for the 164 proposed LTC–DRGs with no LTCH cases in the FY 2002 MedPAR file used in this proposed rule by grouping them to the appropriate proposed low volume quintile. This methodology is consistent with our methodology used in determining proposed relative weights to account for the proposed low volume LTC–DRGs described above.

As we described in the August 30, 2002 LTCH PPS final rule (67 FR 55991), our methodology for determining proposed relative weights for the ''no volume'' proposed LTC–DRGs is as follows: First, we crosswalk the no volume proposed LTC–DRGs by matching them to other similar proposed LTC–DRGs for which there were LTCH cases in the FY 2002 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 proposed relative weight for the applicable proposed low volume quintile to the no volume proposed LTC–DRG if the proposed LTC–DRG to which it is crosswalked is grouped to one of the proposed low volume quintiles. If the proposed LTC–DRG to which the no volume proposed LTC–DRG is crosswalked is not one of the proposed LTC–DRGs to be grouped to one of the proposed low volume quintiles, we compare the proposed relative weight of the proposed LTC–DRG to which the no volume proposed LTC–DRG is crosswalked to the proposed relative weights of each of the five proposed quintiles and we assign the no volume proposed LTC–DRG the proposed relative weight of the proposed low volume quintile with the closest weight. For this proposed rule, a list of the no volume proposed FY 2004 LTC–DRGs and the proposed FY 2004 LTC–DRG to which it is crosswalked in order to determine the appropriate proposed low volume quintile for the assignment of a proposed relative weight for FY 2004 is shown below in Table 2.

TABLE 2.—PROPOSED NO VOLUME LTC–DRG CROSSWALK AND PROPOSED QUINTILE ASSIGNMENT FOR FY 2004

LTC–DRG	Description	Cross walked LTC–DRG	Low volume quintile assigned
2	CRANIOTOMY AGE > 17 W/O CC	1	Quintile 5.
3	CRANIOTOMY AGE 0–17	1	Quintile 5.

TABLE 2.—PROPOSED NO VOLUME LTC–DRG CROSSWALK AND PROPOSED QUINTILE ASSIGNMENT FOR FY 2004—Continued

LTC–DRG	Description	Cross walked LTC–DRG	Low volume quintile assigned
6	CARPAL TUNNEL RELEASE	251	Quintile 1.
26	SEIZURE & HEADACHE AGE 0–17	25	Quintile 2.
30	TRAUMATIC STUPOR & COMA, COMA <1 HR AGE 0–17	29	Quintile 3.
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.
43	HYPHEMA	47	Quintile 1.
45	NEUROLOGICAL EYE DISORDERS	46	Quintile 2.
48	OTHER DISORDERS OF THE EYE AGE 0–17	47	Quintile 1.
49	MAJOR HEAD & NECK PROCEDURES	64	Quintile 4.
50	SIALOADENECTOMY	63	Quintile 3.
51	SALIVARY GLAND PROCEDURES EXCEPT SIALOADENECTOMY	63	Quintile 3.
52	CLEFT LIP & PALATE REPAIR	63	Quintile 3.
54	SINUS & MASTOID PROCEDURES AGE 0–17	63	Quintile 3.
56	RHINOPLASTY	72	Quintile 1.
57	T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17	63	Quintile 3.
58	T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0–17	63	Quintile 3.
59	TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17	63	Quintile 3.
60	TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0–17	63	Quintile 3.
62	MYRINGOTOMY W TUBE INSERTION AGE 0–17	63	Quintile 3.
67	EPIGLOTTITIS	63	Quintile 3.
70	OTITIS MEDIA & URI AGE 0–17	69	Quintile 1.
71	LARYNGOTRACHEITIS	97	Quintile 2.
74	OTHER EAR, NOSE, MOUTH & THROAT DIAGNOSES AGE 0–17	69	Quintile 1.
81	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE 0–17	69	Quintile 1.
91	SIMPLE PNEUMONIA & PLEURISY AGE 0–17	90	Quintile 2.
98	BRONCHITIS & ASTHMA AGE 0–17	97	Quintile 2.
104	CARDIAC VALVE & OTHER MAJOR CARDIOTHORACIC PROC W CARDIAC CATH	110	Quintile 5.
105	CARDIAC VALVE & OTHER MAJOR CARDIOTHORACIC PROC W/O CARDIAC CATH	110	Quintile 5.
106	CORONARY BYPASS W PTCA	110	Quintile 5.
107	CORONARY BYPASS W CARDIAC CATH	110	Quintile 5.
109	CORONARY BYPASS W/O PTCA OR CARDIAC CATH	110	Quintile 5.
111	MAJOR CARDIOVASCULAR PROCEDURES W/O CC	110	Quintile 5.
137	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE 0–17	136	Quintile 2.
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 4.
153	MINOR SMALL & LARGE BOWEL PROCEDURES W/O CC	152	Quintile 4.
155	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W/O CC	171	Quintile 5.
156	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE 0–17	171	Quintile 5.
159	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W CC	161	Quintile 4.
160	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W/O CC	161	Quintile 4.
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	149	Quintile 1.
166	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W CC	148	Quintile 5.
167	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W/O CC	149	Quintile 1.
169	MOUTH PROCEDURES W/O CC	72	Quintile 1.
184	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE 0–17	183	Quintile 2.
186	DENTAL ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AGE 0–17	185	Quintile 2.
187	DENTAL EXTRACTIONS & RESTORATIONS	185	Quintile 2.
190	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE 0–17	189	Quintile 2.
196	CHOLECYSTECTOMY W C.D.E. W/O CC	197	Quintile 3.
198	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W/O CC	197	Quintile 3.
199	HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR MALIGNANCY	200	Quintile 2.
212	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE 0–17	211	Quintile 2.
219	LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE >17 W/O CC	218	Quintile 3.
220	LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE 0–17	218	Quintile 3.
224	SHOULDER, ELBOW OR FOREARM PROC, EXC MAJOR JOINT PROC, W/O CC	234	Quintile 2.
229	HAND OR WRIST PROC, EXCEPT MAJOR JOINT PROC, W/O CC	234	Quintile 2.
252	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE 0–17	234	Quintile 2.
255	FX, SPRN, STRN & DISL OF UPARM, LOWLEG EX FOOT AGE 0–17	234	Quintile 2.
258	TOTAL MASTECTOMY FOR MALIGNANCY W/O CC	257	Quintile 3.

TABLE 2.—PROPOSED NO VOLUME LTC–DRG CROSSWALK AND PROPOSED QUINTILE ASSIGNMENT FOR FY 2004—Continued

LTC–DRG	Description	Cross walked LTC–DRG	Low volume quintile assigned
259	SUBTOTAL MASTECTOMY FOR MALIGNANCY W CC	257	Quintile 3.
260	SUBTOTAL MASTECTOMY FOR MALIGNANCY W/O CC	257	Quintile 3.
267	PERIANAL & PILONIDAL PROCEDURES	158	Quintile 1.
279	CELLULITIS AGE 0–17	78	Quintile 1.
282	TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE 0–17	281	Quintile 2.
286	ADRENAL & PITUITARY PROCEDURES	292	Quintile 4.
289	PARATHYROID PROCEDURES	293	Quintile 3.
290	THYROID PROCEDURES	293	Quintile 3.
291	THYROGLOSSAL PROCEDURES	293	Quintile 3.
298	NUTRITIONAL & MISC METABOLIC DISORDERS AGE 0–17	297	Quintile 2.
303	KIDNEY,URETER & MAJOR BLADDER PROCEDURES FOR NEOPLASM	304	Quintile 5.
307	PROSTATECTOMY W/O CC	306	Quintile 4.
313	URETHRAL PROCEDURES, AGE >17 W/O CC	311	Quintile 1.
314	URETHRAL PROCEDURES, AGE 0–17	311	Quintile 1.
322	KIDNEY & URINARY TRACT INFECTIONS AGE 0–17	326	Quintile 2.
327	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE 0–17	326	Quintile 2.
329	URETHRAL STRICTURE AGE >17 W/O CC	328	Quintile 1.
330	URETHRAL STRICTURE AGE 0–17	328	Quintile 1.
333	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE 0–17	332	Quintile 1.
334	MAJOR MALE PELVIC PROCEDURES W CC	345	Quintile 3.
335	MAJOR MALE PELVIC PROCEDURES W/O CC	345	Quintile 3.
336	TRANSURETHRAL PROSTATECTOMY W CC	341	Quintile 2.
337	TRANSURETHRAL PROSTATECTOMY W/O CC	341	Quintile 2.
338	TESTES PROCEDURES, FOR MALIGNANCY	339	Quintile 1.
340	TESTES PROCEDURES, NON-MALIGNANCY AGE 0–17	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 MALIG W CC	365	Quintile 5.
355	UTERINE,ADNEXA PROC FOR NON-OVARIAN/ADNEXAL MALIG W/O CC	365	Quintile 5.
356	FEMALE REPRODUCTIVE SYSTEM RECONSTRUCTIVE PROCEDURES	360	Quintile 4.
357	UTERINE & ADNEXA PROC FOR OVARIAN OR ADNEXAL MALIGNANCY	360	Quintile 4.
358	UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W CC	360	Quintile 4.
359	UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W/O CC	360	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 2.
364	D&C, CONIZATION EXCEPT FOR MALIGNANCY	367	Quintile 2.
370	CESAREAN SECTION W CC	369	Quintile 3.
371	CESAREAN SECTION W/O CC	367	Quintile 2.
372	VAGINAL DELIVERY W COMPLICATING DIAGNOSES	367	Quintile 2.
373	VAGINAL DELIVERY W/O COMPLICATING DIAGNOSES	367	Quintile 2.
374	VAGINAL DELIVERY W STERILIZATION &/OR D&C	367	Quintile 2.
375	VAGINAL DELIVERY W O.R. PROC EXCEPT STERIL &/OR D&C	367	Quintile 2.
377	POSTPARTUM & POST ABORTION DIAGNOSES W O.R. PROCEDURE	367	Quintile 2.
378	ECTOPIC PREGNANCY	369	Quintile 3.
379	THREATENED ABORTION	376	Quintile 1.
380	ABORTION W/O D&C	376	Quintile 1.
381	ABORTION W D&C, ASPIRATION CURETTAGE OR HYSTEROTOMY	376	Quintile 1.
382	FALSE LABOR	376	Quintile 1.
383	OTHER ANTEPARTUM DIAGNOSES W MEDICAL COMPLICATIONS	376	Quintile 1.
384	OTHER ANTEPARTUM DIAGNOSES W/O MEDICAL COMPLICATIONS	376	Quintile 1.
386	EXTREME IMMATURITY	367	Quintile 2.
387	PREMATURITY W MAJOR PROBLEMS	367	Quintile 2.
388	PREMATURITY W/O MAJOR PROBLEMS	367	Quintile 2.
389	FULL TERM NEONATE W MAJOR PROBLEMS	367	Quintile 2.
390	NEONATE W OTHER SIGNIFICANT PROBLEMS	367	Quintile 2.
391	NORMAL NEWBORN	376	Quintile 1.
392	SPLENECTOMY AGE >17	194	Quintile 2.
393	SPLENECTOMY AGE 0–17	194	Quintile 2.
396	RED BLOOD CELL DISORDERS AGE 0–17	399	Quintile 1.
405	ACUTE LEUKEMIA W/O MAJOR O.R. PROCEDURE AGE 0–17	404	Quintile 2.
407	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R. PROC W/O CC	408	Quintile 3.
417	SEPTICEMIA AGE 0–17	416	Quintile 3.
422	VIRAL ILLNESS & FEVER OF UNKNOWN ORIGIN AGE 0–17	420	Quintile 1.
446	TRAUMATIC INJURY AGE 0–17	445	Quintile 2.
448	ALLERGIC REACTIONS AGE 0–17	455	Quintile 1.
451	POISONING & TOXIC EFFECTS OF DRUGS AGE 0–17	455	Quintile 1.
481	BONE MARROW TRANSPLANT	394	Quintile 1.

TABLE 2.—PROPOSED NO VOLUME LTC–DRG CROSSWALK AND PROPOSED QUINTILE ASSIGNMENT FOR FY 2004—Continued

LTC–DRG	Description	Cross walked LTC–DRG	Low volume quintile assigned
484	CRANIOTOMY FOR MULTIPLE SIGNIFICANT TRAUMA	1	Quintile 5.
485	LIMB REATTACHMENT, HIP AND FEMUR PROC FOR MULTIPLE SIGNIFICANT TR	209	Quintile 5.
491	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF UPPER EXTREMITY	209	Quintile 5.
492	CHEMOTHERAPY W ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS	410	Quintile 3.
496	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION	210	Quintile 4.
504	EXTENSIVE 3RD DEGREE BURNS W SKIN GRAFT	468	Quintile 5.
516	PERCUTANEOUS CARDIVASCULAR PROCEDURE W AMI	578	Quintile 3.
520	CERVICAL SPINAL FUSION W/O CC	498	Quintile 3.
525	HEART ASSIST SYSTEM IMPLANT	468	Quintile 5.
526	PERCUTANEOUS CARVIOVASCULAR PROC W DRUG-ELUTING STENT W AMI	517	Quintile 4.
527	PERCUTANEOUS CARVIOVASCULAR PROC W DRUG-ELUTING STENT W/O AMI	517	Quintile 4.
528	INTRACRANIAL VASCLUAR PROCEDURES WITH PDX HEMORRHAGE	1	Quintile 5.
530	VENTRICULAR SHUNT PROCEDURES WITHOUT CC	529	Quintile 2.
531	SPINAL PROCEDURES WITH CC	519	Quintile 4.
533	EXTRACRANIAL VASCULAR PROCEDURES WITH CC	534	Quintile 5.
535	CARDIAC DEFIB IMPLANT WITH CARDIAC CATH WITH AMI/HF/SHOCK	515	Quintile 5.
537	LOCAL EXCISION AND REMOVAL OF INTERNAL FIXATION DEVICES EXCEPT HIP AND FEMUR WITH CC.	253	Quintile 2.
539	LYMPHOMA AND LEUKEMIA WITH MAJOR O.R. PROCEDURE WITH CC	401	Quintile 5.

To illustrate this methodology, which was established in the August 30, 2002 LTCH PPS final rule (67 FR 55991), for determining the proposed relative weights for the 164 proposed LTC–DRGs with no LTCH cases, we are providing the following examples, which refer to the no volume proposed LTC–DRGs crosswalk information for FY 2004 provided above in Table 2:

Example 1: There were no cases in the FY 2002 MedPAR file used for this proposed rule for proposed 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 proposed LTC–DRG 178 (Uncomplicated Peptic Ulcer Without CC), which is assigned to proposed low volume quintile 1 for the purpose of determining the proposed FY 2004 relative weights, would display similar clinical and resource use. Therefore, we are proposing to assign the same proposed relative weight of LTC–DRG 178 of 0.5711 (proposed Quintile 1) for FY 2004 (Table 11 in the Addendum to this proposed rule) to proposed LTC–DRG 163.

Example 2: There were no LTCH cases in the FY 2002 MedPAR file used in this proposed rule for proposed 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 proposed 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 proposed LTC–DRG 91. There were over 25 cases in proposed LTC–DRG 90. Therefore, it would not be assigned to a proposed low volume quintile for the purpose of determining the proposed LTC–DRG relative weights. However, under our established methodology, proposed LTC–DRG 91, with no LTCH cases, would need to be grouped to a proposed low volume quintile. We identified that the proposed low volume quintile with the closest weight to proposed LTC–DRG 90 (0.7429; see Table 11 in the Addendum to this proposed rule) would be proposed low volume quintile 2 (0.7347; see Table 11 in the Addendum to this proposed rule). Therefore, we are proposing to assign proposed LTC–DRG 91 a proposed relative weight of 0.7347 for FY 2004.

Furthermore, in accordance with the methodology established in the August 30, 2002 final rule (67 FR 55991), we are proposing LTC–DRG relative weights of 0.0000 for heart, kidney, liver, lung, pancreas, and simultaneous pancreas/kidney transplants (proposed LTC–DRGs 103, 302, 480, 495, 512, and 513, respectively) for FY 2004 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, as we discussed in that same final rule (67 FR 55995), 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 propose appropriate weights for the LTC–DRGs affected. At the present time, we would only include these six transplant proposed LTC–DRGs in the GROUPER program for administrative purposes. Since we use the same GROUPER program for LTCHs as is used under the acute care hospital 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 proposed 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 proposed LTC–DRGs and to determine the relative weights in this final rule.

Table 11 in the Addendum to this proposed rule lists the proposed LTC–DRGs and their respective proposed 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 2004.

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)(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.

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. To assess whether technologies would be inadequately paid under the DRGs, we established this threshold at one standard deviation beyond the geometric mean standardized charge for all cases in the DRGs 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). Table 10 in the Addendum to this proposed rule lists the proposed qualifying criteria by DRG, based on the discharge data that we are using to calculate the proposed FY 2004 DRG weights. The thresholds that will be published in the final rule for FY 2004 will be used to evaluate applicants for new technology add-on payments during FY 2005.

In addition to the clinical and cost criteria, we established that, in order to qualify for the new technology add-on payments, a specific technology must be ''new'' under the requirements of § 412.87(b)(2) of our regulations. The statutory provision contemplated the special payment treatment for new technologies until such time as data are available to reflect the cost of the technology in the DRG weights through recalibration (no less than 2 years and no more than 3 years). There is a lag of 2 to 3 years from the point a new technology is first introduced on the market and when data reflecting the use of the technology are used to calculate the DRG weights. For example, data from discharges occurring during FY 2002 are used to calculate the proposed FY 2004 DRG weights in this proposed rule.

Technology may be considered ''new'' for purposes of this provision within 2 or 3 years after the point at which data begin to become available reflecting the costs of the technology. After we have recalibrated the DRGs to reflect the costs of an otherwise new technology, the special add-on payment for new technology will cease (§ 412.87(b)(2)). For example, an approved new technology that received FDA approval in October 2002 would be eligible to receive add-on payments as a new technology at least until FY 2005 (discharges occurring before October 1, 2004), when data reflecting the costs of the technology would be used to recalibrate the DRG weights. Because the FY 2005 DRG weights will be calculated using FY 2003 MedPAR data, the costs of such a new technology would likely be reflected in the FY 2005 DRG weights.

Similar to the timetable for applying for new technology add-on payments during FY 2004, we are proposing that applicants for FY 2005 must submit a formal request, including a full description of the clinical applications of the technology and the results of any clinical evaluations demonstrating that the new technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate the technology meets the high-cost threshold, no later than early October 2003. We are proposing that a complete database must be submitted no later than mid-December 2003. Complete application information is available at our Web site at: *http://www.cms.hhs.gov/providers /hipps/default.asp.* To allow interested parties to identify the technologies under review before the publication of the annual proposed rule, the Web site also lists the tracking forms completed by each applicant.

The new technology add-on payment policy provides additional payments for cases with high costs involving eligible new 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 technology. Under § 412.88, Medicare pays a marginal cost factor of 50 percent for the costs of the new technology in excess of the full DRG payment. If the actual costs of a new technology case exceed the DRG payment by more than the estimated costs of the new 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, we account for projected payments under the new technology provision during the upcoming fiscal year at the same time we estimate the payment effect of changes to the DRG classifications and recalibration. The impact of additional payments under this provision would then be included in the budget neutrality factor, which is applied to the standardized amounts and the hospital-specific amounts.

Because any additional payments directed toward new technology under this provision must be offset to ensure budget neutrality, it is important to consider carefully the extent of this provision and ensure that only technologies representing substantial advances are recognized for additional payments. In that regard, we indicated that we would discuss in the annual proposed and final rules those technologies that were considered under this provision; our determination as to whether a particular technology meets our criteria to be considered new; whether it is determined further that cases involving the new technology would be inadequately paid under the existing DRG payment; and any assumptions that went into the budget neutrality calculations related to additional payments for that new technology, including the expected number, distribution, and costs of these cases.

To balance appropriately the Congress' intent to increase Medicare's 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.

If the target limit is exceeded, we would reduce the level of payments for approved technologies across the board, to ensure estimated payments do not exceed the limit. Using this approach, all cases involving approved new technologies that would otherwise receive additional payments would still receive special payments, albeit at a

reduced amount. Although the marginal payment rate for individual technologies would be reduced, this reduction would be offset by large overall payments to hospitals for new technologies under this provision.

2. FY 2004 Status of Technology Approved for FY 2003 Add-On Payments: Drotrecogin Alfa (Activated)—Xigris®

In the August 1, 2002 IPPS final rule, we stated that cases involving the administration of Xigris® (a biotechnology product that is a recombinant version of naturally occurring Activated Protein C (APC)) as identified by the presence of code 00.11 (Infusion of drotrecogin alfa (activated)) are eligible for additional payments of up to $3,400 (50 percent of the average cost of the drug)'' (67 FR 50013). (The August 1, 2002 final rule contains a detailed discussion of this technology.) Although Xigris® was approved by the FDA in November 2001, it did not qualify for add-on payments until discharges on or after October 1, 2002. Consequently, FY 2002 discharges (between October 1, 2001 and September 30, 2002) may not reflect full utilization of the technology due to the absence of the add-on payment.

Therefore, for FY 2004, we are proposing to continue to make add-on payments for cases involving the administration of Xigris® as identified by the presence of code 00.11. Based on preliminary analysis of the incidence of Xigris® in the first quarter FY 2003 MedPAR file, we are proposing to revise downward our estimate of total add-on payments for Xigris®. For FY 2003, we estimated that total add-on payments would be approximately $74.8 million (22,000 Medicare patients who would be eligible for a $3,400 add-on payment). For FY 2004, we are estimating the total add-on payments would be approximately $50 million (based on 14,000 Medicare patients who would be eligible for a $3,400 add-on payment). We are proposing that this additional payment would be included in the DRG reclassification and recalibration budget neutrality factor, which is applied to the standardized amounts and the hospital-specific amounts. However, we will reevaluate our assumptions regarding this estimate based on preliminary claims data from the FY 2003 MedPAR file before the publication of the FY 2004 IPPS final rule.

3. FY 2004 Applicants for New Technology Add-On Payments

We received two applications for new technologies to be designated eligible for inpatient add-on payments for new technology for FY 2004. A discussion of these applications and our determinations on these applications appears below.

a. Bone Morphogenetic Proteins (BMPs) for Spinal Fusions. An application was submitted by Medtronic Sofamor Danek for the InFUSE™ Bone Graft/LT-CAGE®'' Lumbar Tapered Fusion Device for approval as a new technology eligible for add-on payments. A similar application was submitted last year but was denied because, based on the available data, the technology did not exceed the one standard deviation threshold above the average charges for the DRGs to which the technology is assigned.

The product is applied through use of an absorbable collagen sponge and an interbody fusion device, which is then implanted at the fusion site. The patient undergoes a spinal fusion, and the product is placed at the fusion site to promote bone growth. This procedure is done in place of the more traditional use of autogenous iliac crest bone graft. For a more detailed discussion about InFUSE™ Bone Graft/LT-CAGE® Lumbar Tapered Fusion, see the August 1, 2002 IPPS final rule (67 FR 50016).

On July 2, 2002, the FDA approved InFUSE™ Bone Graft/LT-CAGE® for spinal fusion procedures in skeletally mature patients at one level. Therefore, based on the FDA's approval, multilevel use of this technology would be off-label. In the August 1, 2002 IPPS final rule (67 FR 50017), we stated this technology would meet the cost threshold only if the added costs of multilevel fusions were taken into account. Because the FDA had not approved this technology for multilevel fusions, and the applicant had not submitted data to demonstrate this technology is a substantial clinical improvement for multilevel fusions (the clinical trial upon which the application was based was a single-level fusion trial), we could not issue a substantial clinical improvement determination for multilevel fusions and, consequently, did not consider the costs associated with multilevel fusions in our analysis of whether this technology met the cost threshold. Therefore, because the average charges for this new technology, when used for single-level spinal fusions, did not exceed the threshold to qualify for new technology add-on payment of $37,815, we denied this application for add-on payments for FY 2003. For similar reasons, we did not consider data on the charges for multilevel fusions in our analysis of whether this technology meets the cost threshold for FY 2004.

In its application for add-on payments for FY 2004, Medtronic used data from CMS' FY 2001 Standard Analytical File for physicians and hospitals. The analysis linked a 5-percent sample of hospital spinal fusions cases with the corresponding physician claims. Because there were no ICD–9–M codes to identify multilevel fusions in 2001, multilevel fusions were identified using CPT codes on the physician claims. Average charges were taken from actual cases used in clinical trials.

After grouping these cases into one, two, and three or more levels fused in DRGs 497 and 498 (Spinal Fusion Except Cervical With and Without CC, respectively), the applicant then calculated average charges assuming the use of the InFUSE™ Bone Graft/LT–CAGE® for these cases. For DRG 497, the estimated single-level fusion average charge was $41,321; for DRG 498, the estimated single-level fusion average charge was $37,200. Because these DRGs are not currently split for different numbers of fusion levels involved, Medtronic has calculated its own standard deviation of average charges to determine the threshold for these DRGs using the 5-percent sample data. For DRG 497, the threshold (calculated by Medtronic) was $45,646, which is greater than the estimated average charge of $41,321 for single-level fusions noted above. For DRG 498, the threshold (calculated by Medtronic) was $36,935, which is less than the average charges for single-level fusions in this DRG as noted above.

However, we note the thresholds to qualify for the new technology add-on payments for FY 2003 published in Table 10 of the August 1, 2002 IPPS final rule for DRGs 497 and 498 were $58,040 and $41,923, respectively. These thresholds were computed based on all cases assigned to these DRGs, and do not differentiate between the number of spinal levels fused. Because we are not proposing to redefine these DRGs to differentiate cases on the basis of the number of levels of the spine fused in the manner suggested by the applicant's analysis, the thresholds published in last year's final rule are applicable for a new technology to qualify for add-on payments in these DRGs for FY 2004. Therefore, because the averages calculated by the applicant for single-level fusions do not exceed the published thresholds, we are proposing not to approve this technology on the basis of this analysis.

The applicant also submitted data from actual cases involving the InFUSE™ Bone Graft/LT–CAGE® with single level fusions only. The data submitted included 31 claims from 4

hospitals (only one Medicare patient was included in the sample). All 31 cases were from DRG 498. The average standardized charge for these cases was $47,172. Based on these data, the average standardized charge exceeds the threshold for DRG 498. However, we note that this limited sample excludes any cases from DRG 497.

We note that, effective for discharges occurring on or after October 1, 2002, ICD–9–CM codes 84.51 (Insertion of interbody spinal fusion device) and 84.52 (Insertion of recombinant bone morphogenetic protein) are effective to identify cases involving this technology. Therefore, in an effort to resolve the difficulties in obtaining sufficient data upon which to determine whether this technology exceeds the applicable threshold, we intend to review available MedPAR data for the first several months of FY 2003 to identify these cases and calculate their average standardized charges to compare with the thresholds. We anticipate some of these cases will involve multilevel spinal fusions, and it will be necessary to identify those cases in order to remove them from the calculation of the average charges.

If the technology meets the cost threshold based on the MedPAR data, we will evaluate whether it qualifies as a substantial clinical improvement. According to the applicant:

''InFUSE™ Bone Graft is more appropriate to use and has been proven more effective in its use than autogenous iliac crest bone graft, when either is placed in the LT-Cage™ Lumbar Tapered Fusion Device for anterior lumbar interbody fusion. Use of InFUSE™ Bone Graft instead of autogenous iliac crest bone graft:

- Obviates iliac crest bone graft donor site morbidity.
- Reduces operative time, blood loss and hospitalization.
- Results in greater fusion success.
- We found that the Oswestry Low Back Pain Disability score and SF–36 Physical Component and Pain Index score were consistently 10 percent better in the InFUSE™ Bone Graft group than the autogenous iliac bone graft group.
- Enables earlier return to work.''

Among the issues we will consider are: Does avoiding the complications associated with the iliac crest bone harvesting procedure constitute a substantial clinical improvement; and, with the increased rate of osteoarthritis and osteoporosis in the Medicare population, is there evidence that the technology represents a substantial clinical improvement in spinal fusions among this population? We are particularly interested in data on the results of aged Medicare patients who have been treated with BMP, and any basic biology bench data on the results of using BMP in osteoporotic bones.

b. GLIADEL® Wafer. Glioblastoma Multiforme (GBM) is the most common and most aggressive of the primary brain tumors. Standard care for patients diagnosed with GBM is surgical resection and radiation. According to the manufacturer (Guilford Pharmaceuticals), the GLIADEL® Wafer is indicated for use as an adjunct to surgery to prolong survival in patients with recurrent GBM. Implanted directly into the cavity that is created when a brain tumor is surgically removed, GLIADEL® delivers chemotherapy directly to the site where tumors are most likely to recur.

The FDA approved 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 announcing its approval, the FDA indicated that GLIADEL® was approved:

'' * * * based on the results of a multi-center placebo controlled study in 222 patients who had recurrent malignant glioma after initial treatment with surgery and radiation therapy. Following surgery to remove the tumor, half of the patients were treated with GLIADEL® implants and half with placebo. In patients with glioblastoma multiforme, the 6-month survival rate increased from 36 percent with placebo to 56 percent with GLIADEL®. Median survival increased from 20 weeks with placebo to 28 weeks with GLIADEL®. In patients with pathologic diagnoses other than glioblastoma multiforme, GLIADEL® had no effect on survival.''

Guilford Pharmaceuticals has requested that GLIADEL® still be considered new because, until a new ICD–9–CM code (00.10 Implementation of Chemotherapeutic Agent) was established on October 1, 2002, it was not possible to identify specifically these cases in the MedPAR data. However, as noted previously, technology will no longer be considered new after the costs of the technology are reflected in the DRG weights. Because the costs of GLIADEL® are currently reflected in the DRG weights (despite the absence of a specific code), GLIADEL® does not meet our criterion that a medical service or technology be ''new''. That is, FY 2002 MedPAR data used to calculate the proposed DRG weights for FY 2004 include cases where GLIADEL® was administered (and the corresponding charges of these cases, include charges associated with GLIADEL®). On February 26, 2003, the FDA approved GLIADEL® 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 this is true, the charges associated with this use of GLIADEL® are also reflected in the DRG relative weights.

According to Guilford's application, the current average wholesale price of GLIADEL® is $10,985. Guilford submitted charge data for 23 Medicare patients at 7 hospitals from FY 2000. The charges were then standardized and adjusted for inflation using the hospital market basket inflation factor (from 2000 to 2003) in order to determine an inflated average standardized charge of $33,002. Guilford points out that this charge narrowly misses the DRG 2 threshold published in Table 10 of the August 1, 2002 IPPS final rule of $34,673. However, we note that, according to the manufacturer, as many as 60 percent of current GLIADEL® cases may be assigned to DRG 1 based on the presence of CCs. Based on this assumption, the qualifying threshold for GLIADEL® would be $54,312 (60 percent of the DRG 1 threshold of $67,404, and 40 percent of the DRG 2 threshold of $34,673).

As mentioned above in section II.B.3.a. of this proposed rule, we examined the definitions of DRGs 1 and 2 to determine whether they could be improved, and we are proposing to create a new DRG for patients with an intracranial vascular procedure and an intracranial hemorrhage and two new DRGs for patients with only a vascular shunt procedure (splitting on the presence or absence of a CC). We also compared the data submitted in the application on the charges for GLIADEL® cases with the charges of other procedures in DRGs 1 and 2. We found that, although the $33,002 average standardized charge reported is just below the qualifying threshold in DRG 2, it is actually well below the mean average standardized charge for DRG 1 ($42,092). As noted previously, as many as 60 percent of current GLIADEL® cases may be assigned to DRG 1 based on the presence of CCs. Therefore, we do not believe that any change to the DRG assignment of cases receiving GLIADEL® is warranted at this time. However, we will continue to monitor our data to determine whether a change is warranted in the future.

4. Review of the High-Cost Threshold

The current cost threshold for a new technology to qualify for add-on

payments is that the average standardized charges of cases involving the new technology must be demonstrated to exceed one standard deviation beyond the mean standardized charges of the DRG to which the new technology will be assigned. When we established this threshold in the September 7, 2001 final rule, we expressed our belief that it is important to establish a threshold that recognizes the variability in costs per case within DRGs and maintains the fundamental financial incentives of the IPPS (66 FR 46917).

In its comments on this approach, MedPAC supported the one standard deviation threshold. However, others, particularly representatives of the manufacturers of new technology, have argued this threshold is too high, and that virtually no new technology would qualify for the special payment provision.

We are concerned that establishing higher payments for a great number of new technologies may be inflationary because the add-on payments reduce the efficiency incentives hospitals face when new technologies must otherwise be financed out of current payments for similar cases. Traditionally, new technologies were required to compete with existing treatment methods on clinical and cost criteria. Add-on payments are intended to give new technologies a competitive boost relative to existing treatment methods with the goal of encouraging faster and more widespread adoption of new technologies.

Much of the current variation around the mean within any particular DRG is due to the range of procedures contained within each DRG. Generally, some of these procedures will be more expensive than the mean and some will be less expensive. The threshold should be set high enough to ensure that it identifies truly high-cost technologies. If the threshold were set too low (for example, at $2,500, as some have suggested), additional technologies may qualify merely by association with a procedure only slightly more costly than the mean for the DRG.

For example, consider a DRG with five different procedures and mean charges of $15,000. The mean charges for each procedure are distributed around $15,000, as illustrated in the following table. A qualifying threshold of $2,500 would result in any new technology that is only used for the fifth procedure automatically qualifying for new technology add-on payments (unless the new technology had the unlikely effect of lowering the mean cost for cases with this procedure by at least $2,500). This is because the average charge of $20,000 for cases in this procedure already exceeds the mean charges for the DRG plus $2,500.

Procedure	Mean charge
1	$10,000
2	12,000
3	15,000
4	17,000
5	20,000

At the same time, we recognize that the very limited number of applications that have been submitted the past 2 years (five for FY 2003; two for FY 2004) may indicate that only a very small number of the new technologies that come onto the market every year are costly enough even to apply for new technology add-on payments. Therefore, for FY 2005 and subsequent Fiscal Years, we are proposing to reduce the threshold to 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 (proposed § 412.87(b)(3)).

Based on our analysis of the thresholds for FY 2004, this proposed change would reduce the average threshold across all DRGs to qualify for the add-on payments from approximately $9,900 above the mean standardized charges for each DRG to approximately $7,400. This reduction would maintain the averaging principles of the IPPS while easing the requirement somewhat to allow more technologies to qualify. Furthermore, the situation illustrated above, where a technology qualifies on the basis of its association with a high cost procedure, is much less likely to occur as a result of this reduction than if the threshold were reduced dramatically.

5. Technical Changes

Subpart H of part 412 describes payments to hospitals under IPPS. We have become aware of references to the calculation of IPPS payments in this subpart that inadvertently omit references to new technology add-on payments. For example, § 412.112(c) describes the basis for per case payments. This section refers to outlier payments under subpart F, but was not revised to reflect the implementation of the new technology add-on payments. Therefore, we are proposing to amend § 412.112(c) to add a new paragraph (d) to include a reference to additional payments for new medical services or technologies under subpart F.

Section 412.116(e) currently states that payments for outlier cases are not made on an interim basis. That is, for hospitals receiving payments under a biweekly, lump-sum payment methodology, outlier payments are not included in the calculation of the lump-sum payment amounts. Rather, outlier payments are calculated on a case-by-case basis. Similarly, due to the unique nature of the new technology add-on payments, we are proposing that they would also be calculated on a case-by-case basis rather than included in the calculation of interim payment amounts. Therefore, we are proposing to revise § 412.116(e) to include this policy.

III. Proposed 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 Metropolitan Statistical Areas (MSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs) issued by the Office of Management and Budget (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 since 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. Rural areas are areas outside a designated MSA, PMSA, or NECMA. For purposes of the wage index, we combine all of the rural counties in a State to calculate a rural wage index for that State.

We note that, effective April 1, 1990, the term Metropolitan Area (MA) replaced the term MSA (which had been used since June 30, 1983) to describe the set of metropolitan areas consisting of MSAs, PMSAs, and CMSAs. The terminology was changed by OMB in the March 30, 1990 **Federal Register** to distinguish between the individual metropolitan areas known as MSAs and the set of all metropolitan areas (MSAs, PMSAs, and CMSAs) (55 FR 12154). For

purposes of the IPPS, we will continue to refer to these areas as MSAs.

Under section 1886(d)(8)(B) of the Act, hospitals in certain rural counties adjacent to one or more MSAs are considered to be located in one of the adjacent MSAs if certain standards are met. Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification from a rural area to a MSA, one rural area to another rural area, or from one MSA to another MSA, for purposes of payment under the IPPS.

In a December 27, 2000 notice published in the **Federal Register** (65 FR 82228), the Office of Management and Budget (OMB) issued its revised standards for defining MSAs. In that notice, OMB indicated that it plans to announce in calendar year 2003 new definitions of ''Core Based Statistical Areas'' (CBSAs) based on the new standards and the Census 2000 data. The new standards establish two categories of CBSAs: (1) Metropolitan Statistical Areas (50,000 or more), and (2) Micropolitan Statistical Areas (10,000 to 49,999). After these new CBSAs are announced, we will evaluate the new area designations and their possible effects on the Medicare hospital wage index. Therefore, the earliest these new CBSA definitions would be used is the FY 2005 wage index.

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. As discussed below in section III.F. 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.

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 each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. The initial collection of these data must be completed by September 30, 2003, for application beginning October 1, 2004 (the FY 2005 wage index). In the April 4, 2003 **Federal Register** (68 FR 16516), we published a notice of intent to collect calendar year 2002 data from hospitals. There is a 60-day public comment period on that notice. After considering and responding to the comments we receive, we plan to send the surveys to all IPPS hospitals (and hospitals in Maryland that are under a waiver from the IPPS) through the fiscal intermediaries. We intend to collect these data to be incorporated in the FY 2005 wage index after notice and opportunity for public comment.

B. Proposed FY 2004 Wage Index Update

The proposed FY 2004 wage index values (effective for hospital discharges occurring on or after October 1, 2003 and before October 1, 2004) in section V. of the Addendum to this proposed rule are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2000 (the FY 2003 wage index was based on FY 1999 wage data).

The proposed FY 2004 wage index includes the following categories of data associated with costs paid under the IPPS (as well as outpatient costs), which were also included in the FY 2003 wage index:

- Salaries and hours from short-term, acute care hospitals.
- Home office costs and hours.
- Certain contract labor costs and hours.
- Wage-related costs.

Consistent with the wage index methodology for FY 2003, the proposed wage index for FY 2004 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.

C. FY 2004 Wage Index Proposals

1. Elimination of Wage Costs Associated With Rural Health Clinics and Federally Qualified Health Centers

In the FY 2001 IPPS final rule, we discussed removing from the wage index 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 (65 FR 47074). We noted that because RHC and FQHC costs were not separately reported on Worksheet S–3 of the Medicare cost report, we could not exclude these costs from the prior wage indexes. We further noted that we would evaluate the exclusion of RHC and FQHC wage data in developing the FY 2004 wage index. We now have revised Worksheet S–3 so that it allows for the separate reporting of RHC and FQHC wage costs and hours beginning with FY 2000. Therefore, as we now have the ability to exclude these costs from the wage index, beginning with the FY 2004 wage index, we are proposing to exclude the wage costs and hours data for RHCs and FQHCs from the hospital wage index calculation. An analysis of the effects of this change is included in the Appendix A of this proposed rule.

2. Paid Hours

It has been the longstanding policy of CMS to calculate the wage index using paid hours rather than hours worked (58 FR 46299). This policy reflects our belief that paid hours more appropriately reflect a hospital's total wage costs, which include amounts paid for actual time worked and for covered leave periods (for example, annual, sick, and holiday leave). Therefore, the inclusion of paid lunch hours in the wage index is consistent with our inclusion of other paid nonworking hours.

Several hospitals have requested that we exclude paid lunch or meal break hours from the wage index calculation. At these hospitals, the typical workday is 7½ working hours, plus a ½ hour paid meal break, for a total of 8 paid hours. These hospitals, some of which are municipal-owned and required by their overarching union contracts to provide paid lunch hours, believe they are disadvantaged by wage index policy that requires paid lunch hours to be included in calculating the wage index.

The hospitals argue that their practice of paying employees for meal breaks is not substantially different, in practice, from other hospitals whose employees do not receive paid lunch hours but who are on call during their lunch periods. These hospitals further argue that this policy causes them, in some cases due to union contracts beyond the hospital's control, to be the only hospitals with this category of nonproductive hours included in the wage index.

We are soliciting comments on our policy that paid lunch hours should be excluded from the wage index. Specifically, we would like a broader understanding of the issue of whether some hospitals may, in fact, be truly disadvantaged by this policy through no fault of their own. Any change in our policy would not be implemented until, at the earliest, the FY 2005 wage index.

Some hospitals and associations have also recommended that we exclude the paid hours associated with military and jury duty leave from the wage index calculation. They state that, unlike other paid leave categories for which workers are usually paid at their full hourly rates (for example, annual, sick, and holiday), hospitals typically pay employees on military or jury duty only a fraction of their normal pay. The amount that the hospital pays is intended to only supplement the earnings that the employee receives from the government, so that, while performing military or civic duties, the employee can continue to be paid the same salary level as if he or she were still working at the hospital.

The hospitals and associations believe that including the lower pay rates associated with employees' military and jury duty leave unfairly decreases a hospital's average hourly wage and, therefore, its wage index value. Therefore, we are proposing to exclude from the wage index the paid hours associated with military and jury duty leave, beginning with the FY 2005 wage index. The associated salaries would continue to be reported on Worksheet S–3, Part II, Line 1 of the Medicare cost report.

D. Verification of Wage Data From the Medicare Cost Reports

The data for the proposed FY 2004 wage index were obtained from Worksheet S–3, Parts II and III of the FY 2000 Medicare cost reports. The data file used to construct the proposed wage index includes FY 2000 data submitted to us as of February 18, 2003. 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. Some unresolved data elements are included in the calculation of the proposed FY 2004 wage index, pending their resolution before calculation of the final FY 2004 wage index. We instructed the intermediaries to complete their verification of questionable data elements and to transmit any changes to the wage data no later than April 4, 2003. We believe all unresolved data elements will be resolved by the date the final rule is issued. The revised data will be reflected in the final rule.

Also, as part of our editing process, we removed data for 110 hospitals that failed edits. We identified 72 hospitals with incomplete or inaccurate data resulting in zero or negative, or otherwise aberrant, average hourly wages. Therefore, wage data from these hospitals were removed from the calculation. We have notified the fiscal intermediaries of these hospitals and will continue to work with the fiscal intermediaries to correct these data whenever possible. As a result, the proposed FY 2004 wage index is calculated based on FY 2000 wage data for 4,593 hospitals.

In constructing the proposed FY 2004 wage index, we include the wage data for facilities that were IPPS hospitals in FY 2000, even for those facilities that have terminated their participation in the program as hospitals or have since been designated as a critical access hospital (CAH), 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 received correspondence suggesting that the wage data for hospitals that have subsequently been redesignated as CAHs should be removed from the wage index calculation because CAHs are unique compared to other short-term, acute care hospitals. CAHs are limited to only 15 acute care beds. An additional 10 beds may be designated as swing-beds, but only 15 beds can be used at one time to serve acute care patients. CAHs tend to be located in isolated, rural areas. We solicit comment on whether we should exclude wage data from such hospitals from the wage index calculation. However, we have included the data for CAHs in the proposed FY 2004 wage index if the CAH was paid under the IPPS during FY 2000.

E. Computation of the Proposed FY 2004 Wage Index

The method used to compute the proposed FY 2004 wage index follows:

Step 1—As noted above, we based the proposed FY 2004 wage index on wage data reported on the FY 2000 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, 1999 and before October 1, 2000. In addition, we included data from some hospitals that had cost reporting periods beginning before October 1999 and reported a cost reporting period covering all of FY 2000. 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 2000 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2000 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 1999 and before October 1, 2000), 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. We have removed the wage data of CAHs, after the effective date of the CAH designation, from the calculation of the proposed wage index.

Step 2—Salaries—Beginning with the FY 2003 wage index, the method used to compute a hospital's average hourly wage excludes all GME and CRNA costs.

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, and 6, 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 on Line 4. 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, 9.01, 9.02, 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, 6, 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, 6, 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, 1999 through April 15, 2001 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
10/14/1999	11/15/1999	1.06794
11/14/1999	12/15/1999	1.06447
12/14/1999	01/15/2000	1.06083
01/14/2000	02/15/2000	1.05713
02/14/2000	03/15/2000	1.05335
03/14/2000	04/15/2000	1.04954
04/14/2000	05/15/2000	1.04571
05/14/2000	06/15/2000	1.04186
06/14/2000	07/15/2000	1.03786
07/14/2000	08/15/2000	1.03356
08/14/2000	09/15/2000	1.02898
09/14/2000	10/15/2000	1.02425
10/14/2000	11/15/2000	1.01953
11/14/2000	12/15/2000	1.01482
12/14/2000	01/15/2001	1.01004
01/14/2001	02/15/2001	1.00509
02/14/2001	03/15/2001	1.00000
03/14/2001	04/15/2001	0.99491

For example, the midpoint of a cost reporting period beginning January 1, 2000 and ending December 31, 2000 is June 30, 2000. An adjustment factor of 1.03786 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 2000 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. Annualization is accomplished by dividing the data by the number of days in the cost report and then multiplying the results by 365.

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 $24.5439.

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 $11.5431 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 Pub. L. 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 prospective payment system payments are not greater or less than those that would have been made in the year if this section did not apply. For FY 2004, this change affects 141 hospitals in 44 MSAs. The MSAs affected by this provision are identified by a footnote in Table 4A in the Addendum of this proposed rule.

F. Proposed 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 can elect to reclassify for the wage index or the standardized amount, or both, and as individual hospitals or as rural groups. 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. Hospitals must apply for reclassification to the MGCRB, which 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 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 Pub. L. 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 at § 412.235.

Section 1886(d)(8)(B) of the Act permits a hospital located in a rural county adjacent to one or more urban areas to be designated as being located in the MSA to which the greatest number of workers in the county commute (1) If the rural county would otherwise be considered part of an urban area under the standards published in the **Federal Register** for designating MSAs (and for designating NECMAs), and (2) if the commuting rates used in determining outlying counties (or, for New England, similar recognized area) 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 meet these criteria are deemed urban for purposes of the standardized amounts and for purposes of assigning the wage index.

Revised MSA standards were published in the December 27, 2000 **Federal Register** (65 FR 82228). We are working with the Census Bureau to compile a list of hospitals that meet the new standards based on the 2000 census data; however, that work is not yet complete. Therefore, for purposes of calculating the proposed wage indexes in this proposed rule, we used the list of qualifying hospitals based on the 1990 MSA standards.

However, if the updated list of hospitals meeting the new standards based on the 2000 census data is available in time, we will incorporate it in the final rule to be published by August 1, 2003. To the extent hospitals otherwise reclassified by the MGCRB for FY 2004 are adversely affected by their inclusion on or exclusion from the new list, we will address this in the final rule. Among the options we may consider in the final rule to address situations where hospitals may be adversely affected are: Assigning adversely affected hospitals the highest applicable wage index; or extending the opportunity for adversely affected hospitals to withdraw from a reclassification by the MGCRB for FY 2004.

2. Effects of Reclassification

The methodology for determining the wage index values for redesignated hospitals is applied jointly to the hospitals located in those rural counties that were deemed urban under section 1886(d)(8)(B) of the Act and those hospitals that were reclassified as a result of the MGCRB decisions under section 1886(d)(10) of the Act. 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. Therefore, as provided in section 1886(d)(8)(C) of the Act,[3] 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.
- 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.

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

[3] Although section 1886(d)(8)(C)(iv)(I) of the Act also provides that the wage index for an urban area may not decrease as a result of redesignated 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 Public Law 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 hospital is reclassified (subject to the rules described above) and the wage index calculation of the urban area where the hospital is physically located.

The proposed wage index values for FY 2004 are shown in Tables 4A, 4B, 4C, and 4F in the Addendum to this proposed rule. Hospitals that are redesignated should 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, and those areas have hospitals from more than one State reclassified into them.

Tables 3A and 3B in the Addendum of this proposed rule list the 3-year average hourly wage for each labor market area before the redesignation of hospitals, based on FYs 1998, 1999, and 2000 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 proposed rule includes the adjusted average hourly wage for each hospital from the FY 1998 and FY 1999 cost reporting periods, as well as the FY 2000 period used to calculate the proposed FY 2004 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.

At the time this proposed wage index was constructed, the MGCRB had completed its review of FY 2004 reclassification requests. We have included in this proposed rule Table 9, 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 hospitals reclassified for FY 2004 by the MGCRB (73 for wage index, 66 for the standardized amount, and 33 for both the wage index and the standardized amount), as well as hospitals that were reclassified for the wage index in either FY 2002 (476) or FY 2003 (56) 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 designated rural in accordance with section 1886(d)(8)(E) of the Act (14). In addition, it includes rural hospitals redesignated to an urban area under section 1886(d)(8)(B) of the Act for purposes of the standardized amount and the wage index (42).

Under § 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of this proposed rule in the **Federal Register**. Similarly, hospitals may terminate an existing 3-year reclassification within 45 days of the publication of this 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 2003 must be received by the MGCRB within 45 days of the publication of this 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).

Any changes to the wage index that result from withdrawals of requests for reclassification, wage index corrections, appeals, and the Administrator's review process will be incorporated into the wage index values published in the final rule following this proposed rule. Therefore, the final wage indexes will likely be different from those published in this proposed rule, and, in some cases, they may be quite different. Although, as described above, the statute provides that a reclassified rural hospital may not have a lower wage index after reclassification than before, there is no similar protection for urban hospitals. Therefore, hospitals should carefully evaluate the impacts of their reclassifications prior to the deadline for withdrawing from an approved reclassification.

Applications and other information about MGCRB reclassifications may be obtained via the CMS internet Web site at *http://cms.hhs.gov/providers/prrb/mgcinfo.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.

As noted previously, OMB plans to announce new definitions of CBSAs by the middle of this year, and the earliest these new CBSA definitions would be used for the wage index is FY 2005. Applications for reclassification by the MGCRB for FY 2005 will be due by September 2, 2003. However, by that time, we will not have completed our analysis of the new CBSAs. Therefore, hospitals submitting applications for reclassification by the MGCRB for FY 2005 should base those applications on the current MSAs. We will assess the implications of the new CBSAs on hospitals' reclassification requests in the FY 2005 proposed rule.

G. Requests for Wage Data Corrections

The preliminary wage data file was made available on January 10, 2003 (and subsequently on February 4, 2003), through the Internet on CMS's Web site at *http://www.cms.hhs.gov/providers/hipps/default.asp*. In a memorandum dated December 31, 2002, 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 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 February 17, 2003 (this deadline was initially announced as February 10, 2003, but was changed due to the need to repost some of the data). 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 December 31, 2002 memorandum referenced above.

After reviewing requested changes submitted by hospitals, fiscal intermediaries transmitted any revised cost reports to CMS and forwarded a copy of the revised Worksheet S–3, Parts II and III to the hospitals by April 4, 2003. In addition, fiscal intermediaries were to notify hospitals of the changes or the reasons that changes were not accepted. These deadlines are necessary to allow sufficient time to review and process the data so that the final wage index

calculation can be completed for the development of the final FY 2004 prospective payment rates to be published by August 1, 2003.

If a hospital disagreed with the fiscal intermediary's resolution of a policy issue (for example, whether a general category of cost is allowable in the wage data), the hospital could have contacted CMS in an effort to resolve the issue. We note that the April 4, 2003 deadline also applied to these requests. Requests were required to be sent to CMS at the address below (with a copy to the hospital's fiscal intermediary). The request must have fully documented all attempts by the hospital to resolve the dispute through the process described above, including copies of relevant correspondence between the hospital and the fiscal intermediary. During review, we do not consider issues such as the adequacy of a hospital's supporting documentation, as we believe that fiscal intermediaries are generally in the best position to make evaluations regarding the appropriateness of these types of issues (which should have been resolved earlier in the process).

Hospitals should also examine Table 2 in the Addendum to this proposed rule to verify their data. Table 2 contains each hospital's adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2000 data used to construct the proposed FY 2004 wage index. We note that the hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data and transmitted to CMS prior to February 18, 2003.

We will release a final wage data file in May 2003 to hospital associations and the public on the Internet at *http://www.cms.hhs.gov/providers/hipps/default.asp.* The May 2003 public use file will be 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 4, 2003). If, after reviewing the May 2003 final file, a hospital believes that its wage data are incorrect due to a fiscal intermediary or CMS error in the entry or tabulation of the final wage data, it should send a letter to both its fiscal intermediary and CMS that outlines why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error).

CMS and the fiscal intermediaries must receive these requests no later than June 6, 2003. Requests mailed to CMS should be sent to: Centers for Medicare & Medicaid Services, Center for Medicare Management, Attention: Wage Index Team, Division of Acute Care, C4–07–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Each request also must be sent to the hospital's fiscal intermediary. The intermediary will review requests upon receipt and contact CMS immediately to discuss its findings.

At this point in the process, that is, after the release of the May 2003 wage index file, changes to the hospital wage data will only be 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 will approve 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 4, 2003.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 2003 wage data file.
- Requests to revisit factual determinations or policy interpretations made by the intermediary or CMS during the wage data correction process.

Verified corrections to the wage index received timely (that is, by June 6, 2003) will be incorporated into the final wage index in the final rule to be published by August 1, 2003, and to be effective October 1, 2003.

We have created the process described above to resolve all substantive wage data correction disputes before we finalize the wage data for the FY 2004 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)).

Again, we believe the wage 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 will have access to the final wage data by early May 2003, they will have the opportunity to detect any data entry or tabulation errors made by the fiscal intermediary or CMS before the development and publication of the FY 2004 wage index by August 1, 2003, and the implementation of the FY 2004 wage index on October 1, 2003. If hospitals avail themselves of this opportunity, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified after that date, 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 that the intermediary or CMS made an error in tabulating its data. 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, the requesting hospital must 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 2004 wage index. As indicated earlier, since a hospital will have the opportunity to verify its data, and the fiscal intermediary will notify 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.

H. Modification of the Process and Timetable for Updating the Wage Index

Although the wage data correction process described in section III.G. of this preamble has proven successful in the past for ensuring that the wage data used each year to calculate the wage indexes are generally reliable and accurate, we continue to be concerned about the growing volume of wage data revisions initiated by hospitals after the release of the first public use file in February. This issue has been discussed previously in the FY 1998 IPPS proposed rule (62 FR 29918) and in the FY 2002 IPPS proposed rule (66 FR 22682). In each discussion, we describe the increasing number of revisions to wage data between the proposed rule and the final rule.

Currently, the fiscal intermediaries are required to conduct initial desk reviews on or before November 15 in advance of the preparation of the preliminary wage data public use file in early January (see Program

Memorandum A–02–94, October 4, 2002). Furthermore, they are required to address items that fall outside the established thresholds. This may involve further review of the supplementary documentation or contacting the hospital for additional documentation. In addition, fiscal intermediaries are required to notify State hospital associations regarding hospitals that fail to respond to issues raised during the desk review. These actions are to be completed in advance of sending the data to CMS to prepare the preliminary wage data public use file in early January. However, as we have indicated in prior **Federal Register**s, as much as 30 percent of hospitals subsequently request revisions to their data after the preliminary wage data file is made available.

This high volume of revisions results in an additional workload for the fiscal intermediaries. In particular, much of a fiscal intermediary's efforts prior to submitting the data to prepare the preliminary public use file may be in vain if the hospital subsequently revises all of its data prior to the early February deadline (which is the hospital's right at that point). Therefore, we are proposing to modify the process to release the preliminary wage data file prior to requiring the fiscal intermediaries to conduct their initial desk reviews on the data. This unaudited data would be available on the Internet by early October rather than early January. Hospitals would review this file to ensure it contains their correct data as submitted on their cost reports and request any changes by early November. At that time, the fiscal intermediaries would review the revision requests and conduct desk reviews of the data including all approved changes.

Under this proposed revised timetable, the fiscal intermediaries would notify 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 would also submit the revisions to CMS in early February. Hospitals would then have until early March to submit requests to the fiscal intermediaries for reconsideration of adjustments made by the fiscal intermediaries as a result of the desk review. Other than requesting reconsideration of desk review adjustments, hospitals would not be able to submit new requests for additional changes that were not submitted by early November. By early April, the fiscal intermediaries would notify all hospitals of their decisions regarding the hospitals' requests to reconsider desk review adjustments and submit all of the revised wage data to CMS. From this point (early April) until the publication of the final rule, the process would be identical to the current timetable. Similar to the current timetable, hospitals would also have the opportunity in early April to request CMS consideration of policy disputes.

We believe that the proposed revision of the schedule would improve the quality of the wage index by initiating hospitals' review of their data sooner and allowing the fiscal intermediaries to focus their reviews on the final data submitted by hospitals to be included in the wage index. In addition, we would receive the revised data in time to incorporate them into the wage indexes published in the proposed rule, resulting in fewer changes from the proposed rule to the final rule. This will improve the ability of hospitals to assess whether they should request a withdrawal from a MGCRB reclassification. Because the decision of whether to withdraw a wage index reclassification must be made prior to publication of the final rule, this proposed schedule should decrease the likelihood that the final wage index will be dramatically different from the proposed wage index.

The following table illustrates the proposed timetable that would be applicable for the development of the FY 2005 wage index:

Timeframe	Steps in wage index development process
Early October	Preliminary and unaudited wage data file published as a public use file (PUF) on CMS Web site.
Early November	Deadline for hospitals to send requests for revisions to the fiscal intermediaries.
Early February	Fiscal intermediaries review revisions and desk review wage data; notify hospitals of changes and resolution of revision requests; and submit preliminary revised data to CMS.
Early March	Deadline for hospitals to request wage data reconsideration of desk review adjustments and provide adequate documentation to support the request.
Early April	Deadline for the fiscal intermediaries to submit additional revisions resulting from the hospitals' reconsideration requests. This is also the deadline for hospitals to request CMS intervention in cases where the hospital disagrees with the fiscal intermediary's policy interpretations.
Early May*	Release of final wage data PUF on CMS Web site.
Early June*	Deadline for hospitals to submit correction requests, to both CMS and their fiscal intermediary, for errors due to the mishandling of the final wage data by CMS or the fiscal intermediary.
August 1*	Publication of the final rule.
October 1*	Effective date of updated wage index.

*Indicates no change from prior years.

IV. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs

A. Transfer Payment Policy (§ 412.4)

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.

1. Transfers to Another Acute Care Hospital (§ 412.4(b))

Medicare adopted its IPPS transfer policy because, if we 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 their 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.

Currently, when a patient chooses to depart from a hospital against the medical opinion of treating physicians, the case is 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 are assumed not to involve the active participation of the hospital administration, our policy has been to treat LAMA cases as discharges. This policy applies even if the patient is admitted to another hospital on the date of the LAMA discharge. Consequently, we currently make a full DRG payment for any discharge coded as a LAMA case.

However, we are concerned that some hospitals may be incorrectly coding transfers as LAMA cases. The Office of Inspector General (OIG) issued a report in March 2002 (A–06–99–00045), asserting that of the approximately 60,000 LAMA discharges annually, 1,500 patients were subsequently admitted to another IPPS hospital the same day. The OIG performed a detailed review of the medical records at selected hospitals and found evidence that the hospitals actively participated in transferring the patients to a different IPPS hospital, yet the hospital coded the claim as a LAMA. OIG cited several examples of these cases:

''In the first example, the transferring hospital did not have an inpatient room available for the patient, who had been in the emergency room for 24 hours. The medical record showed that the treating physician contacted another PPS hospital to determine whether the hospital could accept the patient. Specifically, the medical record stated: 'Upon request of the patient, [hospital name] was contacted since there is a good possibility of transferring patient to [name of hospital]. At present, he has been in emergency room for 24 hours waiting for a bed.' ''

In this example, despite the overt participation of the physician in securing the admission to the other IPPS hospital and the fact that the transferring hospital did not have an inpatient room available for the patient, the claim was submitted as a LAMA discharge, rather than as a transfer to another IPPS hospital.

''In the second example, the patient was brought to the first hospital by ambulance. Subsequently, the patient's family indicated that they wanted a neurologist at another hospital to render the treatment needed by the patient. The attending physician contacted the neurologist in order to determine if the neurologist would accept, admit, and treat the patient. The medical record contained ample evidence of knowledge and participation of the transferring hospital, and the discharge should have been reported as a PPS transfer. Specifically, the medical record stated: 'Patient's family wanted to sign the patient out against medical advice and take her to [name of hospital]. The physician spoke with the neurologist at [name of hospital], who agreed to accept the patient. The patient's family signed the patient discharged against medical advice. All the risks of self-discharge were explained.' ''

In this case, although the medical record indicated the patient wanted to leave against medical advice, there is also evidence that the patient's attending physician at the hospital participated in the transfer to another IPPS hospital. While we do not wish to discourage such participation and cooperation in cases where a transfer occurs, this situation would seem almost indistinguishable from other transfer situations. For instance, we have long recognized situations where patients are transferred from a rural hospital to an urban hospital for a surgical procedure, then back to the rural hospital to complete the recuperative care, as appropriate transfer situations as long as the transfers are medically appropriate. In such a case, the rural hospital would receive a payment under the transfer policy for the first portion of the stay, the urban hospital would also receive payment under the transfer policy for the care it provided, and the rural hospital would receive a full DRG payment as the discharging hospital for the recuperative care it provided upon the patient's return from the urban hospital. In such situations, each portion of the stay may be assigned a different DRG.

Therefore, we are proposing to expand 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.

Although we considered proposing a policy that would be based on whether the hospital actively participated in the transfer, and exempting from the transfer definition cases where the hospital had absolutely no knowledge that the patient intended to go to another hospital, we are not proposing such a policy for two reasons. First, it would be difficult to administer equitably a policy that required a determination as to whether the hospital or the physician had knowledge of the patient's intentions. Such a policy would require fiscal intermediaries to make a difficult judgment call in many cases. Second, if we were to base the determination of whether a case is a transfer on the level of involvement of the hospital and the physician caring for the patient, we would be creating a financial disincentive to hospitals for ensuring an efficient and cooperative transfer once a decision has been made by the patient or the patient's family to leave the hospital.

We recognize that, in some cases, a hospital cannot know the patient will go to another hospital. However, we note the claims processing system can identify cases coded as discharges where the date of discharge matches the admission date at another hospital. In these cases, the fiscal intermediary will notify the hospital of the need to submit an adjustment claim. However, if the hospital can present documentation showing that the patient's care associated with the admission to the hospital was completed before discharge, consistent with our current policy, the transfer policy will not be applied.

2. Technical Correction

Section 412.4(b)(2) defines a discharge from one inpatient area of the hospital to another area of the hospital as a transfer. Although this situation may be viewed as an intrahospital transfer, it does not implicate the transfer policy under the IPPS. Therefore, to avoid confusion and to be

consistent with the proposed changes to § 412.4(b) described at section IV.A.3. of this preamble, we are proposing to delete existing § 412.4(b)(2) from the definition of a transfer.

3. Expanding the Postacute Care Transfer Policy to Additional DRGs (§§ 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 requires 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. Also, 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 the following DRGs to be subject to the special 10 DRG transfer rule:

- DRG 14 (Intracranial Hemorrhage and Stroke with Infarction (formerly ''Specific Cerebrovascular Disorders Except Transient Ischemic Attack''));
- DRG 113 (Amputation for Circulatory System Disorders Except Upper Limb and Toe);
- DRG 209 (Major Joint Limb Reattachment Procedures of Lower Extremity);
- DRG 210 (Hip and Femur Procedures Except Major Joint Procedures Age >17 With CC);
- DRG 211 (Hip and Femur Procedures Except Major Joint Procedures Age >17 Without CC);
- DRG 236 (Fractures of Hip and Pelvis);
- DRG 263 (Skin Graft and/or Debridement for Skin Ulcer or Cellulitis With CC);
- DRG 264 (Skin Graft and/or Debridement for Skin Ulcer or Cellulitis Without CC);
- DRG 429 (Organic Disturbances and Mental Retardation); and
- DRG 483 (Tracheostomy With Mechanical Ventiliation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses (formerly ''Tracheostomy Except for Face, Mouth, and Neck Diagnoses'')).

Similar to the policy for transfers between two acute care hospitals, the transferring hospital in a postacute care transfer for 7 of the 10 DRGs receives twice the per diem rate the first day and the per diem rate for each following day of the stay before the transfer, up to the full DRG payment. However, 3 of the 10 DRGs exhibit a disproportionate share of costs very early in the hospital stay in postacute care transfer situations. For these 3 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. This is consistent with section 1886(d)(5)(J)(i) of the Act, which recognizes that in some cases ''a substantial portion of the costs of care are incurred in the early days of the inpatient stay.''

Section 1886(d)(5)(J)(iv) of the Act authorizes the Secretary to expand the postacute transfer policy beyond 10 DRGs. In the May 9, 2002 IPPS proposed rule, we discussed the possibility of expanding this policy to either all DRGs or a subset of additional DRGs (we identified 13 additional DRGs in that proposed rule) (67 FR 31455). However, as discussed further in the August 1, 2002 final rule (65 FR 50048), we did not expand the postacute transfer provision to additional DRGs for FY 2003. The commenters on the options in the May 9, 2002 proposed rule raised many issues regarding the impact of expanding this policy that we needed to consider further before proceeding. In particular, due to the limited time between the close of the comment period and the required publication date of August 1, we were unable to completely analyze and respond to all of the points that were raised. We indicated that we would continue to conduct research to assess whether further expansion of this policy may be warranted and, if so, how to design any such refinements.

Many commenters on the May 9, 2002 proposed rule argued that, in a system based on averages, expansion of the postacute care transfer policy negatively influences, and in fact penalizes, hospitals for efficient care. They claimed that this policy indiscriminately penalizes hospitals for efficient treatment and for ensuring that patients receive the right care at the right time in the right place. They believed that the postacute care transfer provision creates an inappropriate incentive for hospitals to keep patients longer.

Commenters also expressed concern that the expansion of the transfer provision violates the fundamental principle of the IPPS. The DRG system is based on payments that will, on average, be adequate. These commenters argued that expansion of the postacute care transfer policy would give the IPPS a per-diem focus and would mean that hospitals would be paid less for shorter than average lengths of stay, although they would not be paid more for the cases that are longer than average (except for outlier cases).

We agree that the transfer policy should not hamper the provision of effective patient care, and any future expansion must consider both the need to reduce payments to reflect cost-shifting due to reductions in length of stay attributable to early transfers to postacute care and the need to ensure that payments, on average, remain adequate to ensure effective patient care. Therefore, we have assessed the extent to which the current postacute transfer policy balances these objectives.

The table below displays the results of our analysis. We first examined whether the 10 DRGs included in the policy continue to exhibit a relatively high percentage of cases transferred to postacute care settings, particularly

among cases with lengths of stay shorter than the geometric mean for the DRG (these cases would be affected by the reduced payments for transfers). The table shows that these DRGs continue to contain high percentages of cases transferred to postacute care settings similar to those we reported in the FY 1999 final rule (63 FR 40975). These results would appear to demonstrate that the postacute transfer policy has not greatly altered hospitals' treatment patterns for these cases.

This similarity in treatment patterns is further evidenced by the fact that, for 6 of the 10 DRGs, the geometric mean length of stay has continued to decline in the 5 years since the policy was implemented. Accordingly, hospitals have continued to transfer many patients in these DRGs before the mean length of stay, despite the transfer policy. As we stated in the July 31, 1998 final rule, the transfer provision adjusts payments to hospitals to reflect the reduced lengths of stay arising from the shift of patient care from the acute care setting to the postacute setting (63 FR 40977). This policy does not require a change in physician clinical decisionmaking nor in the manner in which physicians and hospitals practice medicine: it simply addresses the appropriate level of payments once those decisions have been made.

With respect to whether this policy alters the fundamental averaging principles of the IPPS, we believe the current policy, which targets specific DRGs where evidence shows hospitals have aggressively moved care to postacute care settings, does not alter the averaging principles of the system. In fact, it could be said to enhance those principles because a transfer case is counted as only a fraction of a case toward DRG recalibration based on the ratio of its transfer payment to the full DRG payment for nontransfer cases. This methodology ensures the DRG weight calculation is consistent with the payment policy for transfer cases. The last column of the table below indicates that all but three of these DRGs have experienced increases in DRG weights since the policy was implemented. By reducing the contribution of transfer cases to the calculation of the DRG average charge, the relative weights (the result of dividing the DRG average charge by the national average charge per case) are higher than they would otherwise be. This is because transfers, particularly short-stay transfers, have lower total charges, on average.

DRG	DRG title	All transfer cases	Percent of all cases transferred to postacute care setting	Percent of all cases transferred prior to mean length of stay	Percent change in mean length of stay FYs 92–98	Percent change in mean length of stay FYs 98–03	Percent change in DRG relative weight FYs 98–03
14	Intracranial Hemorrhage and Stroke with Infarction.	143,649	48.88	11.74	−29.17	−5.88	8.53
113	Amputation for Circulatory System Disorders Except Upper Limb and Toe.	24,470	66.57	30.12	−32.17	7.22	9.21
209	Major Joint and Limb Reattachment Procedures of Lower Extremity.	244,969	66.66	19.76	−47.52	−15.09	−8.09
210	Hip and Femur Procedures Except Major Joint Age >17 With CC.	87,253	76.26	35.67	−42.98	−6.15	0.1
211	Hip and Femur Procedures Except Major Joint Age >17 Without CC.	20,239	72.38	15.89	−44.44	−8.00	1.39
236	Fractures of Hip and Pelvis	26,583	69.86	11.20	−34.85	−6.98	−1.43
263	Skin Graft and/or Debridement for Skin Ulcer or Cellulitis with CC.	13,158	62.00	31.35	−41.45	4.49	9.36
264	Skin Graft and/or Debridement for Skin Ulcer or Cellulitis Without CC.	1,759	49.97	18.81	−37.21	1.85	5.36
429	Organic Disturbances and Mental Retardation.	30,349	53.25	15.22	−28.95	−12.96	−5.27
483	Tracheostomy With Mechanical Ventilation 96 + Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses.	21,818	52.93	27.34	−15.29	2.37	1.38

After determining the current 10 DRG postacute care transfer policy appears to be appropriately balancing the objectives to reduce payments to reflect cost-shifting due to reductions in length of stay attributable to early postacute care transfers and to ensure that payments, on average, remain adequate to ensure effective patient care, we once again undertook the analysis to identify additional DRGs to which the policy may be expanded. However, it should be noted that, at this time, we have decided not to expand the policy to all DRGs. Although we still believe expanding the postacute care transfer policy to all DRGs might be the most equitable approach because a policy that is limited to certain DRGs may result in disparate payment treatment across hospitals, at this time, we believe an incremental expansion is appropriate. That is, we believe further analysis is necessary to assess whether it would be appropriate to apply a reduced payment for postacute care transfers across all DRGs. In particular, it is important to attempt to distinguish between DRGs where the care is increasingly being shifted to postacute care sites versus DRGs where some patients have always been discharged to postacute care early in the stay. For the latter DRGs, it may not be appropriate to reduce payment for these DRGs if the base payment already reflects a similar postacute care utilization rate (for example, in these cases there would be no cost shifting).

As described below, we have identified an additional 19 DRGs, based on declining mean lengths of stay and high percentages of postacute transfers, for which an expansion of the current policy appears warranted.

MedPAC has also conducted analysis on the current postacute care transfer policy. Most recently, in its March 2003 Report to Congress, MedPAC recommended adding 13 additional DRGs to the 10 DRGs covered under the current policy (page 46). The 13 DRGs were the same DRGs included in one of our proposals to expand the postacute care transfer policy in last year's IPPS proposed rule. MedPAC did not recommend expanding the policy to include all DRGs at this time, noting

that this expansion might reduce payments to some hospitals by as much as 4 percent. Rather, it suggested evaluating the impact of a limited expansion before extending the policy to more DRGs.

MedPAC's report cites several reasons for expanding the postacute care transfer policy beyond the current 10 DRGs. First, it notes the continuing shifts in services from the acute care setting to the postacute care setting. Second, the report points to different postacute care utilization for different hospitals, particularly based on geographic location. Third, the report states: ''the expanded transfer policy provides a better set of incentives to protect beneficiaries from potential premature discharge to postacute care.'' Fourth, MedPAC notes that the policy improves payment equity across hospitals by: Reducing payments to hospitals that transfer patients to postacute care while making full payments to hospitals that provide all of the acute inpatient services in an acute care setting; and maintaining more accurate DRG weights that reflect the true resource utilization required to provide the full course of acute inpatient care, as distinguished from the partial services provided to patients who are transferred to postacute care.

Since the publication of last year's rule, we have conducted an extensive analysis to identify the best method by which to expand the postacute care transfer policy. Similar to the analysis used to identify the current 10 DRGs, we are proposing to identify DRGs with high postacute care transfer rates and at least 14,000 transfer cases. However, rather than ranking DRGs on the basis of the percentage of all postacute care transfers, we are proposing to rank DRGs on the basis of the percentage of postacute care transfers occurring before the DRG geometric mean length of stay. This is because only transfers that occur before the geometric mean length of stay, minus one day due to the policy that hospitals receive double the per diem for the first day, are impacted by the transfer policy. In order to focus on those DRGs where this policy would have the most impact, we are proposing to include only DRGs where at least 10 percent of all cases that were transferred to postacute care before the geometric mean length of stay. The next proposed criterion is to identify DRGs with at least a 7-percent decline in length of stay over the past 5 years (from FY 1998 to FY 2003). This criterion would focus on those DRGs for which hospitals have been most aggressively discharging patients sooner into postacute care settings. Finally, we are proposing to include only DRGs with a geometric mean length of stay of at least 3 days because the full payment is reached on the second day for a DRG with a 3-day length of stay.

Using these criteria, we have identified 19 additional DRGs to include in the postacute care transfer policy. However, some of the 13 DRGs proposed last year (and included in MedPAC's proposed expansion) are not included in this proposed rule. For example, DRGs 79 and 80 (Respiratory Infections and Inflammations Age >17 With and Without CC, respectively) were included in last year's proposed expansion but are not included in this proposed rule for FY 2004. DRGs 79 and 80 are excluded from this proposed rule because they did not exhibit a decline in length of stay of at least 7 percent over the past 5 years.

We note that 7 of these 19 DRGs are paired DRGs (that is, they contain a CC and no-CC split). Because these DRGs are paired DRGs (that is, the only difference in the cases assigned to DRG 130, for example, as opposed to DRG 131 is that the patient has a complicating or comorbid condition), we are proposing to include both DRGs under this expanded policy. If we were to include only DRG 130 in the transfer policy, there would be an incentive for hospitals not to include any code that would identify a complicating or comorbid condition, so that a transfer case would be assigned to DRG 131 instead of DRG 130.

Using the selection criteria described above, we identified the following 19 DRGs that we are proposing to include under the postacute care transfer policy (in addition to the 10 DRGs already subject to the policy).

DRG	DRG title	All transfer cases	Percent of all cases transferred to postacute care setting	Percent of cases transferred prior to mean length of stay	Percent change in mean length of stay FYs 1992–1998	Percent change in mean length of stay FYs 1998–2003
12	Degenerative Nervous System Disorders	39,034	54.13	13.10	−21.74	−12.00
24	Seizure and Headache Age >17 With CC	19,239	35.67	11.63	−20.75	−7.69
25	Seizure and Headache Age >17 Without CC	4,738	19.15	2.15	−14.29	−10.71
89	Simple Pneumonia and Pleurisy Age > 17 With CC	175,441	34.86	11.37	−18.31	−11.11
90	Simple Pneumonia and Pleurisy Age >17 Without CC	9,544	20.86	2.82	−20.37	−15.00
121	Circulatory Disorders With AMI and Major Complication, Discharged Alive.	79,242	52.52	20.46	−21.95	−11.67
122	Circulatory Disorders With AMI Without Major Complications Discharged Alive.	33,028	48.91	24.09	−26.67	−23.08
130	Peripheral Vascular Disorders With CC	31,106	37.78	14.27	−13.11	−11.76
131	Peripheral Vascular Disorders Without CC	5,723	23.08	5.42	−4.44	−19.51
239	Pathological Fractures and Musculoskeletal and Connective Tissue Malignancy.	23,188	53.54	21.96	−22.67	−7.55
243	Medical Back Problems	36,772	41.49	13.61	−14.00	−7.50
277	Cellulitis Age >17 With CC	35,015	37.77	14.03	−21.43	−7.84
278	Cellulitis Age >17 Without CC	6,526	22.05	3.11	−18.87	−10.00
296	Nutritional and Miscellaneous Metabolic Disorders Age >17 With CC.	104,216	40.05	11.88	−21.67	−9.30
297	Nutritional and Miscellaneous Metabolic Disorders Age >17 Without CC.	12,649	28.03	2.17	−17.50	−10.00
320	Kidney and Urinary Tract Infectious Age >17 With CC	77,669	44.64	12.40	−23.88	−8.51
321	Kidney and Urinary Tract Infections Age >17 Without CC	8,610	29.90	5.67	−20.41	−13.89
462	Rehabilitation	147,211	56.59	22.69	−22.54	−11.43
468	Extensive O.R. Procedure Unrelated to Principal Diagnosis	24,783	44.51	18.53	−20.30	−7.07

We are proposing to revise § 412.4(d) to incorporate these additional 19 DRGs as qualifying DRGs for transfer payments and to make a conforming change to § 412.4(c).

We also examined whether any of these DRGs would qualify for the alternative payment methodology of 50 percent of the full DRG payment plus 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 specified in existing regulations under § 412.4(f). To identify the DRGs that might qualify, the average charges for all cases with a length of stay of 1 day were compared to the average charges of all cases in a particular DRG. To qualify for the alternative methodology, the average charges of 1-day discharge cases must be at least 50 percent of the average charges for all cases in the DRG.

Based on this analysis, we determined that 5 out of the 19 DRGs would qualify for this payment method (DRGs 25, 122, 131, 297, and 321). However, the fact that the average charges of 1-day stays equal at least 50 percent of the average charges for all cases in these DRGs is due to the very short lengths of stay for these DRGs. Therefore, we do not believe that it is necessary to include them in the alternative payment methodology. For example, for a DRG with a 3-day geometric mean length of stay, full DRG payment will be met on the second day of the stay, regardless of which payment methodology is used. Therefore, we are proposing that none of the 19 additional DRGs that we are proposing to add to the postacute care transfer policy would be paid under the alternative payment methodology.

We also have analyzed the 10 DRGs that are currently subject to the postacute care transfer policy. Of the three DRGs that are receiving payments under the special payment (transfers after 1 day incur charges equal to at least 50 percent of the average charges for all cases). Unlike the five DRGs that would otherwise meet this criterion, the geometric mean lengths of stay of both DRG 209 and 211 are over 4 days. In addition, DRG 210 is currently paid under the special payment methodology, but our current analysis indicates average charges for one day stays are less than 50 percent of the average charges for all cases in the DRG. Nonetheless, DRG 210 is a paired with DRG 211, which meets the criteria. Therefore, we are proposing DRG 210 will continue to be paid under the special payment methodology. Similar to our rationale for including both paired DRGs when one qualifies for inclusion in the postacute care transfer policy, we are including both DRGs in this pair under the special payment methodology. Accordingly, we are proposing that only DRGs 209, 210, and 211 that are currently paid under the alternative transfer payment methodology would continue to be paid under this methodology.

Finally, we note that the OIG has prepared several reports that examined hospitals' compliance with proper coding of patients' discharge status as transferred under our guidelines, and has found substantial noncompliance leading to excessive payments.[4] Specifically, the OIG found hospitals submitting claims indicating the patient had been discharged when, in fact, the patient was transferred to a postacute care setting. As we indicated in the May 8, 1998 **Federal Register** (63 FR 25593), hospitals found to be intentionally engaging in such practices may be investigated for fraudulent or abusive billing practices. We intend to work with the OIG to develop the most appropriate response to ensure all hospitals become compliant with our guidelines.

B. 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 amount rather than the rural standardized amount. Although the other urban and rural standardized amounts are the same for discharges beginning with that date, rural referral centers continue to receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Rural referral centers with a disproportionate share percentage of at least 30 percent are not subject to the 5.25 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.

[4] The OIG report identification numbers are: A–04–00–02162, A–04–00–01220 and A–04–01210. A fourth report is expected out soon.

As discussed in **Federal Register** documents at 62 FR 45999 and 63 FR 26325, under section 4202 of Public Law 105–33, a hospital that was classified as a rural referral center for FY 1991 is to be considered as a rural referral center for FY 1998 and later years so long as that hospital continues to be located in a rural area and does not voluntarily terminate its rural referral center status. Effective October 1, 2000, if a hospital located in what is now an urban area was ever a rural referral center, it is reinstated to rural referral center status (65 FR 47089). 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 mean case-mix index value for FY 2004 includes all urban hospitals nationwide, and the proposed regional values for FY 2004 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 2002 (October 1, 2001 through September 30, 2002) and include bills posted to CMS' records through December 2002.

We are proposing 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, 2003, rural hospitals with fewer than 275 beds must have a case-mix index value for FY 2002 that is at least—

- 1.3374; 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 proposed 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)	1.2252
2. Middle Atlantic (PA, NJ, NY)	1.2270
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.3157
4. East North Central (IL, IN, MI, OH, WI)	1.2485
5. East South Central (AL, KY, MS, TN)	1.2511
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.1841
7. West South Central (AR, LA, OK, TX)	1.2733
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.3511
9. Pacific (AK, CA, HI, OR, WA)	1.2834

The preceding numbers will be revised in the final rule to the extent required to reflect the updated FY 2002 MedPAR file, which will contain data from additional bills received through March 31, 2002.

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. We are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2002 (that is, October 1, 2001 through September 30, 2002).

Therefore, we are proposing 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, 2003, must have as the number of discharges for its cost reporting period that began during FY 2002 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, as indicated in the following table:

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	7,476
2. Middle Atlantic (PA, NJ, NY)	8,906
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	9,497
4. East North Central (IL, IN, MI, OH, WI)	8,439
5. East South Central (AL, KY, MS, TN)	6,894
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	3,991
7. West South Central (AR, LA, OK, TX)	7,629
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,908
9. Pacific (AK, CA, HI, OR, WA)	7,021

These numbers will be revised in the final rule based on the latest available cost report data.

C. Indirect Medical Education (IME) Adjustment (§ 412.105) and Disproportionate Share Hospital (DSH) Adjustment (§ 412.105)

1. Available Beds and Patient Days: Background (§ 412.105(b) and § 412.106(a)(1)(ii))

Section 1886(d)(5)(B) of the Act provides that subsection (d) hospitals that have residents in approved graduate medical education (GME) programs receive an additional payment for each discharge of Medicare beneficiaries to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The existing regulations regarding the calculation of this additional payment, known as the indirect medical education (IME) adjustment, are located at § 412.105. The additional payment is based on the IME adjustment factor, calculated using

hospitals' ratios of residents to beds. The determination of the number of beds, based on available bed days, is specified at § 412.105(b). 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)(l)(i).

Section 1886(d)(5)(F) of the Act specifies two methods for a hospital to qualify for the Medicare DSH adjustment. The primary method, which is the subject of a provision in this proposed rule, is for a hospital to qualify based on a complex statutory formula under which payment adjustments are based on the level of the DSH patient percentage. The first computation includes the number of patient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits. This number is divided by the total number of patient days that are associated with patients entitled to benefits under Medicare Part A. The second computation includes hospital patient days that are furnished to patients who, for those days, were eligible for Medicaid but were not entitled to benefits under Medicare Part A. This number is divided by the number of total hospital inpatient days in the same period.

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 adjustments for urban hospitals with 100 or more beds and rural hospitals with 500 or more beds, hospitals that qualify as rural referral centers or SCHs, and other hospitals.

We are combining our discussion of proposed changes to the policies for counting beds and patient days, in relation to the calculations at §§ 412.105(b) and 412.106(a)(1)(ii) because the underlying concepts are similar, and we believe they should generally be interpreted in a consistent manner for both purposes. Specifically, we are proposing to clarify 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), 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 associated with these beds that are located 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. For example, neonatal intensive care unit beds are included in the determination of available beds because the costs and patient days associated with these beds are directly included in the determination of the allowable costs of inpatient hospital care under the IPPS. In contrast, beds and patient days associated with these beds that are located in excluded distinct-part psychiatric or rehabilitation units would not be counted for purposes of §§ 412.105(b) and 412.106(a)(1)(ii) under any circumstances, because the costs associated with those units or wards are excluded from the determination of the costs of allowable inpatient care under IPPS.

This policy has been upheld in the past by various courts. (See, for example, *Little Co. of Mary Hospital and Health Care Centers* v. *Shalala,* 165 F.3d 1162 (7th Cir. 1999; *Grant Medical Center* v. *Shalala,* 905 F. Supp. 460 (S.D. Ohio 1995); *Sioux Valley Hospital* v. *Shalala*, No. 93–3741SD, 1994 U.S. App. LEXIS 17759 (8th Cir. July 20, 1996) (unpublished table decision); *Amisub* v. *Shalala*, No. 94–1883 (TFH) (D.D.C. December 4, 1995) (mem.).) In these cases, the courts agreed with the Secretary's position distinguishing between the treatment of neonatal intensive care unit beds and well-baby nursery beds based on the longstanding policy of CMS that neonatal intensive care unit days are considered intensive care days (part of inpatient routine care) rather than nursery days.

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).

However, some courts have applied our current rules in a manner that is inconsistent with our current policy and that would result in inconsistent treatment of beds, patient days, and costs. For example, in *Clark Regional Medical Center* v. *United States Department of Health & Human Services*, 314 F.3d 241 (6th Cir. 2002), the court upheld the district court's ruling that all bed types not specifically excluded from the definition of available bed days in the regulations must be included in the count of available bed days. Similarly, in a recent decision in the Ninth Circuit Court of Appeals *Alhambra* v. *Thompson,* 259 F.3d 1071 (Ninth Cir. 2001), the court ruled that days attributable to groups of beds that are not separately certified as distinct part beds (that is, nonacute care beds in which care provided is at a level below the level of routine inpatient acute care) but are adjacent to or in an acute care ''area'' are included in the ''areas of the hospital that are subject to the prospective payment system'' and should be counted in calculating the Medicare DSH patient percentage.

These courts considered subregulatory guidance (program instructions) in formulating their decisions. Although this proposed rule would clarify the underlying principles for our bed and patient days counting policies and would amend the relevant regulations to be consistent with these clarifications, we recognize the need to revise some of our program instructions to make them fully consistent with these clarifications and will act to do so as soon as possible.

While some of the topics discussed below pertain only to counting available beds (unoccupied beds) and some only to counting patient days (section 1115 waiver days, dual-eligible days, and Medicare+Choice days), several important topics are applicable to both bed-counting and day-counting policies (nonacute care beds and days, 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.

2. Unoccupied Beds

The current policy for counting hospital beds for IME and DSH is specified at § 412.105(b). That count is based on total available bed days during