DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS–1428–P]

RIN 0938–AM80

Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 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-related costs to implement changes arising from our continuing experience with these systems; and to implement a number of changes made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), enacted on December 8, 2003. In addition, in the Addendum to this proposed rule, we describe the 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 proposed changes would be applicable to discharges occurring on or after October 1, 2004. 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 that are paid on a reasonable cost basis subject to these limits.

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

DATES: Comments will be considered if received at the appropriate address, as provided below, no later than 5 p.m. on July 12, 2004.

ADDRESSES:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed rule to assist in fully considering issues and developing policies. You can assist us by referencing the file code CMS–1428–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Submit electronic comments to: *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm?AGENCY=CMS* or *www.regulations.gov*.

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Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1428–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.

(Because access to the interior of the Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters who wish to retain proof of filing by stamping in and keeping an extra copy of the comments being filed.)

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Inspection of Public Comments: All comments received before the close of the comment period will be available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS will post all electronic comments received before the close of the period on its public Web sites. Written comments received timely will be available for public inspection as they are received, generally beginning approximately 4 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.

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 C4–24–02, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Attn: Dawn Willinghan, CMS–1428–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: Jim Hart, (410) 786–9520, Operating Prospective Payment, Diagnosis-Related Groups (DRGs), Wage Index, New Medical Services and Technology, Standardized Amounts, Hospital Geographic Reclassifications, Postacute Care Transfers, and Disproportionate Share Hospital Issues.

Tzvi Hefter, (410) 786–4487, Capital Prospective Payment, Excluded Hospitals, Graduate Medical Education, Critical Access Hospitals, and Long-Term Care (LTC)—DRGs Issues.

Mary Collins, (410) 786–3189, CAH Bed Limits and Distinct Part Unit Issues.

John Eppinger, (410) 786–4518, CAH Periodic Interim Payment Issues.

Maria Hammel, (410) 786–1775, Quality Improvement Organization Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Project Issues.

Jeannie Miller, (410) 786–3164, Bloodborne Pathogens Standards, Hospital Conditions of Participation for Discharge Planning, and Fire Safety Requirements Issues.

Dr. Mark Krushat, (410) 786–6809, and Dr. Anita Bhatia, (410) 786–7236 Quality Data for Annual Payment Update Issues.

SUPPLEMENTARY INFORMATION:

Availability of Copies and Electronic Access

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Acronyms

ACGME—Accreditation Council on Graduate Medical Education
AHIMA—American Health Information Management Association
AHA—American Hospital Association
AOA—American Osteopathic Association
ASC—Ambulatory Surgical Center
BBA—Balanced Budget Act of 1997, Public Law 105–33
BIPA—Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS—Bureau of Labor Statistics
CAH—Critical access hospital
CART—CMS Abstraction & Reporting Tool
CBSAs—Core-Based Statistical Areas
CC—Complication or comorbidity
CMS—Centers for Medicare & Medicaid Services
CMSA—Consolidated Metropolitan Statistical Area
COBRA—Consolidated Omnibus Reconciliation Act of 1985, Public Law 99–272
CoP—Condition of Participation
CPI—Consumer Price Index
CRNA—Certified registered nurse anesthetist
DRG—Diagnosis-related group
DSH—Disproportionate share hospital
ESRD—End-stage renal disease
FDA—Food and Drug Administration
FQHC—Federally qualified health center
FSES—Fire Safety Evaluation System
FTE—Full-time equivalent
FY—Federal fiscal year
GME—Graduate medical education
HCRIS—Hospital Cost Report Information System
HIPC—Health Information Policy Council
HIPAA—Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HHA—Home health agency
HPSA—Health Professions Shortage Area
ICD–9–CM—International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–PCS—International Classification of Diseases, Tenth Edition, Procedure Coding System
ICF/MRs—Intermediate care facilities for the mentally retarded
IME—Indirect medical education
IPPS—Acute care hospital inpatient prospective payment system
IPF—Inpatient psychiatric facility
IRF—Inpatient rehabilitation facility
JCAHO—Joint Commission on the Accreditation of Healthcare Organizations
LAMA—Left Against Medical Advice
LTC–DRG—Long-term care diagnosis-related group
LTCH—Long-term care hospital
LSC—Life Safety Code
MCE—Medicare Code Editor
MCO—Managed care organization
MDC—Major diagnostic category
MDH—Medicare-dependent small rural hospital
MedPAC—Medicare Payment Advisory Commission
MedPAR—Medicare Provider Analysis and Review File
MEI—Medicare Economic Index
MGCRB—Medicare Geographic Classification Review Board
MMA—Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MPFS—Medicare Physician Fee Schedule
MSA—Metropolitan Statistical Area
NECMA—New England County Metropolitan Areas
NCHS—National Center for Health Statistics
NCVHS—National Committee on Vital and Health Statistics
NFPA—National Fire Protection Association
NPR—Notice of Program Reimbursement
NQF—National Quality Forum
NVHRI—National Voluntary Hospital Reporting Initiative
OES—Occupational Employment Statistics
OIG—Office of the Inspector General
OMB—Executive Office of Management and Budget
O.R.—Operating room
OSCAR—Online Survey Certification and Reporting (System)
OSHA—Occupational Safety and Health Act
PACE—Programs of All-Inclusive Care for the Elderly
PIP—Periodic interim payment
PMS—Performance Measurement System
PMSAs—Primary Metropolitan Statistical Areas
PPS—Prospective payment system
PRA—Per resident amount
ProPAC—Prospective Payment Assessment Commission
PRRB—Provider Reimbursement Review Board
PS&R—Provider Statistical and Reimbursement System
QIO—Utilization and Quality Control Quality Improvement Organization
RHC—Rural health clinic
RHQDAPU—Reporting Hospital Quality Data for Annual Payment Update
RRC—Rural referral center
SCH—Sole community hospital
SNF—Skilled nursing facility
SOCs—Standard occupational classifications
SOM—State Operations Manual
SSA—Social Security Administration
SSI—Supplemental Security Income
TEFRA—Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
UHDDS—Uniform Hospital Discharge Data Set

Table of Contents

I. Background
A. Summary
1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)
2. Hospitals and Hospital Units Excluded from the IPPS
a. IRFs
b. LTCH
c. IPFs
3. Critical Access Hospitals (CAHs)
4. Payments for Graduate Medical Education (GME)
B. Provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003
C. Major Contents of this Proposed Rule
1. Proposed Changes to the DRG Reclassifications and Recalibrations of Relative Weights
2. Proposed Changes to the Hospital Wage Index
3. Other Decisions and Proposed Changes to the PPS for Inpatient Operating and GME Costs
4. Proposed Changes to the PPS for Capital-Related Costs
5. Proposed Changes for Hospitals and Hospital Units Excluded from the IPPS
6. Proposed Changes to QIO Disclosure of Information Requirements
7. Proposed Changes Relating to Medicare Provider Agreements: Bloodborne Pathogens Standards, Hospital Conditions of Participation for Discharge Planning, and Fire Safety Requirements for Certain Health Care Facilities
8. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits
9. Impact Analysis
10. Recommendation of Update Factor for Hospital Inpatient Operating Costs
11. Discussion of Medicare Payment Advisory Commission Recommendations
II. Proposed Changes to DRG Classifications and Relative Weights

A. Background
B. DRG Reclassification
1. General
2. MDC 1 (Diseases and Disorders of the Nervous System): Intracranial Hemorrhage and Stroke with Infarction
3. MDC 5 (Diseases and Disorders of the Circulatory System)
a. Heart Assist System Transplant
b. Cardiac Resynchronization Therapy and Heart Failure
c. Combination Cardiac Pacemaker Devices and Lead Codes
4. MDC 6 (Diseases and Disorders of the Digestive System): Artificial Anal Sphincter
5. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)
a. 360 Spinal Fusion
b. Multiple Level Spinal Fusion
6. MDC 15 (Newborns and Other Neonates with Conditions Originating in the Perinatal Period)
7. MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders): Drug-Induced Dementia
8. MDC 22 (Burns): Burn Patients on Mechanical Ventilation
9. Pre-MDC: Tracheostomy
10. Medicare Code Editor (MCE) Changes
11. Surgical Hierarchies
12. Refinement of Complications and Comorbidities (CC) List
13. Review of Procedure Codes in DRGs 468, 476, and 477
a. Moving Procedure Codes from DRG 468 or DRG 477 to MDCs
b. Reassignment of Procedures among DRGs 468, 476, and 477
c. Adding Diagnosis or Procedure Codes to MDCs
14. Pancreatic Islet Cell Transplantation in Clinical Trials
15. Changes to the ICD–9–CM Coding System
16. Other Issues
a. Craniotomy Procedures
(1) Unruptured Cerebral Aneurysms
(2) GLIADEL® Chemotherapy Wafers
(3) DRG 3 (Craniotomy Age 0–17)
b. Coronary Stent Procedures
c. Severe Sepsis
d. Implantable Cardiac Defibrillators
C. Recalibration of DRG Weights
D. Proposed LTC–DRG Reclassifications and Relative Weights for LTCHs for FY 2005
1. Background
2. Proposed Changes in the LTC–DRG Classifications
a. Background
b. Patient Classifications into DRGs
3. Development of the Proposed FY 2005 LTC–DRG Relative Weights
a. General Overview of Development of the LTC–DRG Relative Weights
b. Data
c. Hospital-Specific Relative Value Methodology
d. Low-Volume LTC–DRGs
4. Steps for Determining the Proposed FY 2005 LTC–DRG Relative Weights
E. Proposed Add-On Payments for New Services and Technologies
1. Background
2. Other Provisions of Section 503 of Public Law 108–173
3. FY 2005 Status of Technology Approved for FY 2004 Add-On Payments
a. Drotrecogin Alfa (Activated)—Xigris®
b. InFUSE™ (Bone Morphogenetic Proteins (BMPs) for Spinal Fusions)
4. Reevaluation of FY 2004 Applications That Were Not Approved
5. FY 2005 Applicants for New Technology Add-On Payments
a. InFUSE™ Bone Graft (Bone Morphogenetic Proteins (BMPs) for Tibia Fractures)
b. Norian Skeletal Repair System(SRS)® Bone Void Filler
c. InSync® Defibrillator System (Cardiac Resynchronization Therapy with Defibrillation (CRT–D))
d. GliaSite® Radiation Therapy System (RTS)
e. Natrecor®—Human B–Type Natriuretic Peptide (hBNP)
f. Kinetra® Implantable Neurostimulator for Deep Brain Stimulation
g. Intramedullary Skeletal Kinetic Distractor (ISKD)
h. Acticon™ Neosphincter
i. TandemHeart™ Percutaneous Left Ventricular Assist System
j. Aquadex™ System 100 Fluid Removal System (System 100)
III. Proposed Changes to the Hospital Wage Index
A. Background
B. Revised OMB Definitions for Geographical Statistical Areas
1. Current Labor Market Areas Based on MSAs
2. Core-Based Statistical Areas
3. Revised Labor Market Areas
a. New England MSAs
b. Metropolitan Divisions
c. Micropolitan Areas
d. Transition Period
C. Proposed Occupational Mix Adjustment to Proposed FY 2005 Index
1. Development of Data for the Occupational Mix Adjustment
2. Proposed Calculation of the Occupational Mix Adjustment Factor and the Proposed Occupational Mix Adjusted Wage Index
D. Worksheet S–3 Wage Data for the Proposed FY 2005 Wage Index Update
E. Verification of Worksheet S–3 Wage Data
F. Computation of the Unadjusted Wage Index
G. Computation of the Proposed FY 2005 Blended Wage Index
H. Proposed Revisions to the Wage Index Based on Hospital Redesignation
1. General
2. Effects of Reclassification
3. FY 2005 Issues
a. FY 2005 MGCRB Reclassifications
b. Implementation of New MSAs
c. Redesignations under Section 1886(d)(8)(B) of the Act
d. Reclassifications Under Section 508 of Public Law 108–173
e. Proposed Wage Index Adjustment Based on Commuting Patterns of Hospital Employees
(1) Data
(2) Qualifying Counties
(3) The Adjustment
(4) Automatic Adjustments
4. Proposed FY 2005 Reclassifications
I. Process for Requests for Wage Index Data Corrections
1. Worksheet S–3 Wage Data
2. Occupational Mix Data
3. All FY 2005 Wage Index Data
J. Proposed Revision of the Labor-Related Share of the Wage Index
IV. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs
A. Postacute Care Transfer Payment Policy
1. Background
2. Proposed Changes to DRGs Subject to the Postacute Care Transfer Policy
B. Payments for Inpatient Care in Providers That Change Classification Status During a Patient Stay
C. Geographic Reclassifications—Definitions of Urban and Rural Areas
D. Equalization of Urban and Rural Standardized Amounts
E. Reporting of Hospital Quality Data for Annual Hospital Payment Update
1. Background
2. Requirements for Hospital Reporting of Quality Data
3. Submission of Hospital Data for FYs 2006 and 2007
4. Proposed Regulation Change
F. Proposed Revision of the Labor-Related Share of the Hospital Wage Index
G. Wage Index Adjustment for Commuting Patterns of Hospital Employees
H. Additional Payments for New Medical Services and Technology: Proposed Policy Changes
I. Rural Referral Centers
1. Case-Mix Index
2. Discharges
J. Additional Payments to Hospitals with High Percentage of End-Stage Renal Disease (ESRD) Discharges
K. Indirect Medical Education (IME) Adjustment
1. IME Adjustment Factor Formula Multipliers
2. IME Adjustment Formula Multiplier for Redistributed FTE Resident Slots
3. Technical Changes
L. Payment to Disproportionate Share Hospitals
1. Enhanced DSH Adjustment for Rural Hospitals and Urban Hospitals with Fewer Than 100 Beds
2. Proposals Relating to Available Beds and Patient Days for the DSH Adjustment
M. Payment Adjustments for Low-Volume Hospitals
N. Medicare Geographic Classification Review Board (MGCRB) Reclassifications
1. Background
2. Standardized Amount Reclassification Provisions
3. Reclassification of Urban Rural Referral Centers
4. Special Circumstances of Sole Community Hospitals (SCHs) in Low Population Density States
5. Possible Reclassifications for Dominant Hospitals and Hospitals in Single-Hospital MSAs
6. Special Circumstances of Hospitals in All-Urban States

O. Payment for Direct Graduate Medical Education
1. Background
2. Reductions of and Increases in Hospitals' FTE Resident Caps for GME Payment Purposes under Section 422 of Public Law 108–173
a. General Background on Methodology for Determining the FTE Resident Count
b. Reduction of Hospitals' FTE Resident Caps under the Provisions of Section 422 of Public Law 108–173
c. Hospitals Subject to the FTE Resident Cap Reduction
d. Exemption from FTE Resident Cap Reduction for Certain Rural Hospitals
e. Determining the Estimated Number of FTE Resident Slots Available for Redistribution
f. Determining the Possible Reduction to a Hospital's FTE Resident Cap
(1) Reference Resident Level—General
(2) Expansion of an Existing Program
(3) Audits of the Reference Cost Reporting Periods
(4) Expansions Under Newly Approved Programs
(5) Affiliations
g. Criteria for Determining Hospitals That Will Receive Increases in Their FTE Resident Caps
h. Application Process for the Increases in Hospitals' FTE Resident Caps
i. CMS Evaluation of Applications for Increases in FTE Resident Caps
j. Application of Locality-Adjusted National Average Per Resident Amount (PRA)
k. Application of Section 422 to Hospitals That Participate in Demonstration Projects or Voluntary Reduction Programs
l. Application of Section 422 to Hospitals That File Low Utilization Medicare Cost Reports
m. Specific Solicitation for Public Comment on the Proposals
n. CMS Evaluation Form
o. CMS Central and CMS Regional Office Mailing Addresses for Applications for Increases in FTE Resident Caps
3. Direct GME Initial Residency Period
a. Background
b. Direct GME Initial Residency Period Limitation: Simultaneous Match Issue
c. Exception to Initial Residency Period for Geriatric Residency or Fellowship Programs
4. Per Resident Amount: Extension of Update Limitation on High-Cost Programs
5. Residents Training in Nonhospital Settings
a. Background
b. Moratorium on Disallowances of Allopathic or Osteopathic Family Practice Residents Training Time in Nonhospital Settings
(1) Cost Reports That Are Settled Between January 1, 2004 and December 31, 2004
(2) Family Practice Residents That Are Training in Nonhospital Settings Between January 1, 2004 and December 31, 2004
c. Requirements for Written Agreements for Residency Training in Nonhospital Settings
P. Rural Community Hospital Demonstration Program
Q. Special Circumstances of Hospitals Facing High Malpractice Insurance Rate Increases
V. Proposed Changes to the PPS for Capital-Related Costs
A. Background
B. Payments to Hospitals Located in Puerto Rico
C. Exception Payment for Extraordinary Circumstances
A. Treatment of Hospitals Previously Reclassified for the Operating PPS
E. Definition of Large Urban Area Standardized Amounts
VI. Proposed Changes for Hospitals and Hospital Units Excluded from the IPPS
A. Payments to Excluded Hospitals and Hospital Units
1. Payments to Existing Excluded Hospitals and Hospital Units
2. Updated Caps for New Excluded Hospitals and Units
3. Implementation of a PPS for IRFs
4. Implementation of a PPS for LTCHs
5. Development of a PPS for IPFs
6. Technical Changes Related to Establishment of Payments for Excluded Hospitals
B. Criteria for Classification of Hospitals-Within-Hospitals
C. Critical Access Hospitals (CAHs)
1. Background
2. Payment Amounts for Inpatient CAH Services
3. Condition for Application of Special Professional Service Payment Adjustment
4. Coverage of Costs for Certain Emergency Room On-Call Providers
5. Authorization of Periodic Interim Payments for CAHs
6. Revision of the Bed Limit for CAHs
7. Authority to Establish Psychiatric and Rehabilitation Distinct Part Units of CAHs
8. Waiver Authority for Designation of a CAH as a Necessary Provider
9. Payment for Clinical Diagnostic Laboratory Tests
10. Proposed Technical Changes in Part 489
VII. Proposed Changes to the Disclosure of Information Requirements for Quality Improvement Organizations (QIOs)
A. Background
B. Provisions of the Proposed Regulations
C. Technical Changes
VIII. Proposed Policy Changes Relating to Medicare Provider Agreements for Compliance with Bloodborne Pathogens Standards, Hospital Conditions of Participation for Discharge Planning, and Fire Safety Requirements for Certain Health Care Facilities
A. Conditions of Participation for Discharge Planning
1. Background
2. Implementation
B. Compliance with Bloodborne Pathogens Standards
C. Fire Safety Requirements for Certain Health Care Facilities
1. Background
2. Proposed Changes to the Regulations
IX. MedPAC Recommendations
X. Other Required Information
A. Requests for Data from the Public
1. CMS Wage Data
2. CMS Hospital Wage Indices (Formerly: Urban and Rural Wage Index Values Only)
3. PPS SSA/FIPS MSA State and County Crosswalk
4. Reclassified Hospitals New Wage Index (Formerly: Reclassified Hospitals by Provider Only)
5. PPS–IV to PPS–XII Minimum Data Set
6. PPS–IX to PPS–XII Capital Data Set
7. PPS–XIII to PPS–XIX Hospital Data Set
8. Provider-Specific File
9. CMS Medicare Case-Mix Index File
10. DRG Relative Weights (Formerly Table 5 DRG)
11. PPS Payment Impact File
12. AOR/BOR Tables
13. Prospective Payment System (PPS) Standardizing File
B. Collection of Information Requirements
C. Public Comments

Regulation Text

Addendum—Proposed Schedule of Standardized Amounts Effective with Discharges Occurring On or After October 1, 2004 and Update Factors and Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning On or After October 1, 2004

Tables

Table 1A—National Adjusted Operating Standardized Amounts, Labor/Nonlabor (71.1 Percent Labor Share/28.9 Percent Nonlabor Share If Wage Index Is Greater Than 1)
Table 1B—National Adjusted Operating Standardized Amounts, Labor/Nonlabor (62 Percent Labor Share/38 Percent Nonlabor Share If Wage Index Is Less Than or Equal to 1)
Table 1C—Adjusted Operating Standardized Amounts for Puerto Rico, Labor/Nonlabor
Table 1D—Capital Standard Federal Payment Rate
Table 2—Hospital Case-Mix Indexes for Discharges Occurring in Federal Fiscal Year 2003; Hospital Average Hourly Wage for Federal Fiscal Years 2003 (1999 Wage Data), 2004 (2000 Wage Data), and 2005 (2001 Wage Data) Wage Indexes and 3-Year Average of Hospital Average Hourly Wages
Table 3A—3-Year Average Hourly Wage for Urban Areas
Table 3B—3-Year Average Hourly Wage for Rural Areas
Table 4A—Wage Index and Capital Geographic Adjustment Factor for Urban Areas
Table 4B—Wage Index and Capital Geographic Adjustment Factor for Rural Areas
Table 4C—Wage Index and Capital Geographic Adjustment Factor for Hospitals That Are Reclassified
Table 4F—Puerto Rico Wage Index and Capital Geographic Adjustment Factor
Table 4G—Pre-Reclassified Wage Index for Urban Areas

Table 4H—Pre-Reclassified Wage Index for Rural Areas
Table 4J—Wage Index Adjustment for Commuting Hospital Employees (Out-Migration) In Qualifying Counties—FY 2005
Table 5—List of Diagnosis-Related Groups (DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay (LOS)
Table 6A—New Diagnosis Codes
Table 6B—New Procedure Codes
Table 6C—Invalid Diagnosis Codes
Table 6D—Invalid Procedure Codes
Table 6E—Revised Diagnosis Code Titles
Table 6F—Revised Procedure Code Titles
Table 6G—Additions to the CC Exclusions List
Table 6H—Deletions from the CC Exclusions List
Table 7A—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2003 MedPAR Update December 2003 GROUPER V21.0
Table 7B—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2003 MedPAR Update December 2003 GROUPER V22.0
Table 8A—Statewide Average Operating Cost-to-Charge Ratios for Urban and Rural Hospitals (Case-Weighted)
Table 8B—Statewide Average Capital Cost-to-Charge Ratios (Case-Weighted)
Table 9A—Hospital Reclassifications and Redesignations by Individual Hospital—FY 2004
Table 9B—Hospital Reclassifications and Redesignation by Individual Hospital Under Section 508 of Public Law 108–173—FY 2004
Table 10—Geometric Mean Plus the Lesser of .75 of the National Adjusted Operating Standardized Payment Amount (Increased to Reflect the Difference Between Costs and Charges) or .75 of One Standard Deviation of Mean Charges by Diagnosis-Related Groups (DRGs)—March 2004
Table 11—Proposed FY 2005 LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and 5/6ths of the Geometric Average Length of Stay
Appendix A—Regulatory Impact Analysis
Appendix B—Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

A. Summary

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

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

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

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

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

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

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

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid the higher of a hospital-specific rate based on their costs in a base year (the higher of FY 1982, FY 1987, or FY 1996) or the IPPS rate based on the standardized amount. For example, sole community hospitals (SCHs) are the sole source of care in their areas, and Medicare-dependent, small rural hospitals (MDHs) are a major source of care for Medicare beneficiaries in their areas. Both of these categories of hospitals are afforded this special payment protection in order to maintain access to services for beneficiaries (although MDHs receive only 50 percent of the difference between the IPPS rate and their hospital-specific rates if the hospital-specific rate is higher than the IPPS rate).

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

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

2. Hospitals and Hospital Units Excluded From the IPPS

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

The existing regulations governing payments to excluded hospitals and

hospital units are located in 42 CFR Parts 412 and 413.

a. IRFs

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

b. LTCHs

Under the authority of sections 123(a) and (c) of Public Law 106–113 and section 307(b)(1) of Public Law 106–554, LTCHs are being transitioned from being paid for inpatient hospital services based on a blend of reasonable cost-based reimbursement under section 1886(b) of the Act to 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 June 6, 2003 LTCH PPS final rule (68 FR 34122)). 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. IPFs

Sections 124(a) and (c) of Public Law 106–113 provide for the development of a per diem PPS for payment for inpatient hospital services furnished in IPFs under the Medicare program, effective for cost reporting periods beginning on or after October 1, 2002. This system must include an adequate patient classification system that reflects the differences in patient resource use and costs among these hospitals and maintains budget neutrality. We published a proposed rule to implement the PPS for IPFs on November 28, 2003 (68 FR 66920). The November 28, 2003 proposed rule proposed an April 1, 2004 effective date for purposes of ratesetting and calculating impacts. However, the proposed rule was unusually complex because it proposed a completely new payment system for inpatient hospital services furnished by psychiatric hospitals and units and the public requested additional time to comment. As a result, we extended the comment period for the proposed rule. Thus, we are still in the process of analyzing public comments and developing a final rule for publication. Consequently, an April 1, 2004 effective date for the IPF PPS is no longer possible.

3. Critical Access Hospitals (CAHs)

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

4. Payments for Graduate Medical Education (GME)

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

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

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

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, was enacted. Public Law 108–173 made a number of changes to the Act relating to prospective payments to hospitals for inpatient services, payments to excluded hospitals and units, and payments to CAHs. This proposed rule would implement amendments made by the following sections of Public Law 108–173:

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

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

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

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

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

Section 405(c), which provides that eligible CAHs may receive payments for their inpatient services on a periodic interim payment (PIP) basis, effective

with payments made on or after July 1, 2004.

Section 405(d), which allows CAHs to elect to receive payments under the optional payment method (a payment encompassing both inpatient CAH services and physician and practitioner services to outpatients) even if some practitioners do not reassign to the CAH their rights to bill for professional services to CAH outpatients. This provision applies to cost reporting periods occurring on or after July 1, 2004, except that in the case of a CAH that made an election of the optional payment method before November 1, 2003, the provision applies to cost reporting periods beginning on or after July 1, 2001.

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

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

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

Section 406, which provides for a graduated adjustment to the inpatient prospective payment rates to account for the higher costs associated with hospitals described under section 1886(d) of the Act that are located more than 25 road miles from another subsection (d) hospital and that have less than 800 discharges during a fiscal year, effective for discharges occurring on or after October 1, 2004. The increase in these payments may not be greater than 25 percent and the determination of the percentage payment increase is not subject to administrative or judicial review.

Section 410A, which authorizes the Secretary to establish a demonstration program to test the feasibility and advisability of the establishment of rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The Secretary must select up to 15 rural community hospitals to participate in the demonstration. The Secretary must implement the demonstration program not later than January 1, 2005, but may not implement the program before October 1, 2004.

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

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

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

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

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

Section 503(b), which provides for changes to the threshold amount for determining eligibility of new technologies or medical services for add-on payments; provides for public input on applications for new technology or medical service add-on payments prior to the publication of a proposed rule; provides for reconsideration of applications received for FY 2004 that were denied; provides for preference in the use of DRG adjustments; and provides that new technology or medical service payments shall not be budget neutral. This provision is effective for fiscal years beginning in FY 2005.

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

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

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

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

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

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

Section 733, which provides for the Medicare payment of routine costs, as well as costs relating to the transplantation and appropriate related items and services, for Medicare beneficiaries participating in a clinical trial involving pancreatic islet cell

transplantation, beginning no earlier than October 1, 2004.

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

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

C. 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 under the IPPS for FY 2005. We also are setting forth proposed changes relating to payments for GME costs, payments to certain hospitals and units that continue to be excluded from the IPPS and paid on a reasonable cost basis, payments for DSH, requirements and payments for CAHs, conditions of participation for hospitals relating to discharge planning and fire safety requirements, requirements for Medicare provider agreements relating to bloodborne pathogen standards, and QIO disclosure of information requirements. The changes being proposed would be effective for discharges occurring on or after October 1, 2004, unless otherwise noted.

The following is a summary of the major changes that we 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 are proposing annual adjustments to the DRG classifications and relative weights. Based on analyses of Medicare claims data, in section II. of this preamble, 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 2005 are set forth in section II. of this preamble.

Among the proposed changes discussed are:

- Restructuring and retitling of several DRGs to reflect expanded coverage of heart assist systems such as ventricular assist devices (VAD) or left ventricular assist devices (LVAD) as destination (or permanent) therapy for end-stage heart failure patients who are not candidates for heart transplantation: DRG 103 (Heart Transplant or Implant of Heart Assist System) (proposed title change), DRG 104 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization) and DRG 105 (Cardiac Valve and Other Major Cardiothoracic Procedures Without Cardiac Catheterization), and DRG 525 (Other Heart Assist System Implant) (proposed title change).
- Addition of pacemaker device and lead procedure code combinations that could lead to the assignment of DRG 115 (Permanent Cardiac Pacemaker Implant with Acute Myocardial Infarction, Heart Failure, or Shock or ACID Lead or Generator Procedures) and DRG 116 (Other Permanent Cardiac Pacemaker Implant).
- Movement of the procedure code for 360 spinal fusion from DRG 496 (Combined Anterior/Posterior Spinal Fusion) to DRG 497 (Spinal Fusion Except Cervical With CC) and DRG 498 (Spinal Fusion Except Cervical Without CC).
- Addition of combination codes, which also include heart failure, to the list of major problems under DRG 387 (Prematurity With Major Problems) and DRG 389 (Full-Term Neonate With Major Problems).
- Modification of DRGs 504 through 509 under MDC 22 (Burns) to recognize the impact of long-term mechanical ventilation on burn cases and renaming DRG 504 as proposed title ''Extensive Burns or Full Thickness Burns With Mechanical Ventilation 96+ Hours With Skin Graft'' and DRG 505 as proposed title ''Extensive Burns or Full Thickness Burns With Mechanical Ventilation 96+ Hours Without Skin Graft.''
- Deletion of DRG 483 (Tracheostomy for Face, Mouth, and Neck Diagnoses) and splitting the assignment of cases to two proposed new DRGs on the basis of the performance of a major operating room procedure: proposed new DRGs 541 and 542 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnosis With and Without Major Operating Room Procedure, respectively).

We also are presenting our reevaluation of FY 2004 applicants for add-on payments for high-cost new medical services and technologies, and our analysis of FY 2005 applicants (including public input, as directed by Public Law 108–173, obtained in a town meeting).

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

2. Proposed Changes to the Hospital Wage Index

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

- The proposed FY 2005 wage index update, using wage data from cost reporting periods that began during FY 2001.
- Proposed revised labor market areas as a result of OMB revised definitions of geographical statistical areas.
- A discussion of the collection of occupational mix data and the proposed occupational mix adjustment to the wage index that we are proposing to apply beginning October 1, 2004.
- The proposed revisions to the wage index based on hospital redesignations and reclassifications, including changes that reflect the new OMB standards for assignment of hospitals to geographic areas.
- The proposed adjustment to the wage index based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index, to implement section 505 of Public Law 108–173.
- A discussion of eligible hospitals reclassified under the one-time appeals process under section 508 of Public Law 108–173.
- Proposed changes to the labor-related share to which the wage index is applied in determining the PPS rate for hospitals located in specific geographic areas, to implement section 403 of Public Law 108–173.
- The revised timetable for reviewing and verifying the wage data that is in effect for the proposed 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 a number of provisions of the regulations in 42 CFR Parts 412 and 413 and set forth proposed changes concerning the following:

- Proposed expansion of the current postacute care transfer policy.
- Payments for inpatient care in providers that change classification status during a patient stay.
- Proposed changes in the definitions of urban and rural areas for geographic reclassifications purposes.

- Equalization of the standardized amount for urban and rural hospitals.
- The reporting of hospital quality data as a condition for receiving the full annual payment update increase.
- Proposed revision of the regulations to reflect the revision of the labor share of the wage index.
- Proposed revision of the regulations to reflect the wage index adjustment for commuting patterns of hospital employees who live in one county and commute to work in other areas with higher level wages.
- Proposed changes in the threshold amount for eligibility for new medical services and technology add-on payments.
- Proposed revision to our policy on additional payments to hospitals with high percentages of ESRD discharges.
- Proposed changes to the IME adjustment formula multipliers, and the formula multiplier applicable to redistribution of unused numbers of FTE residents slots.
- Proposed changes in DSH adjustment payments to rural and small urban hospitals.
- Proposed payment adjustments for low-volume hospitals.
- Proposed changes in policy affecting hospitals that apply as a group for reclassification and a discussion of possible reclassifications for dominant hospitals and hospitals in single-hospital MSAs.
- Proposed changes in policies governing payments for direct GME, including the redistribution of unused FTE resident slots; changes in the GME initial residency period; extension of the update limitation on hospital-specific per resident amounts; and changes in the policies on residents training in nonhospital settings, including written agreements for teaching physician compensation.
- An announcement of the rural community hospital demonstration to be established under section 410A of Public Law 108–173 and the opportunity for eligible hospitals to apply for participation in the demonstration program.
- A solicitation of public comments on the effect of increases in malpractice insurance premiums on hospitals participating in the Medicare program and beneficiary access of services.

4. Proposed Changes to the PPS for Capital-Related Costs

In section V. of this preamble, we discuss the payment requirements for capital-related costs and propose changes relating to capital payments to hospitals located in Puerto Rico, changes in the policies on exception payments for extraordinary circumstances, treatment of hospitals previously reclassified for the operating standardized amounts, and capital payment adjustments based on the proposed changes in geographic classifications.

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

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

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

6. Proposed Changes to QIO Disclosure of Information Requirements

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

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

In section VIII. of this preamble, we are proposing to—

- Require hospitals, as part of the discharge planning standard under the Medicare hospital conditions of participation, to furnish a list of Medicare-participating home health agencies to patients who receive home health services after discharge and to provide information on Medicare-certified SNFs to patients who are likely to need posthospital extended care services.
- Require that Medicare provider agreements include provisions that would ensure that all hospital employees who may come into contact with human blood in the course of their duties are provided proper protection from bloodborne pathogens.
- Correct a technical error relating to the application of the 2000 edition of the Life Safety Code as the fire safety requirements for certain health care facilities; and clarify the effective date for the prohibition on the use of roller latches in these facilities.

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

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

9. Impact Analysis

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

10. Recommendation of Update Factor for Hospital Inpatient Operating Costs

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

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by hospitals and hospital units excluded from the IPPS.

11. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, the Medicare Payment Advisory Commission (MedPAC) is required to submit a report to Congress, no later than March 1 of each year, that reviews and makes recommendations on Medicare payment policies. MedPAC's March 2004 recommendation

concerning hospital inpatient payment policies addressed only the update factor for inpatient hospital operating costs and capital-related costs under the IPPS and for hospitals and distinct part hospital units excluded from the IPPS. This recommendation is addressed in Appendix B. For further information relating specifically to the MedPAC March 1 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's Web site at: *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, 2004, are discussed below.

B. DRG Reclassifications

[If you choose to comment on issues in this section, please include the caption ''DRG Reclassifications'' at the beginning of your comment.]

1. General

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

For FY 2004, cases are assigned to one of 522 DRGs in 25 major diagnostic categories (MDCs). Most MDCs are based on a particular organ system of the body. For example, MDC 6 is Diseases and Disorders of the Digestive System. This approach is used because clinical care is generally organized in accordance with the organ system affected. However, some MDCs are not constructed on this basis because they involve multiple organ systems (for example, MDC 22 (Burns)). The table below lists the 25 MDCs.

Major diagnostic categories (MDCs).

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

In general, cases are assigned to an MDC based on the patient's principal diagnosis before assignment to a DRG. However, for FY 2004, there are eight DRGs to which cases are directly assigned on the basis of ICD–9–CM procedure codes. These DRGs are for heart, liver, bone marrow, lung, simultaneous pancreas/kidney, and pancreas transplants and for tracheostomies. Cases are assigned to these DRGs before they are classified to an MDC. The table below lists the current eight pre-MDCs.

Pre-Major Diagnostic Categories (Pre-MDCs)

DRG 103—Heart Transplant.
DRG 480—Liver Transplant.

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

Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are based on a hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. Medical DRGs generally are differentiated on the basis of diagnosis and age (less than or greater than 17 years of age). Some surgical and medical DRGs are further differentiated based on the presence or absence of a complication or a comorbidity (CC).

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

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

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

After cases are screened through the MCE and assigned to a DRG by the GROUPER, a base DRG 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 additional factors associated with each hospital, such as IME and DSH adjustments. These additional factors increase the payment amount to hospitals above the base DRG payment.

The records for all Medicare hospital inpatient discharges are maintained in the Medicare Provider Analysis and Review (MedPAR) file. The data in this file are used to evaluate possible DRG classification changes and to recalibrate the DRG weights. However, in the July 30, 1999 IPPS final rule (64 FR 41500), we discussed a process for considering non-MedPAR data in the recalibration process. In order for us to consider using particular non-MedPAR data, we must have sufficient time to evaluate and test the data. The time necessary to do so depends upon the nature and quality of the non-MedPAR data submitted. Generally, however, a significant sample of the non-MedPAR data should be submitted by mid-October for consideration in conjunction with the next year's proposed rule. This allows us time to test the data and make a preliminary assessment as to the feasibility of using the data. Subsequently, a complete database should be submitted by early December for consideration in conjunction with the next year's proposed rule.

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

The changes we are proposing to the DRG classification system for the FY 2005 GROUPER version 22.0 and to the methodology used to recalibrate the DRG weights are set forth below. Unless otherwise noted in this proposed rule, our DRG analysis is based on data from the December 2003 update of the FY 2003 MedPAR file, which contains hospital bills received through December 31, 2003 for discharges in FY 2003.

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

It has come to our attention that the title of DRG 14 (Intracranial Hemorrhage and Stroke With Infarction) may be misleading because it implies that a combination of conditions exists when the DRG is assigned. When we developed this title, we did not intend to imply that a combination of conditions exists. Therefore, we are proposing to change the title of DRG 14 to read ''Intracranial Hemorrhage or Cerebral Infarction''.

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

a. Heart Assist System Implant

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

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

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

- 37.62, Insertion of nonimplantable heart assist system
- 37.63, Repair of heart assist system

- 37.65, Implant of external heart assist system
- 37.66, Insertion of implantable heart assist system

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

Commenters on the May 19, 2003 proposed rule that preceded the August 1, 2003 IPPS (FY 2004) final rule notified us that procedure code 37.66 was neither a clinical nor a financial match to the rest of the procedure codes now assigned to DRG 525. We did not modify DRG 525 for FY 2004. We agreed that we would continue to evaluate whether to make further changes to DRG 525. After publication of the August 1, 2003 final rule, we again reviewed the MedPAR data concerning DRG 525, and came to the conclusion that procedure code 37.62 is different in terms of clinical procedures and resource utilization from the other procedure codes assigned to DRG 525. Therefore, in a correction to the August 1, 2003 IPPS (FY 2004) final rule, published on October 6, 2003 (68 FR 57733), we revised the composition of DRG 525 by correcting the assignment of procedures to DRG 525 in light of the lower charges associated with procedure code 37.62. We moved code 37.62 into DRG 104 (Cardiac Valve and Other Major Cardiothoracic Procedures With Cardiac Catheterization) and DRG 105 (Cardiac Valve and Other Major Cardiothoracic Procedures Without Cardiac Catheterization), and left procedure codes 37.63, 37.65, and 37.66 in DRG 525.

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

As a result of that review, effective for services performed on or after October 1, 2003, VADs have been approved as destination therapy for patients requiring permanent mechanical cardiac support. Briefly, VADs used for destination therapy are covered only if they have received approval from the FDA for that purpose, and the device is used according to the FDA-approved labeling instructions. VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of less than 2 years). Implanting facilities as well as patients must also meet all of the additional conditions that are listed in the national coverage determination for artificial hearts and related devices, which is posted on the above CMS Web site.

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

DRG with code 37.66 reported	Count	Average length of stay	Average charges
103	14	77.36	$836,011
483	6	100.50	1,400,706
525	45	38.93	308,725

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

Commenters on the FY 2004 final rule suggested adding code 37.66 to DRG 103. We were concerned with the timing of that comment, as it was received after publication of the proposed rule. We noted that the commenter's suggestions on the structure of the DRGs involved were significant, and that change of that magnitude should be subject to public review and comment. We also noted that we would evaluate the suggestion further. (68 FR 45370) However, as one of the indications for this device has become destination therapy, and as this new indication is more clinically aligned with DRG 103, we are proposing to remove procedure code 37.66 from DRG 525 and assign it to DRG 103. We also are proposing to change the title of DRG 103 to ''Heart Transplant or Implant of Heart Assist System''. The proposed restructured DRG 103 would include any principal diagnosis in MDC 5, plus one of the following surgical procedure codes:

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

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

In conjunction with the above data review, we also looked at DRGs 104 and 105.

DRGs 104 and 105 had been restructured in FY 2003 by assigning code 37.62 to them. (**Note:** The code title for 37.62 has been revised, effective FY 2005, as reflected in Table 6F of the Addendum to this proposed rule). We examined the MedPAR data and found that the average charges were $113,667 and $82,899, respectively, for DRGs 104 and 105 for cases not reporting code 37.62, while cases containing code 37.62 had average charges of $124,559 and $166,129, respectively.

The removal of code 37.66 from DRG 525 would have the effect of clinically realigning that DRG to be more coherent. As a result of the proposal to remove code 37.66 from DRG 525 and assign it to DRG 103, we also are proposing to remove code 37.62 from DRGs 104 and 105 and assign it back into DRG 525. In addition, the average

charges for code 37.62 shown above in DRGs 104 and 105 ($124,559 and $166,129) more closely match the average charges reported for the 171 cases in DRG 525, absent code 37.66 ($168,388).

The proposed restructured DRG 525 would include any principal diagnosis in MDC 5, plus the following surgical procedure codes:

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

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

b. Cardiac Resychronization Therapy and Heart Failure

We received a request from a manufacturer of a Cardiac Resynchronization Therapy Defibrillator (CRT–D) device for a modification to DRG 535 (Cardiac Defibrillator Implant With Cardiac Catheterization With Acute Myocardial Infarction/Heart Failure/Shock) and DRG 536 (Cardiac Defibrillator Implant With Cardiac Catheterization Without Acute Myocardial Infarction/Heart Failure/Shock). The commenter pointed out that defibrillator device implantations, including the CRT–D type of defibrillator, are assigned to DRG 535 when the patient also has a cardiac catheterization and has either an acute myocardial infarction, heart failure, or shock as a principal diagnosis. If the patient receiving the defibrillator implant and cardiac catheterization does not have a principal diagnosis of acute myocardial infarction, heart failure, or shock, the cases are assigned to DRG 536.

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

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

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

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

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

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

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

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

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

c. Combination Cardiac Pacemaker Devices and Lead Codes

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

- 00.53 & 37.70

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

These codes are defined as follows:

- 00.53, Implantation or replacement of cardiac resynchronization pacemaker, pulse generator only [CRT–P]
- 37.70, Initial insertion of pacemaker lead [electrode], not otherwise specified
- 37.71, Initial insertion of transvenous lead [electrode] into ventricle
- 37.72, Initial insertion of transvenous lead [electrode] into atrium and ventricle
- 37.73, Initial insertion of transvenous lead [electrode] into atrium
- 37.74, Initial insertion or replacement of epicardial lead [electrode] into epicadium
- 37.76, Replacement of transvenous atrial and/or ventricular lead(s) [electrode]

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

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

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

Therefore, we reviewed the FY 2003 MedPAR data for the presence of codes 49.75 and 49.76. We then arrayed the results by DRG, count, average length of stay, charges, and the presence or absence of a secondary diagnosis that could be classified as a CC. We found that there were a total of 13 cases in 5 total DRGs with CCs, and 9 cases in 4 total DRGs without CCs, for a total of 22 cases that reported these procedure codes. We had anticipated that the majority of cases would have been found in DRGs 157 (Anal and Stomal Procedures With CC) and 158 (Anal and Stomal Procedures Without CC), but found only 2 cases grouped to DRG 157 and 4 cases grouped to DRG 158. Our data showed average charges of $22,374 for the cases with CC, and average charges of $20,831 for the cases without CC. Average charges for DRG 157 were $18,196, while average charges for DRG 158 were $9,348.

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

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

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

a. 360 Spinal Fusions

We received a comment that suggested procedure code 81.61 (360 Spinal fusion) should not be included in DRG 496 (Combined Anterior/Posterior Spinal Fusion). The commenter stated that code 81.61 does not represent the same types of cases as other codes included in DRG 496. The commenter indicated that cases reported with code 81.61 involve making only one incision, and then fusing both the anterior and posterior portion of the spine. All other cases in DRG 496 involve two separate surgical approaches used to reach the site of the spinal fusion. For these other patients, an incision is made into the patient, and a fusion is made in part of the spine. The patient is then turned over and a separate incision is made so that a fusion can be made in another part of the spine. The commenter added that these two separate incisions and fusions are more time consuming than the single incision used for code 81.61. The commenter also stated that patients receiving the two surgical approaches have a longer recovery period and use more hospital resources.

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

DRG	Count	Average length of stay	Average charges
496—All Cases	2,706	8.0	$74,967.33
496—Cases with code 81.61	829	4.7	50,659.69
496—Cases with code 81.61 with CC	451	5.4	55,639.50
496—Cases with code 81.61 without CC	378	3.8	44,718.16
496—Cases without 81.61	1877	9.4	85,703.09

We also examined cases in related DRG 497 (Spinal Fusion Except Cervical With CC) and DRG 498 (Spinal Fusion Except Cervical Without CC) in which code 81.61 was not reported. The chart below reflects our findings.

DRG	Count	Average length of stay	Average charges
497	16,965	6.19	$49,315.27
498	11,598	3.95	37,450.68

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

b. Multiple Level Spinal Fusion

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

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

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

The following current spinal fusion DRGs separate cases based on whether or not a CC is present: DRG 497 (Spinal Fusion Except Cervical With CC) and DRG 498 (Spinal Fusion Except Cervical Without CC); DRG 519 (Cervical Spinal Fusion With CC) and DRG 520 (Cervical Spinal Fusion Without CC). However, the difference in charges associated with the current CC split was only slightly greater than the difference attributable to the number of levels fused as found by the commenter's analysis. In addition, adopting the commenter's recommendation would have necessitated adjusting the DRG relative weights using non-MedPAR data because Medicare claims data with the new ICD–9–CM codes would not have been available until the FY 2003 MedPAR file. Therefore, at that time, we did not redefine the spinal fusion DRGs to differentiate on the basis of the number of levels of vertebrae involved in a spinal fusion procedure.

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

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

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

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

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

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

In the IPPS final rule for FY 2004 (68 FR 45360), we added heart failure

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

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

We agree that the codes listed above also include heart failure and should also be added to DRGs 387 and 389 as major problems. Therefore, we are proposing to add the heart failure codes listed above to DRGs 387 and 389 as major problems.

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

We received a request from a commenter that we remove the principal diagnosis code 292.82 (Drug-induced dementia) from MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders) and the following DRGs under MDC 20:

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

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

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

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

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

In the August 1, 2002 final rule, we modified DRGs 482 and 483 to recognize code 96.72 (Continuous mechanical ventilation for 96+ hours) for the first time in the DRG assignment (67 FR 49996). The modification was partially in response to concerns that hospitals could omit diagnosis codes indicating face, mouth, or neck diagnoses in order to have cases assigned to DRG 483 rather than the much lower paying DRG 482 (the payment for DRG 483 is more than four times greater than the DRG 482 payment weight). In addition, we noted that many patients assigned to DRG 483 did not have code 96.72 recorded. We believed this was due, in part, to the limited number of procedure codes (six) that can be submitted on the current billing form and the fact that code 96.72 did not affect the DRG assignment prior to FY 2003. The modification was the first attempt to refine DRGs 482 and 483 so that patients who receive long-term mechanical ventilation for more than 96 hours are differentiated from those who receive mechanical ventilation for less than 96 hours. The modification was intended to ensure that patients who have a tracheostomy and continuous mechanical ventilation greater than 96 hours (code 96.72) would be assigned to DRG 483. By making the GROUPER recognize long-term mechanical ventilation and assigning those patients to the higher weighted DRG 483, we encouraged hospitals to be more aware of the importance of reporting code 96.72 and to increase reporting of code 96.72 when, in fact, patients had been on the mechanical ventilator for greater than 96 hours. We stated in the August 1, 2002 final rule that, once we received more accurate data, we would give consideration to further modifying DRGs 482 and 483 based on the presence of code 96.72.

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

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

The following chart summarizes those findings:

DRG	Count	Average length of stay	Average charges
483—All cases	31,754	37.68	$210,631.94
483—Cases with code 96.72 reported	19,669	36.54	195,171.66

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

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

We noted that there were 21 cases that reported code 96.72 within DRG 510. Since the 21 patients were on continuous mechanical ventilation for 96 consecutive hours or more, it seems surprising that the principal diagnosis was listed as one of the nonextensive burn codes included in DRG 510. A closer review of these cases shows some questionable coding and reporting of information. It would appear that hospitals did not always correctly select the principal diagnosis (the reason after study that led to the hospital admission). For instance, one admission was for a second-degree burn of the ear. This patient was on a ventilator for over 96 hours. It would appear that the reason for the admission was a diagnosis other than the burn of the ear. Other cases where the patient received long-term mechanical ventilation included those with a principal diagnosis of first degree burn of the face, second degree burn of the nose, second degree burn of the lip, and an unspecified burn of the foot. These four cases reported average charges ranging from $48,551 to $186,824 and had lengths of stay ranging from 8 to 36 days.

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

- Proposed DRG 504 (Extensive Burns or Full Thickness Burns With Mechanical Ventilation 96+ Hours With Skin Graft)
- Proposed DRG 505 (Extensive Burns or Full Thickness Burns With Mechanical Ventilation 96+ Hours Without Skin Graft)

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

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

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

9. Pre-MDC: Tracheostomy

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

We examined cases in the MedPAR file in which code 96.72 was reported

within DRGs 482 and 483. The following chart illustrates the average charges and lengths of stays for cases within DRGs 482 and 483 with and without code 96.72 reported:

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

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

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

As stated earlier, we are concerned that hospitals may not always report code 96.72 because of space limitations. The electronic billing system limits the number of procedure codes that can be reported to six codes. We then looked at whether or not another major O.R. procedure is performed in addition to a tracheostomy. The DRG 483 logic requires that all patients assigned to DRG 483 have a tracheostomy. We examined cases in DRG 483 in the MedPAR file and discovered that those patients in DRG 483 who have a major procedure performed in addition to the tracheostomy have higher charges. A major procedure is a procedure whose code is included on the list that would be assigned to DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), except for tracheostomy codes 31.21 and 31.29. Currently, this additional O.R. procedure does not affect the DRG assignment for cases assigned to DRG 483. The following chart reflects our findings.

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

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

Therefore, as a result of our findings, we are proposing to modify DRG 483 by dividing these cases into two new DRGs depending on whether or not there is a major O.R. procedure reported (in addition to the tracheostomy). We are proposing to delete DRG 483 and create two new DRGs as follows:

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

We are specifically seeking comments on our proposal to delete DRG 483 and replace it with two proposed new DRGs by splitting the assignment of cases on the basis of the performance of a major O.R. procedure (in addition to the tracheostomy).

10. Medicare Code Editor (MCE) Changes

[If you choose to comment on issues in this section, please include the caption ''Medicare Code Editor'' at the beginning of your comment.]

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

a. Edit 11 (Noncovered Procedures) in the MCE contains codes that describe procedures for which Medicare does not provide reimbursement. We received a request to remove procedure codes relating to stem cell transplants from Edit 11 to conform the MCE edit to our published coverage decisions in the Medicare Coverage Issues Manual. In accordance with chapter 13, section 4 of the Program Integrity Manual (PIM), contractor discretion exists to cover diagnoses that are not explicitly stated in a national coverage decision as noncovered. Specifically this section states: that ''a local medical review policy (LMRP)'' must be clear, concise, properly formatted and not restrict or conflict with NCDs or coverage provision in interpretive manuals. If an NCD or coverage provision in an interpretive manual states that a given

item is ''covered for diagnoses/conditions A, B, and C,'' contractors may not use that as a basis to develop LMRP to cover only ''diagnosis/conditions A, B, C''. When an NCD or coverage provision in an interpretive manual does not exclude coverage for other diagnoses/conditions, contractors must allow for individual consideration unless the LMRP supports automatic denial for some or all of those other diagnoses/conditions.''

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

We agree that we need to make conforming changes relating to stem cell transplants. Therefore, we are proposing the following restructure of Edit 11:

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

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

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

Procedure List

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

Principal or Secondary Diagnosis List

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

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

Procedure List

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

Principal or Secondary Diagnosis List

- 203.00, Multiple myeloma, without mention of remission
- 203.01, Multiple myeloma, in remission

The following list contains ICD–9–CM procedure codes identified as ''Non-Covered Procedures'' except when there is at least one principal or secondary diagnosis code present from both list 1 and list 2.

Procedure List

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

Procedure List 1

- 250.00, Diabetes mellitus without mention of complication, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
- 250.01, Diabetes mellitus without mention of complication, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
- 250.02, Diabetes mellitus without mention of complication, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
- 250.03, Diabetes mellitus without mention of complication, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
- 250.10, Diabetes with ketoacidosis, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
- 250.11, Diabetes with ketoacidosis, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
- 250.12, Diabetes with ketoacidosis, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
- 250.13, Diabetes with ketoacidosis, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
- 250.20, Diabetes with hyperosmolarity, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
- 250.21, Diabetes with hyperosmolarity, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
- 250.22, Diabetes with hyperosmolarity, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
- 250.23, Diabetes with hyperosmolarity, type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
- 250.30, Diabetes with other coma, type II [non-insulin dependent type]

[NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
- 250.31, Diabetes with other coma, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
- 250.32, Diabetes with other coma, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
- 250.33, Diabetes with other coma, type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
- 250.40, Diabetes with renal manifestation, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
- 250.41, Diabetes with renal manifestation, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
- 250.42, Diabetes with renal manifestation, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
- 250.43, Diabetes with renal manifestation, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
- 205.50, Diabetes with ophthalmic manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
- 205.51, Diabetes with ophthalmic manifestations, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
- 205.52, Diabetes with ophthalmic manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
- 205.53, Diabetes with ophthalmic manifestations, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
- 250.60, Diabetes with neurological manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
- 250.61, Diabetes with neurological manifestations, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
- 250.62, Diabetes with neurological manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
- 250.63, Diabetes with neurological manifestations, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
- 250.70, Diabetes with peripheral circulatory disorders, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
- 250.71, Diabetes with peripheral circulatory disorders type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
- 250.72, Diabetes with peripheral circulatory disorders, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
- 250.73, Diabetes with peripheral circulatory disorders, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled
- 250.80, Diabetes with other specified manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
- 250.81, Diabetes with other specified manifestations, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
- 250.82, Diabetes with other specified manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
- 250.83, Diabetes with other specified manifestations, type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled
- 250.90, Diabetes with unspecified complication, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled
- 250.91, Diabetes with unspecified complication, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled
- 250.92, Diabetes with unspecified complication, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled
- 250.93, Diabetes with unspecified complication, type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled

Diagnosis List 2

- 403.01, Malignant hypertensive renal disease, with renal failure
- 403.11, Benign hypertensive renal disease, with renal failure
- 403.91, Unspecified hypertensive renal disease, with renal failure
- 404.02, Malignant hypertensive heart and renal disease, with renal failure
- 404.03, Malignant hypertensive heart and renal disease, with heart failure and renal failure
- 404.12, Benign hypertensive heart and renal disease, with renal failure
- 404.13, Benign hypertensive heart and renal disease, with heart failure and renal failure
- 404.92, Unspecified hypertensive heart and renal disease, with renal failure
- 404.93, Unspecified hypertensive heart and renal disease, with heart failure and renal failure
- 585, Chronic renal failure
- V42.0, Organ or tissue replaced by transplant, kidney
- V43.89, Organ or tissue replaced by other means, other

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

- 289.52, Splenic sequestration
- 571.3, Acute chest syndrome
- 785.52, Septic shock

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

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

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

11. Surgical Hierarchies

[If you choose to comment on the issues in this section, please include the caption ''Surgical Hierarchies'' at the beginning of your comment.]

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

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

In MDC 8, we are proposing to—

- Reorder DRG 496 (Combined Anterior/Posterior Spinal Fusion), DRG 497 (Spinal Fusion Except Cervical With CC), and DRG 498 (Spinal Fusion Except Cervical Without CC) above DRG 471 (Bilateral or Multiple Major Joint Procedures of the Lower Extremity).
- Reorder DRG 519 (Cervical Spinal Fusion With CC) and DRG 520 (Cervical Spinal Fusion Without CC) above DRG 216 (Biopsies of the Musculoskeletal System and Connective Tissue).
- Reorder DRG 213 (Amputation for the Musculoskeletal System and Connective Tissue Disorders) above DRG 210 (Hip and Femur Procedures Except Major Joint Age > 17 With CC), DRG 211 (Hip and Femur Procedures Except Major Joint Age > 17 Without CC), and DRG 212 (Hip and Femur Procedures Except Major Joint Age 0–17).
- Reorder DRG 499 (Back and Neck Procedures Except Spinal Fusion With CC) and DRG 500 (Back and Neck Procedures Except Spinal Fusion Without CC) above DRG 218 (Lower Extremity and Humerus Procedures Except Hip, Foot, and Femur Age > 17 With CC), DRG 219 (Lower Extremity and Humerus Procedures Except Hip, Foot, and Femor Age > 17 Without CC), and DRG 220 (Lower Extremity and Humerus Procedures Except Hip, Foot, and Femur Age 0–17).

12. Refinement of Complications and Comorbidities (CC) List

[If you choose to comment on issues in this section, please include the caption ''CC List'' at the beginning of your comment.]

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. We developed this list of diagnoses, using physician panels, to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity. In previous years, we have made changes to the list of CCs, either by adding new CCs or deleting CCs already on the list. 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) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

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

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

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, 2004. (*See* section II.B.15. of this preamble for a discussion of ICD–9–CM changes.) We are proposing these changes 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 proposed revisions to the CC Exclusions List that would be effective for discharges occurring on or after October 1, 2004. Each table shows the principal diagnoses with changes to the excluded CCs. Each of these principal diagnoses is shown with an asterisk, and the additions or deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis.

CCs that are added to the list are in Table 6G—Additions to the CC Exclusions List. Beginning with discharges on or after October 1, 2004, the indented diagnoses 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, 2004, 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 $152.50 plus shipping and handling. A request for the FY 1988 CC Exclusions List (which should include the identification accession number (PB) 88–133970) should be made to the following address: National Technical Information Service, United States Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161; or by calling (800) 553–6847.

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

Alternatively, the complete documentation of the GROUPER logic, including the current CC Exclusions List, is available from 3M/Health Information Systems (HIS), which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. The current DRG Definitions Manual, Version 21.0, is available for $225.00, which includes $15.00 for shipping and handling. Version 22.0 of this manual, which includes the final FY 2004 DRG changes, is available for $225.00. These manuals may be obtained by writing 3M/HIS at the following address: 100 Barnes Road, Wallingford, CT 06492; or by calling (203) 949–0303. Please specify the revision or revisions requested.

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

[If you choose to comment on issues in this section, please include the caption ''DRGs 468, 476, and 477'' at the beginning of your comment.]

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

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

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

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

[1] 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; the August 1, 2002 final rule (67 FR 49998) for the FY 2003 revisions; and the August 1, 2003 final rule (68 FR 45364) for the FY 2004 revisions.) In the July 30, 1999 final rule (64 FR 41490), we did not modify the CC Exclusions List for FY 2000 because we did not make any changes to the ICD–9–CM codes for FY 2000.

[2] In the August 1, 2003 final rule (68 FR 45365) we moved several procedures from DRG 468 to DRGs 476 and 477 because the procedures are nonextensive. The original list of the ICD–9–CM

Continued

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 procedures in DRG 477 that should be removed. Therefore, we are not proposing to move any procedures from DRG 477 to one of the surgical DRGs.

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

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

The commenter suggested that a laparoscopic procedure was probably not an extensive O.R. procedure; it was more likely a nonextensive O.R. procedure. We agree and, therefore, are proposing this change. In addition, we are proposing to add several new procedure codes to DRGs 476 and 477. These procedures are also listed on Table 6B—New Procedure Codes in the Addendum to this proposed rule. However, DRGs 476 and 477 are not limited to one MDC, so the new codes are also included here for nonextensive cases in which the procedures are unrelated to the principal diagnosis:

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

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

We are not proposing to move any procedure codes 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.

14. Pancreatic Islet Cell Transplantation in Clinical Trials

[If you choose to comment on issues in this section, please include the caption ''Pancreatic Islet Cell Transplantation'' at the beginning of your comment.]

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

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

The add-on payment would be a single amount that includes pre-transplant tests and services, pancreas procurement, and islet isolation services. We are proposing to use an

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

add-on as opposed to increasing the DRG amount because the DRGs at issue are also applied in cases involving a variety of other procedures that do not include the costly islet cell acquisition required for this procedure. Thus, including these costs in the DRGs would have the potential of skewing the weights for all other DRGs. We are asking for specific comments on whether an add-on payment amount is the appropriate way to reimburse islet cell acquisition costs, or whether another methodology may be more appropriate.

In addition, while we have some data available regarding the cost of pancreas procurement, we are specifically asking for any other data that support the costs of acquisition and the costs of isolation cell resource centers.

Because we do not yet have enough data, we are unable to publish a proposed acquisition amount in this proposed rule. After analyzing data submitted during the comment period, other data acquired by CMS, and any suggested changes from the methodology proposed, we will issue the final organ acquisition payment amount in the IPPS final rule.

Pancreatic islet cell transplantation during the clinical trial will be performed to decrease or eliminate the need for insulin in patients with Type I diabetes. Islet cells are acquired from a cadaveric pancreas donor (islet allotransplantation).

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

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

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

As each case is assigned to a DRG based on all of the ICD–9–CM codes reported, cases could also be assigned to DRGs other than those mentioned above. In fact, our review of FY 2003 MedPAR data revealed that codes 52.84 and 52.85 were present in only four cases, and that each case was assigned to a different DRG. We found one case each in DRG 18 (Cranial and Peripheral Nerve Disorders With CC), DRG 192 (Pancreas, Liver, and Shunt Procedures Without CC), DRG 207 (Disorders of the Biliary Tract With CC), and DRG 302 (Kidney Transplant).

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

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

[If you choose to comment on issues in this section, please include the caption ''ICD–9–CM Coding'' at the beginning of your comment.]

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 $25.00 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 individual physicians, medical record administrators, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2005 at public meetings held on April 3, 2003 and December 4–5, 2003, and finalized the coding changes after consideration of comments received at the meetings and in writing by January 12, 2004. Those coding changes are announced in Tables 6A through 6F in the Addendum to this proposed rule. Copies of the minutes of the procedure codes discussions at the Committee's 2003 meetings can be obtained from the CMS Web site: *http://www.cms.gov/paymentsystems/icd9/*. The minutes of

the diagnoses codes discussions at the 2003 meetings are found at: *http://www.cdc.gov/nchs/icd9.htm.* Paper copies of these minutes are no longer available and the mailing list has been discontinued.

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

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

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

The ICD–9–CM code changes that have been approved will become effective October 1, 2004. The new ICD–9–CM codes are listed, along with their DRG classifications, in Tables 6A and 6B (New Diagnosis Codes and New Procedure Codes, respectively) in the Addendum to this 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, 2004. Table 6D usually contains invalid procedure codes, however, for FY 2005, there are no invalid procedure codes. Revisions to diagnosis code titles are in Table 6E (Revised Diagnosis Code Titles), which also includes the DRG assignments for these revised codes. Table 6F includes revised procedure code titles for FY 2005.

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

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

While the new requirement states that the Secretary shall not adjust the payment of the DRG classification for the April 1 new codes, the Department will have to update its DRG software and other systems in order to recognize and accept the new codes. We will also have to publicize the code changes and the need for a mid-year systems update by providers to capture the new codes. Hospitals will have to obtain the new code books and encoder updates, and make other system changes in order to capture and report the new codes. We are aware of the additional burden this will have on health care providers.

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

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

We are proposing to implement section 503(a) by developing a mechanism for approving, in time for the April update, diagnoses and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We are proposing the following process for

making these determinations. Topics considered during the October ICD–9–CM Coordination and Maintenance Committee meeting would be considered for an April 1 update if a strong and convincing case is made by the requestor at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report would be provided the opportunity to comment on this expedited request. All other topics would be considered for the October 1 update. Participants at the Committee meeting would be encouraged to comment on all such requests.

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

The Department of Health and Human Services has been actively working on the development of new coding systems to replace the ICD–9–CM. In December 1990, the National Committee on Vital and Health Statistics (NCVHS) issued a report noting that, while the ICD–9–CM classification system had been responsive to changing technologies and identifying new diseases, there was concern that the ICD classification might be stressed to a point where the quality of the system would soon be compromised. The ICD–10–CM (for diagnoses) and the ICD–10–PCS (for procedures) were developed in response to these concerns. These efforts have become increasingly important because of the growing number of problems with the ICD–9–CM, which was implemented 25 years ago.

In November 2003, the NCVHS recommended that the Secretary prepare a notice of proposed rulemaking for the implementation of 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.* The Department is studying these recommendations.

16. Other Issues

[If you choose to comment on issues in this section, please include the caption ''Other DRG Issues'' at the beginning of your comments.]

a. Craniotomy Procedures

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

As discussed below, we have received further comments regarding the composition of DRGs 1 and 2 that relate to the appropriate DRG assignment of unruptured cerebral aneurysm cases and cases involving implantation of GLIADEL® chemotherapy wafers. We have also received comments on possible revisions to DRG 3 (Craniotomy Age 0–17).

(1) Unruptured Cerebral Aneurysms

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

We now have examined cases in the FY 2003 MedPAR file that reported unruptured cerebral aneurysms. We found 657 unruptured aneurysm cases assigned to DRG 1 and 481 unruptured cerebral aneurysm cases assigned to DRG 2. The average charges for these unruptured cerebral aneurysm cases in DRG 1 ($50,879) are slightly lower than the overall charges for all cases in that DRG ($51,300). For unruptured cerebral aneurysm cases assigned to DRG 2, we found the average charges of approximately $29,524 are consistent with the overall average charges of that DRG of approximately $28,416.

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

(2) GLIADEL® Chemotherapy Wafers

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

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

We have now examined more complete MedPAR data (December 2003 update for FY 2003) on cases reporting GLIADEL® chemotherapy wafers. We found a total of 127 cases in which procedure code 00.10 was reported for cases assigned to DRGs 1 and 2. There were 80 cases assigned to DRG 1 and 47 cases assigned to DRG 2. The average

charges for these cases in DRGs 1 and 2 were approximately $61,866 and $47,189, respectively. The average charges for these cases are higher than the overall charges of DRGs 1 and 2 of approximately $51,300 and $28,416, respectively. Although the average charges for the GLIADEL® wafer cases within these DRGs are higher than the average charges of all cases in these DRGs, they remain within the range of average charges for other procedures included in these DRGs. The majority of the GLIADEL® wafer cases are assigned to the second highest weighted DRG in MDC 1 behind DRG 528 (Intracranial Vascular Procedure With a Principal Diagnosis of Hemorrhage) in which the weights were derived from average charges of approximately $113,884. In DRG 1, there are 10 procedures that have higher average charges than the GLIADEL® wafer cases. However, in DRG 2, the charges associated with GLIADEL® wafer cases are the highest of the procedures included within the DRG.

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

Commenters also have proposed the reassignment of GLIADEL® wafer cases to other existing DRGs, such as DRG 484 (Craniotomy for Multiple Significant Trauma), DRG 528 (Intracranial Vascular Procedures With Principal Diagnosis of Hemorrhage), DRG 492 (Chemotherapy With Acute Leukemia as a Secondary Diagnoses or With Use of a High Dose Chemotherapeutic Agent), or DRG 481 (Bone Marrow Transplant). We have examined these alternatives, and have come to the conclusion that none of these alternatives meets the standard of clinical coherence under the DRG system. For example, reconfiguring DRG 484 to include GLIADEL® wafer cases would not produce a clinically coherent DRG because DRG 484 contains cases where craniotomy is performed in the setting of multiple significant trauma. Similarly, assigning GLIADEL® wafer cases to DRG 528 would not produce a clinically coherent DRG because DRG 528 contains cases where craniotomy is performed as part of a vascular procedure with a primary diagnosis of hemorrhage, as in the case of a ruptured aneurysm. DRG 492 is clinically inappropriate because it contains cases of acute leukemia treated with chemotherapy, and DRG 481 is clinically inappropriate because it contains cases involving bone marrow transplant. None of these DRGs contains cases of glioblastoma multiforme or other primary brain tumors. Therefore, we are not proposing to adopt any of these changes at this time.

We also considered several other approaches to reassigning GLIADEL® wafer cases in a manner that is appropriate both in terms of clinical coherence and resource use. For example, we considered the creation of a new DRG that includes GLIADEL® wafer cases along with other types of local therapy for intracerebral malignant disease. Specifically, we considered the creation of a new DRG that includes GLIADEL® wafers and a Gliasite Radiation Therapy System, a relatively new form of intracavitary brachytherapy. Such a DRG would be clinically coherent because it would contain cases of malignant brain tumors treated with local therapy. However, our analysis of existing MedPAR data suggests that such a DRG would probably not provide enhanced reimbursement for the GLIADEL® wafer cases, and that, in fact, decreased reimbursement for GLIADEL® wafer cases is a more likely result. Therefore, we are not proposing a change at this time. However, we will continue to monitor our data to determine whether a change is warranted in the future.

We recognize that the implantation of chemotherapeutically active wafers for local therapy of malignant brain tumors represents a significant medical technology that currently offers clinical benefits to patients and holds out the promise of future innovation in the treatment of these brain tumors. Therefore, we invite further comments and suggestions regarding the appropriate DRG assignment for this technology. (3) DRG 3 (Craniotomy Age 0–17)

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

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

b. Coronary Stent Procedures

We have received comments and recommendations from several industry representatives about the DRG assignments for coronary artery stents. These representatives expressed concern about whether the reimbursement for stents is adequate, especially for insertion of multiple stents. They also expressed concern about whether the current DRG structure represents the most clinically coherent classification of stent cases.

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

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

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

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

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

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

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

The manufacturer presented an analysis based on FY 2002 MedPAR data, in which it evaluated charges and lengths of stay for cases with expected high resource use, and reclassified cases into the recommended new structure of paired ''complex'' and ''noncomplex'' DRGs. The analysis shows some evidence of clinical and resource coherence in the recommended DRG structure. However, the analysis does not yet provide a convincing case for adopting the recommended restructure. First, the analysis does not reveal significant gains in resource coherence compared to previous DRGs for stenting cases. Second, the analysis is limited in assessing the feasibility of using the recommended DRG restructure versus the current DRG structure for classification of stent cases. Because the manufacturer used FY 2002 MedPAR data in its analysis, it was not able to compare the resource coherence of the recommended structure with the current structure of four DRGs, but only with the two DRGs that preceded the approval of drug-eluting stents. While the manufacturer asserted that ''similar results would be expected'' from a comparison between its recommended DRG restructure and the current DRG structure, we do not believe that it is advisable to undertake a critical DRG restructuring without examining the recommendation against actual experience under the current structure. Nevertheless, we believe that this recommendation may have merit, and we will conduct a full analysis of the recommendation in comparison to the current DRG structure once adequate data become available.

The drug-eluting stents had not yet been FDA approved when we calculated the relative weights for DRGs 526 and 527 for the FY 2003 IPPS final rule. Therefore, in the absence of MedPAR data, we based our FY 2003 relative weight calculations on prices in countries where drug-eluting stents were already being used. A full discussion of this process can be found in the FY 2004 IPPS final rule (68 FR 45370). For computation of the proposed relative weights for FY 2005 for this proposed rule, we are using the December update of FY 2003 MedPAR data. There have been a total of 42,356 cases in DRG 526, and 33,179 cases in DRG 527, with adjustments made for transfers to other facilities. For computation of the final FY 2005 relative weights, we will use the latest update of the MedPAR data file for cases in these two DRGs. No foreign data will be used to compute the relative weights for DRGs 526 and 527 in FY 2005.

c. Severe Sepsis

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

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

d. Implantable Cardiac Defibrillators

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

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

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

We believe that, within the PPS for inpatient hospital operating costs, there are several ways to deal with the expanding use of simpler, lower cost defibrillators. One possibility is to maintain the current DRG configuration, under which complex, expensive devices and simpler, less costly devices would remain within the same DRGs and receive the same payment rates. This approach would encourage use of the simpler devices, which would receive relatively higher reimbursement because their lower charges would be averaged in with the higher charges for the more complex devices in setting the DRG weights. However, it could lead to complaints that the program is underpaying for the more complex, expensive devices as the lower charges for simpler, less expensive devices begin to affect (lower) the DRG weights.

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

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

C. Recalibration of DRG Weights

[If you choose to comment on issues in this section, please include the caption ''DRG Weights'' at the beginning of your comment.]

We are proposing to use the same basic methodology for the FY 2005 recalibration as we did for FY 2004 (August 1, 2003 IPPS final rule (68 FR 45373)). That is, we are proposing to recalibrate the DRG weights based on charge data for Medicare discharges using the most current charge information available (the FY 2003 MedPAR file).

The MedPAR file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2003 MedPAR data used in this proposed rule include discharges occurring between October 1, 2002 and September 30, 2003, based on bills received by CMS through December 31, 2003, 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 2003 MedPAR file includes data for approximately 11,717,744 Medicare discharges. Discharges for Medicare beneficiaries enrolled in a Medicare+Choice managed care plan are excluded from this analysis. The data excludes CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken.

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

- To the extent possible, all the claims were regrouped using the DRG classification revisions discussed in section II.B. of this preamble.

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

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

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

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

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

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

The proposed new weights are normalized by a proposed adjustment factor of 1.46899 so that the average case weight after recalibration is equal to the average case weight before recalibration. This proposed adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We are proposing to use that same case threshold in recalibrating the proposed DRG weights for FY 2005. Using the FY 2003 MedPAR data set, there are 42 DRGs that contain fewer than 10 cases. We are proposing to compute the weights for these low-volume DRGs by adjusting the FY 2004 weights of these DRGs by the percentage change in the average weight of the cases in the other DRGs.

Section 1886(d)(4)(C)(iii) of the Act requires that, beginning with FY 1991, reclassification and recalibration changes be made in a manner that assures that the aggregate payments are neither greater than nor less than the aggregate payments that would have been made without the changes. Although normalization is intended to achieve this effect, equating the average case weight after recalibration to the average case weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case weight. Therefore, as we have done in past years and as discussed in section II.A.4.a. of the Addendum to this 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 2005

[If you choose to comment on issues in this section, please include the caption ''LTC–DRGs'' at the beginning of your comment.]

1. Background

In the June 6, 2003 LTCH PPS final rule (68 FR 34122), we changed the LTCH PPS annual payment rate update cycle to be effective July 1 through June 30 instead of October 1 through September 30. In addition, 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 final rule, we explained that the annual update of the long-term care diagnosis-related group (LTC–DRG) classifications and relative weights will continue to remain linked to the annual reclassification and recalibration of the CMS–DRGs under the IPPS.

The annual update to the IPPS DRGs is based on the annual revisions to the ICD–9–CM codes and is effective each October 1. In the health care industry, annual changes to the ICD–9–CM codes are effective for discharges occurring on or after October 1 each year. The use of the ICD–9-CM coding system is also compliant with the requirements of the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104–191, under 45 CFR Parts 160 and 162. Therefore, the manual and electronic versions of the 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 June 6, 2003 LTCH PPS final rule (68 FR 34128), we specified that we will continue to update the LTC–DRG classifications and relative weights to be effective for discharges occurring on or after October 1 through September 30 each year. Furthermore, we stated that we will publish the annual update of the LTC–DRGs in the proposed and final rules for the IPPS.

In this proposed rule, we are proposing revisions to the LTC–DRG classifications and relative weights and will finalize them in the IPPS final rule, to be effective October 1, 2004 through September 30, 2005. The proposed LTC–DRGs and relative weights for FY 2005 in this proposed rule are based on the IPPS DRGs (GROUPER version 22.0) discussed in section II. of this proposed rule.

2. Proposed Changes in the LTC–DRG Classifications

a. Background

Section 123 of Public Law 106–113 specifically requires that the PPS for LTCHs be a per discharge system with a DRG-based patient classification system reflecting the differences in patient resources and costs in LTCHs while maintaining budget neutrality. Section 307(b)(1) of Public Law 106–554 modified the requirements of section 123 of Public Law 106–113 by specifically requiring that the Secretary examine ''the feasibility and the impact of basing payment under such a system [the LTCH PPS] on the use of existing (or refined) hospital diagnosis-related groups (DRGs) that have been modified to account for different resource use of long-term care hospital patients as well as the use of the most recently available hospital discharge data.''

In accordance with section 307(b)(1) of Public Law 106–554 and § 412.515 of our existing regulations, the LTCH PPS uses information from LTCH patient

records to classify patient cases into distinct LTC–DRGs based on clinical characteristics and expected resource needs. The LTC–DRGs used as the patient classification component of the LTCH PPS correspond to the DRGs under the IPPS for acute care hospitals. Thus, in this proposed rule, we are proposing to use the IPPS version 22.0 GROUPER for FY 2005 to process LTCH PPS claims. The proposed changes to the IPPS DRG classification system for FY 2005 (Grouper 22.0) are discussed in section II.B. of this preamble.

Under the LTCH PPS, we determine relative weights for each of the CMS DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCH patients. In a departure from the IPPS, as we discussed in the August 30, 2002 final rule (67 FR 55985), which implemented the LTCH PPS, and the August 1, 2003 IPPS final rule (68 FR 45374), we use low-volume quintiles in determining the LTC–DRG weights for LTC–DRGs with less than 25 LTCH cases, since LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Specifically, we group those low-volume LTC–DRGs (LTC–DRGs with fewer than 25 cases) into 5 quintiles based on average charge per discharge. (A listing of the composition of low-volume quintiles for the FY 2004 LTC–DRGs (based on FY 2002 MedPAR data) appears in section II.D.3. of the August 1, 2003 IPPS final rule (68 FR 45377—45380).) We also adjust for cases in which the stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay; that is, short-stay outlier cases (§ 412.529), as discussed below in section II.D.4. of this preamble.

b. Patient Classifications Into DRGs

Generally, under the LTCH PPS, Medicare payment is made at a predetermined specific rate for each discharge; that is, payment varies by the LTC–DRG to which a beneficiary's stay is assigned. Similar to case classification for acute care hospitals under the IPPS (see section II.B. of this preamble), cases are classified into LTC–DRGs for payment under the LTCH PPS based on the principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the stay, as well as age, sex, and discharge status of the patient. The diagnosis and procedure information is reported by the hospital using codes from the ICD–9–CM.

As discussed above in section II.B. of this preamble, the CMS DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Accordingly, the principal diagnosis determines MDC assignment. Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Some surgical and medical DRGs are further differentiated based on the presence or absence of CCs. (See section II.B. of this preamble for further discussion of surgical DRGs and medical DRGs.)

Because the assignment of a case to a particular LTC–DRG will help determine the amount that is paid for the case, it is important that the coding is accurate. As used under the IPPS, classifications and terminology used under the LTCH PPS are consistent with the ICD–9–CM and the Uniform Hospital Discharge Data Set (UHDDS), as recommended to the Secretary by the National Committee on Vital and Health Statistics (''Uniform Hospital Discharge Data: Minimum Data Set, National Center for Health Statistics, April 1980'') and as revised in 1984 by the Health Information Policy Council (HIPC) of the U.S. Department of Health and Human Services. We wish to point out again that the ICD–9–CM coding terminology and the definitions of principal and other diagnoses of the UHDDS are consistent with the requirements of the Administrative Simplification Act of 1996 of the HIPAA (45 CFR Parts 160 and 162).

The emphasis on the need for proper coding cannot be overstated. Inappropriate coding of cases can adversely affect the uniformity of cases in each LTC–DRG and produce inappropriate weighting factors at recalibration and result in inappropriate payments under the LTCH PPS. LTCHs are to follow the same coding guidelines used by the acute care hospitals to ensure accuracy and consistency in coding practices. There will be only one LTC–DRG assigned per long-term care hospitalization; it will be assigned at the discharge. Therefore, it is mandatory that the coders continue to report the same principal diagnosis on all claims and include all diagnostic codes that coexist at the time of admission, that are subsequently developed, or that affect the treatment received. Similarly, all procedures performed during that stay are to be reported on each claim.

Upon the discharge of the patient from a LTCH, the LTCH must assign appropriate diagnosis and procedure codes from the ICD–9–CM. As of October 16, 2002, a LTCH that was required to comply with the HIPAA Administrative Simplification Standards and that had not obtained an extension in compliance with the Administrative Compliance Act (Public Law 107–105) is obligated to comply with the standards at 45 CFR 162.1002 and 45 CFR 162.1102. Completed claim forms are to be submitted to the LTCH's Medicare fiscal intermediary. Medicare fiscal intermediaries enter the clinical and demographic information into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into an LTC–DRG can be made.

After screening through the MCE, each LTCH claim will be classified into the appropriate LTC–DRG by the Medicare LTCH GROUPER. The LTCH GROUPER is specialized computer software based on the same GROUPER used under the IPPS. After the LTC–DRG is assigned, the Medicare fiscal intermediary determines the prospective payment by using the Medicare LTCH PPS PRICER program, which accounts for LTCH hospital-specific adjustments. As provided for under the IPPS, we provide an opportunity for the LTCH to review the LTC–DRG assignments made by the fiscal intermediary and to submit additional information within a specified timeframe (§ 412.513(c)).

The GROUPER is used both to classify past cases in order to measure relative hospital resource consumption to establish the LTC–DRG weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible DRG classification changes and to recalibrate the DRG weights during our annual update (as discussed in section II. of this preamble). The LTC–DRG relative weights are based on data for the population of LTCH discharges, reflecting the fact that LTCH patients represent a different patient mix than patients in short-term acute care hospitals.

3. Development of the Proposed FY 2005 LTC–DRG Relative Weights

a. General Overview of Development of the LTC–DRG Relative Weights

As we stated in the August 30, 2002 LTCH PPS final rule (67 FR 55981), one of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of care to Medicare patients. The system must be able to account adequately for each

LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly. To accomplish these goals, we adjust the LTCH PPS standard Federal prospective payment system rate by the applicable LTC–DRG relative weight in determining payment to LTCHs for each case.

Under the LTCH PPS, relative weights for each LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each LTC–DRG that represents the resources needed by an average inpatient LTCH case in that LTC–DRG. For example, cases in 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 2005 in this proposed rule, we obtained total Medicare allowable charges from FY 2003 Medicare hospital bill data from the December 2003 update of the MedPAR file, and we used the proposed Version 22.0 of the CMS GROUPER for IPPS, as discussed in section II.B. of this preamble, to classify cases. Consistent with the methodology under the IPPS, we are proposing to recalculate the FY 2005 LTC–DRG relative weights based on the best available data for the final rule.

As we discussed in the August 1, 2003 final rule (68 FR 45376), 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 2005 LTC–DRG relative weights, we have excluded the data of the 22 all-inclusive rate providers and the 3 LTCHs that are paid in accordance with demonstration projects that had claims in the FY 2003 MedPAR file.

In the August 1, 2003 final rule (68 FR 45367), we discussed coding inaccuracies that were found in claims data for a large chain of LTCHs in the FY 2002 MedPAR file used to determine the LTC–DRG relative weights for FY 2004. Specifically, the principal diagnosis was not reported correctly on many of those LTCHs' claims, which resulted in those claims being incorrectly assigned to a LTC–DRG. As we explained in that same final rule, we were able to determine the correct diagnoses and procedure codes for the claims that contained the coding errors, and we used them to group each LTCH case to the appropriate LTC–DRG for determining the LTC–DRG relative weights for FY 2004. In addition, we stated that since the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002 (FY 2003), we believe that this problem will be self-correcting as LTCHs submit more completely coded data in the future.

As we discussed in the May 7, 2004 LTCH PPS final rule (69 FR 25673), an analysis of LTCH claims data from the September 2003 update of the FY 2003 MedPAR file contained coding errors. Specifically, a large hospital chain of LTCHs continued to consistently code diagnoses inaccurately on the claims it submitted, and these coding errors were reflected in the September 2003 update of the FY 2003 MedPAR file. Upon discovering the coding errors, we notified the large chain of LTCHs whose claims contained the coding inaccuracies to request that they resubmit those claims with the correct diagnoses codes by December 31, 2003, so that those corrected claims would be contained in the December 2003 update of the FY 2003 MedPAR file. As we discussed in that same final rule, it appears that those claims were submitted timely with the correct diagnoses codes. Therefore, it was not necessary to correct the FY 2003 MedPAR data for the development of the rates and factors established in the May 7, 2004 LTCH PPS final rule. Accordingly, we are proposing to use LTCH claims data from the December 2003 update of the FY 2003 MedPAR file for the determination of the proposed FY 2005 LTC–DRG relative weights in this proposed rule.

c. Hospital-Specific Relative Value Methodology

By nature LTCHs often specialize in certain areas, such as ventilator-dependent patients and rehabilitation and wound care. Some case types (DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. 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, we use a hospital-specific relative value method to calculate the LTC–DRG relative weights instead of the methodology used to determine the DRG relative weights under the IPPS described above in section II.C. of this preamble. We believe this method will remove this hospital-specific source of bias in measuring LTCH average charges. Specifically, we reduce the impact of the variation in charges across providers on any particular LTC–DRG relative weight by converting each LTCH's charge for a case to a relative value based on that LTCH's average charge.

Under the hospital-specific relative value method, we standardize charges for each LTCH by converting its charges for each case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, averages 1.0 for each LTCH). The average relative weight for a LTCH is its case-mix, so it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the cases it treats relative to the complexity of the cases treated by all other LTCHs (the average case-mix of all LTCHs).

In accordance with the methodology established under § 412.523, we standardize charges for each case by first dividing the adjusted charge for the case (adjusted for short-stay outliers under § 412.529 as described in section II.D.4. (step 3) of this preamble) by the average adjusted charge for all cases at the LTCH in which the case was treated. Short-stay outliers under § 412.529 are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the LTC–DRG. The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio is multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

Multiplying by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight in a LTCH with higher average costs than they would at a LTCH with low average costs which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. Because we standardize charges in this manner, we count charges for a Medicare patient at a LTCH with high average charges as less resource intensive than they would

be at a LTCH with low average charges. For example, a $10,000 charge for a case in a LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case in a LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

d. Low-Volume LTC–DRGs

In order to account for LTC–DRGs with low-volume (that is, with fewer than 25 LTCH cases), in accordance with the methodology discussed in the August 1, 2002 final rule (67 FR 55984), 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 2003 update of the FY 2003 MedPAR file, we identified 171 LTC–DRGs that contained between 1 and 24 cases. This list of proposed LTC–DRGs was then divided into one of the five low-volume quintiles, each containing a minimum of 34 LTC–DRGs (171/5 = 34 with 1 LTC–DRG as the remainder). For FY 2005, we are proposing to make an assignment to a specific low-volume quintile by sorting the 171 low-volume proposed LTC–DRGs in ascending order by average charge. Since the number of LTC–DRGs with less than 25 LTCH cases is not evenly divisible by five, the average charge of the proposed low-volume LTC–DRG was used to determine which low-volume quintile received the proposed additional LTC–DRG. After sorting the 171 low-volume proposed LTC–DRGs in ascending order, we are proposing that the first fifth (34) of low-volume LTC–DRGs with the lowest average charge would be grouped into Quintile 1. The highest average charge cases would be grouped into Quintile 5. Since the average charge of the proposed 69th LTC–DRG in the sorted list is closer to the previous proposed LTC–DRG's average charge (assigned to Quintile 2) than to the average charge of the proposed 70th LTC–DRG in the sorted list (to be assigned to Quintile 3), we are proposing to place it into Quintile 2. This process was repeated through the remaining low-volume proposed LTC–DRGs so that 4 proposed low-volume quintiles contain 34 proposed LTC–DRGs and 1 proposed low-volume quintile contains 35 proposed LTC–DRGs.

In order to determine the proposed relative weights for the proposed LTC–DRGs with low volume for FY 2005, in accordance with the methodology described in the August 1, 2002 final rule (67 FR 55984), we are proposing to use the five proposed low-volume quintiles described above. The composition of each of the five proposed low-volume quintiles shown below in Table 1 would be used in determining the proposed LTC–DRG relative weights for FY 2005. 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 proposed 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
	QUINTILE 1
11	NERVOUS SYSTEM NEOPLASMS W/O CC.
43	HYPHEMA.
45	NEUROLOGICAL EYE DISORDERS.
47	OTHER DISORDERS OF THE EYE AGE >17 W/O CC.
84	MAJOR CHEST TRAUMA W/O CC.
95	PNEUMOTHORAX W/O CC.
110	MAJOR CARDIOVASCULAR PROCEDURES W CC.
119	VEIN LIGATION & STRIPPING.
143	CHEST PAIN.
149	MAJOR SMALL & LARGE BOWEL PROCEDURES W/O CC.
178	UNCOMPLICATED PEPTIC ULCER W/O CC.
193	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W CC.
208	DISORDERS OF THE BILIARY TRACT W/O CC.
229	HAND OR WRIST PROC, EXCEPT MAJOR JOINT PROC, W/O CC.
241	CONNECTIVE TISSUE DISORDERS W/O CC.
260	SUBTOTAL MASTECTOMY FOR MALIGNANCY W/O CC.
273	MAJOR SKIN DISORDERS W/O CC.
284	MINOR SKIN DISORDERS W/O CC.
301	ENDOCRINE DISORDERS W/O CC.
323	URINARY STONES W CC, &/OR ESW LITHOTRIPSY.
324	URINARY STONES W/O CC.
326	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W/O CC .
339	TESTES PROCEDURES, NON-MALIGNANCY AGE >17.
347	MALIGNANCY, MALE REPRODUCTIVE SYSTEM, W/O CC.
367	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM W/O CC.
404	LYMPHOMA & NON-ACUTE LEUKEMIA W/O CC.
414	OTHER MYELOPROLIF DIS OR POORLY DIFF NEOPL DIAG W/O CC.
433	ALCOHOL/DRUG ABUSE OR DEPENDENCE, LEFT AMA.
450	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W/O CC.
479	OTHER VASCULAR PROCEDURES W/O CC.

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

Proposed LTC–DRG	Description
500	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W/O CC.
509	FULL THICKNESS BURN W/O SKIN GRFT OR INH INJ W/O CC OR SIG TRAUMA.
522	ALC/DRUG ABUSE OR DEPEND W REHABILITATION THERAPY W/O CC
523	ALC/DRUG ABUSE OR DEPEND W/O REHABILITATION THERAPY W/O CC
	QUINTILE 2
8	PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W/O CC.
22	HYPERTENSIVE ENCEPHALOPATHY.
25	SEIZURE & HEADACHE AGE >17 W/O CC.
31	CONCUSSION AGE >17 W CC.
69*	OTITIS MEDIA & URI AGE >17 W/O CC.
109	CORONARY BYPASS W/O PTCA OR CARDIAC CATH.
128	DEEP VEIN THROMBOPHLEBITIS.
129	CARDIAC ARREST, UNEXPLAINED.
140	ANGINA PECTORIS.
175	G.I. HEMORRHAGE W/O CC.
177	UNCOMPLICATED PEPTIC ULCER W CC.
181	G.I. OBSTRUCTION W/O CC.
227	SOFT TISSUE PROCEDURES W/O CC.
228	MAJOR THUMB OR JOINT PROC, OR OTH HAND OR WRIST PROC W CC.
234	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W/O CC.
237	SPRAINS, STRAINS, & DISLOCATIONS OF HIP, PELVIS & THIGH.
250	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W CC.
251	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W/O CC .
276	NON-MALIGANT BREAST DISORDERS.
295	DIABETES AGE 0–35.
305	KIDNEY,URETER & MAJOR BLADDER PROC FOR NON-NEOPL W/O CC.
307	PROSTATECTOMY W/O CC.
325	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W CC.
328	URETHRAL STRICTURE AGE >17 W CC.
348	BENIGN PROSTATIC HYPERTROPHY W CC.
349	BENIGN PROSTATIC HYPERTROPHY W/O CC.
399	RETICULOENDOTHELIAL & IMMUNITY DISORDERS W/O CC.
420	FEVER OF UNKNOWN ORIGIN AGE >17 W/O CC.
427	NEUROSES EXCEPT DEPRESSIVE.
441	HAND PROCEDURES FOR INJURIES.
447	ALLERGIC REACTIONS AGE >17.
449	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W CC.
467	OTHER FACTORS INFLUENCING HEALTH STATUS.
511	NON-EXTENSIVE BURNS W/O CC OR SIGNIFICANT TRAUMA
532	SPINAL PROCEDURES W/O CC
	QUINTILE 3
17	NONSPECIFIC CEREBROVASCULAR DISORDERS W/O CC.
21	VIRAL MENINGITIS.
29	TRAUMATIC STUPOR & COMA, COMA <1 HR AGE >17 W/O CC.
44	ACUTE MAJOR EYE INFECTIONS.
53	SINUS & MASTOID PROCEDURES AGE >17.
83	MAJOR CHEST TRAUMA W CC.
122	CIRCULATORY DISORDERS W AMI W/O MAJOR COMP, DISCHARGED ALIVE.
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG.
136	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE >17 W/O CC.
159	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W CC.
185	DENTAL & ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AG >17.
200	HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR NON-MALIGNANCY.
262	BREAST BIOPSY & LOCAL EXCISION FOR NON- MALIGNANCY.
266	SKIN GRAFT &/OR DEBRID EXCEPT FOR SKIN ULCER OR CELLULITIS W/O CC.
270	OTHER SKIN, SUBCUT TISS & BREAST PROC W/O CC.
275	MALIGNANT BREAST DISORDERS W/O CC.
288	O.R. PROCEDURES FOR OBESITY.
299	INBORN ERRORS OF METABOLISM.
306	PROSTATECTOMY W CC.
319*	KIDNEY & URINARY TRACT NEOPLASMS W/O CC
336	TRANSURETHRAL PROSTATECTOMY W CC.
352	OTHER MALE REPRODUCTIVE SYSTEM DIAGNOSES.
369	MENSTRUAL & OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS.
394	OTHER O.R. PROCEDURES OF THE BLOOD AND BLOOD FORMING ORGANS.
410	CHEMOTHERAPY W/O ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS.
476	PROSTATIC O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS.

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

Proposed LTC–DRG	Description
493	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W CC.
496	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION.
497	SPINAL FUSION EXCEPT CERVICAL W CC.
502	KNEE PROCEDURES W PDX OF INFECTION W/O CC.
517	PERC CARDIO PROC W NON-DRUG ELUTING STENT W/O AMI.
518	PERC CARDIO PROC W/O CORONARY ARTERY STENT OR AMI.
538	LOCAL EXCIS & REMOV OF INT FIX DEV EXCEPT HIP & FEMUR W/O CC
539	LYMPHOMA & LEUKEMIA W MAJOR OR PROCEDURE W CC
	QUINTILE 4
1	CRANIOTOMY AGE >17 W CC.
63	OTHER EAR, NOSE, MOUTH & THROAT O.R. PROCEDURES.
86*	PLEURAL EFFUSION W/O CC.
102*	OTHER RESPIRATORY SYSTEM DIAGNOSES W/O CC.
108	OTHER CARDIOTHORACIC PROCEDURES.
115	PRM CARD PACEM IMPL W AMI/HR/SHOCK OR AICD LEAD OR GNRTR.
116	OTHER PERMANENT CARDIAC PACEMAKER IMPLANT.
157	ANAL & STOMAL PROCEDURES W CC.
168	MOUTH PROCEDURES W CC.
201	OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES.
216	BIOPSIES OF MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE.
218	LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE >17 W CC.
224	SHOULDER, ELBOW OR FOREARM PROC,EXC MAJOR JOINT PROC, W/O CC.
226	SOFT TISSUE PROCEDURES W CC.
268	SKIN, SUBCUTANEOUS TISSUE & BREAST PLASTIC PROCEDURES.
292	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W CC.
303	KIDNEY, URETER & MAJOR BLADDER PROCEDURES FOR NEOPLASM.
304	KIDNEY, URETER & MAJOR BLADDER PROC FOR NON-NEOPL W CC.
308	MINOR BLADDER PROCEDURES W CC.
310	TRANSURETHRAL PROCEDURES W CC.
312	URETHRAL PROCEDURES, AGE >17 W CC.
345	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROC EXCEPT FOR MALIGNANCY.
401	LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W CC.
408	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W OTHER O.R. PROC.
419	FEVER OF UNKNOWN ORIGIN AGE >17 W CC.
455	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W/O CC.
485	LIMB REATTACHMENT, HIP AND FEMUR PROC FOR MULTIPLE SIGNIFICANT TRA .
487	OTHER MULTIPLE SIGNIFICANT TRAUMA.
501	KNEE PROCEDURES W PDX OF INFECTION W CC.
503	KNEE PROCEDURES W/O PDX OF INFECTION.
505	EXTENSIVE BURNS OF FULL THICKNESS BURNS WITH MECH VENT 96+HRS WITHOUT SKIN GRAFT.
506	FULL THICKNESS BURN W SKIN GRAFT OR INHAL INJ W CC OR SIG TRAUMA.
519	CERVICAL SPINAL FUSION W CC
529	VENTRICULAR SHUNT PROCEDURES W CC
	QUINTILE 5
46	OTHER DISORDERS OF THE EYE AGE >17 W CC.
55	MISCELLANEOUS EAR, NOSE, MOUTH & THROAT PROCEDURES.
77	OTHER RESP SYSTEM O.R. PROCEDURES W/O CC.
117	CARDIAC PACEMAKER REVISION EXCEPT DEVICE REPLACEMENT.
118	CARDIAC PACEMAKER DEVICE REPLACEMENT.
125	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG.
150	PERITONEAL ADHESIOLYSIS W CC.
152	MINOR SMALL & LARGE BOWEL PROCEDURES W CC.
154	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W CC.
161	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W CC.
171*	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W/O CC.
191	PANCREAS, LIVER & SHUNT PROCEDURES W CC.
197	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W CC.
206*	DISORDERS OF LIVER EXCEPT MALIG,CIRR,ALC HEPA W/O CC.
209	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF LOWER EXTREMITY.
210	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W CC.
230	LOCAL EXCISION & REMOVAL OF INT FIX DEVICES OF HIP & FEMUR.
261	BREAST PROC FOR NON-MALIGNANCY EXCEPT BIOPSY & LOCAL EXCISION.
267	PERIANAL & PILONIDAL PROCEDURES.
338	TESTES PROCEDURES, FOR MALIGNANCY.
341	PENIS PROCEDURES.
365	OTHER FEMALE REPRODUCTIVE SYSTEM O.R. PROCEDURES.
406	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R. PROC W CC.

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

Proposed LTC–DRG	Description
424	O.R. PROCEDURE W PRINCIPAL DIAGNOSES OF MENTAL ILLNESS.
443*	OTHER O.R. PROCEDURES FOR INJURIES W/O CC.
454	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W CC.
486	OTHER O.R. PROCEDURES FOR MULTIPLE SIGNIFICANT TRAUMA.
488	HIV W EXTENSIVE O.R. PROCEDURE.
499	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W CC.
515	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH.
531	SPINAL PROCEDURES W CC.
533	EXTRACRANIAL PROCEDURES W CC.
535	CARDIAC DEFIB IMPLANT W CARDIAC CATH W AMI/HF/SHOCK.
536	CARDIAC DEFIB IMPLANT W CARDIAC CATH W/O AMI/HF/SHOCK.

*One of the original 171 proposed low-volume LTC–DRGs initially assigned to this low-volume quintile; removed from the low-volume quintiles in addressing nonmonotonicity (see step 5 below).

4. Steps for Determining the Proposed FY 2005 LTC–DRG Relative Weights

As we noted previously, the proposed FY 2005 LTC–DRG relative weights are determined in accordance with the methodology described in the August 1, 2003 final rule (68 FR 45380). In summary, LTCH cases must be grouped in the appropriate LTC–DRG, while taking into account the low-volume LTC–DRGs as described above, before the proposed FY 2005 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 2005 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 2005 LTC–DRG relative weights.

Step 1—Remove statistical outliers.

The first step in the calculation of the proposed FY 2005 LTC-DRG relative weights is to remove statistical outlier cases. We define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each LTC–DRG. These statistical outliers 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 2005 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 because 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 2005 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 2005 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 2005 LTC–DRG relative weights is to adjust each LTCH's charges per discharge for short-stay outlier cases (that is, a patient with a length of stay that is less than or equal to five-sixths the average length of stay of the LTC–DRG).

We make this adjustment by counting a short-stay outlier as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the 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 1, 2003 final rule (68 FR 45380), 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, we adjust for short-stay outlier cases under § 412.529 in this manner since it results in more appropriate payments for all LTCH cases.

Step 4—Calculate the Proposed FY 2005 LTC–DRG relative weights on an iterative basis.

The process of calculating the proposed 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 2005 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 2005 LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

As explained in section II.B. of this preamble, the proposed FY 2005 CMS DRGs, upon which the proposed FY 2005 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 1, 2003 final rule (68 FR 45381), 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, 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 the LTCH PPS was only implemented for cost reporting periods beginning on or after October 1, 2002 (FY 2003) and LTCHs were previously paid under cost-based reimbursement, which is not based on patient diagnoses, coding by LTCHs for these cases may not have been as detailed as possible.

Thus, in developing the FY 2003 LTC–DRG relative weights for the LTCH PPS based on FY 2001 claims data, as we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 55990), we found on occasion that the data suggested that cases classified to the LTC–DRG ''with CCs'' of a ''with CC''/''without CC'' pair had a lower average charge than the corresponding LTC–DRG ''without CCs.'' Similarly, based on FY 2003 claims data, we also found on occasion that the data suggested that cases classified to the proposed LTC–DRG ''with CCs'' of a ''with CC''/''without CC'' pair have a lower average charge than the corresponding proposed LTC–DRG ''without CCs'' for FY 2005.

We believe this anomaly may be due to coding that may not have fully reflected all comorbidities that were present. Specifically, LTCHs may have failed to code relevant secondary diagnoses, which resulted in cases that actually had CCs being classified into a ''without CC'' LTC–DRG. It would not be appropriate to pay a lower amount for the ''with CC'' LTC–DRG. Therefore, in this proposed rule, we grouped both the cases ''with CCs'' and ''without CCs'' together for the purpose of calculating the proposed FY 2005 LTC–DRG relative weights in this proposed rule. As we stated in the August 30, 2002 LTCH PPS final rule (67 FR 55990), we will continue to employ this methodology to account for nonmonotonically increasing relative weights until we have adequate data to calculate appropriate separate weights for these anomalous LTC–DRG pairs. We expect that, as was the case when we first implemented the IPPS, this problem will be self-correcting, as LTCHs submit more completely coded data in the future.

There are three types of ''with CC'' and ''without CC'' pairs that could be nonmonotonic, that is, where the ''without CC'' 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 2003 update of the FY 2003 MedPAR file, we identified two of the three types of nonmonotonic LTC–DRG pairs.

The first category of nonmonotonically increasing proposed relative weights for FY 2005 LTC–DRG pairs ''with and without CCs'' contains 2 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, did not fall into one of the 5 low-volume quintiles. For those nonmonotonic LTC–DRG pairs, 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. In this proposed rule, we are proposing that, for FY 2005, proposed LTC–DRGs 144 and 145 and LTC–DRGs 444 and 445 are in this category.

The second category of nonmonotonically increasing relative weights for proposed LTC–DRG pairs with and without CCs consists of zero 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, we would 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 low-volume quintile the ''combined LTC–DRG'' would be grouped. Both proposed LTC–DRGs in the pair would then be grouped into the same proposed low-volume quintile, and thus would have the same proposed relative weight. For FY 2005, in this proposed rule, there are no proposed LTC–DRGs that fall into this category.

The third category of nonmonotonically increasing relative weights for proposed LTC–DRG pairs with and without CCs consists of 7 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. 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 2005, in this proposed rule, we are proposing the following proposed LTC–DRGs would be in this category: LTC–DRGs 68 and 69; LTC–DRGs 85 and 86; LTC–DRGs 101 and 102; LTC–DRGs 170 and 171; LTC–DRGs 205 and 206; LTC–DRGs 318 and 319; and LTC–DRGs 442 and 443.

Step 6—Determine a proposed FY 2005 LTC-DRG relative weight for proposed 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 2003 update of the FY 2003 MedPAR file. Of the 519 proposed LTC–DRGs for FY 2005, we identified 170 proposed LTC–DRGs for which there were no LTCH cases in the database. That is, based on data from the FY 2003 MedPAR file used in this proposed rule, no patients who would have been classified to those proposed LTC–DRGs were treated in LTCHs during FY 2003 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 170 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 2005, we assign proposed relative weights to each of the 170 ''no volume'' proposed LTC–DRGs based on clinical similarity and relative costliness to one of the remaining 349 (519 − 170 = 349) proposed LTC–DRGs for which we are able to determine proposed relative weights, based on FY 2003 claims data.

As there are currently no LTCH cases in these ''no volume'' proposed LTC–DRGs, we determine proposed relative weights for the 170 proposed LTC–DRGs with no LTCH cases in the FY 2003 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.

Our methodology for determining proposed relative weights for the ''no volume'' proposed LTC–DRGs is as follows: First, we crosswalk the proposed no volume LTC–DRGs by matching them to other similar proposed LTC–DRGs for which there were LTCH cases in the FY 2003 MedPAR file based on clinical similarity and intensity of use of resources as determined by care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, post-operative care, and length of stay. We assign the proposed relative weight for the applicable proposed low-volume quintile to the proposed no volume 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 proposed no volume 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 proposed no volume LTC–DRG is crosswalked to the proposed relative weights of each of the five quintiles and we assign the proposed no volume LTC–DRG the proposed relative weight of the proposed low-volume quintile with the closest proposed weight. For this proposed rule, a list of the proposed no volume FY 2005 LTC–DRGs and the proposed FY 2005 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 2005 is shown below in Table 2.

TABLE 2.—PROPOSED NO VOLUME LTC–DRG CROSSWALK AND PROPOSED QUINTILE ASSIGNMENT FOR FY 2005

Proposed LTC–DRG	Description	Proposed cross-walked LTC–DRG	Proposed low-volume quintile assigned.
2	CRANIOTOMY AGE >17 W/O CC	1	Quintile 4.
3	CRANIOTOMY AGE 0–17	1	Quintile 4.
6	CARPAL TUNNEL RELEASE	251	Quintile 2.
26	SEIZURE & HEADACHE AGE 0–17	25	Quintile 2.
30	TRAUMATIC STUPOR & COMA, COMA <1 HR AGE 0–17	29	Quintile 3.
32	CONCUSSION AGE >17 W/O CC	25	Quintile 2.
33	CONCUSSION AGE 0–17	25	Quintile 2.
36	RETINAL PROCEDURES	47	Quintile 1.
37	ORBITAL PROCEDURES	47	Quintile 1.
38	PRIMARY IRIS PROCEDURES	47	Quintile 1.
39	LENS PROCEDURES WITH OR WITHOUT VITRECTOMY	47	Quintile 1.
40	EXTRAOCULAR PROCEDURES EXCEPT ORBIT AGE >17	47	Quintile 1.
41	EXTRAOCULAR PROCEDURES EXCEPT ORBIT AGE 0–17	47	Quintile 1.
42	INTRAOCULAR PROCEDURES EXCEPT RETINA, IRIS & LENS	47	Quintile 1.
48	OTHER DISORDERS OF THE EYE AGE 0–17	47	Quintile 1.
49	MAJOR HEAD & NECK PROCEDURES	64	Quintile 4.
50	SIALOADENECTOMY	63	Quintile 4.
51	SALIVARY GLAND PROCEDURES EXCEPT SIALOADENECTOMY	63	Quintile 4.
52	CLEFT LIP & PALATE REPAIR	63	Quintile 4.
54	SINUS & MASTOID PROCEDURES AGE 0–17	53	Quintile 3.
56	RHINOPLASTY	53	Quintile 3.
57	T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17	69	Quintile 2.
58	T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0–17	69	Quintile 2.
59	TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17	69	Quintile 2.
60	TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0–17	69	Quintile 2.

TABLE 2.—PROPOSED NO VOLUME LTC–DRG CROSSWALK AND PROPOSED QUINTILE ASSIGNMENT FOR FY 2005—Continued

Proposed LTC–DRG	Description	Proposed cross-walked LTC–DRG	Proposed low-volume quintile assigned.
61	MYRINGOTOMY W TUBE INSERTION AGE >17	69	Quintile 2.
62	MYRINGOTOMY W TUBE INSERTION AGE 0–17	69	Quintile 2.
66	EPISTAXIS	69	Quintile 2.
67	EPIGLOTTITIS	63	Quintile 4.
70	OTITIS MEDIA & URI AGE 0–17	69	Quintile 2.
71	LARYNGOTRACHEITIS	97	Quintile 1.
72	NASAL TRAUMA & DEFORMITY	53	Quintile 3.
74	OTHER EAR, NOSE, MOUTH & THROAT DIAGNOSES AGE 0–17	69	Quintile 2.
81	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE 0–17	69	Quintile 2.
91	SIMPLE PNEUMONIA & PLEURISY AGE 0–17	90	Quintile 2.
98	BRONCHITIS & ASTHMA AGE 0–17	97	Quintile 1.
104	CARDIAC VALVE & OTH MAJOR CARDIOTHORACIC PROC W CARD CATH	110	Quintile 1.
105	CARDIAC VALVE & OTH MAJOR CARDIOTHORACIC PROC W/O CARD CATH	110	Quintile 1.
106	CORONARY BYPASS W PTCA	110	Quintile 1.
107	CORONARY BYPASS W CARDIAC CATH	110	Quintile 1.
111	MAJOR CARDIOVASCULAR PROCEDURES W/O CC	110	Quintile 1.
137	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE 0–17	136	Quintile 3.
146	RECTAL RESECTION W CC	148	Quintile 5.
147	RECTAL RESECTION W/O CC	148	Quintile 5.
151	PERITONEAL ADHESIOLYSIS W/O CC	150	Quintile 5.
153	MINOR SMALL & LARGE BOWEL PROCEDURES W/O CC	152	Quintile 5.
155	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W/O CC	154	Quintile 5.
156	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE 0–17	154	Quintile 5.
158	ANAL & STOMAL PROCEDURES W/O CC	157	Quintile 4.
160	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W/O CC	159	Quintile 3.
162	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W/O CC	178	Quintile 1.
163	HERNIA PROCEDURES AGE 0–17	178	Quintile 1.
164	APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W CC	148	Quintile 5.
165	APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W/O CC	148	Quintile 5.
166	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W CC	148	Quintile 5.
167	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W/O CC	148	Quintile 5.
169	MOUTH PROCEDURES W/O CC	53	Quintile 3.
184	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE 0–17	183	Quintile 2.
186	DENTAL & ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AGE 0–17	185	Quintile 3.
187	DENTAL EXTRACTIONS & RESTORATIONS	185	Quintile 3.
190	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE 0–17	189	Quintile 3.
192	PANCREAS, LIVER & SHUNT PROCEDURES W/O CC	191	Quintile 5.
194	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W/O CC	193	Quintile 1.
195	CHOLECYSTECTOMY W C.D.E. W CC	197	Quintile 5.
196	CHOLECYSTECTOMY W C.D.E. W/O CC	197	Quintile 5.
198	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W/O CC	197	Quintile 5.
199	HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR MALIGNANCY	200	Quintile 3.
211	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W/O CC	210	Quintile 5.
212	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE 0–17	210	Quintile 5.
219	LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE >17 W/O CC]	218	Quintile 4.
220	LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE 0–17	218	Quintile 4.
223	MAJOR SHOULDER/ELBOW PROC, OR OTHER UPPER EXTREMITY PROC W CC	224	Quintile 4.
232	ARTHROSCOPY	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.
257	TOTAL MASTECTOMY FOR MALIGNANCY W CC	275	Quintile 3.
258	TOTAL MASTECTOMY FOR MALIGNANCY W/O CC	275	Quintile 3.
259	SUBTOTAL MASTECTOMY FOR MALIGNANCY W CC	275	Quintile 3.
279	CELLULITIS AGE 0–17	273	Quintile 1.
282	TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE 0–17	281	Quintile 3.
286	ADRENAL & PITUITARY PROCEDURES	53	Quintile 3.
289	PARATHYROID PROCEDURES	53	Quintile 3.
290	THYROID PROCEDURES	53	Quintile 3.
291	THYROGLOSSAL PROCEDURES	53	Quintile 3.
293	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W/O CC	292	Quintile 2.
298	NUTRITIONAL & MISC METABOLIC DISORDERS AGE 0–17	297	Quintile 2.
309	MINOR BLADDER PROCEDURES W/O CC	308	Quintile 4.
311	TRANSURETHRAL PROCEDURES W/O CC	310	Quintile 4.
313	URETHRAL PROCEDURES, AGE >17 W/O CC	312	Quintile 4.
314	URETHRAL PROCEDURES, AGE 0–17	305	Quintile 2.
322	KIDNEY & URINARY TRACT INFECTIONS AGE 0–17	326	Quintile 1.
327	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE 0–17	326	Quintile 1.
329	URETHRAL STRICTURE AGE >17 W/O CC	305	Quintile 2.
330	URETHRAL STRICTURE AGE 0–17	305	Quintile 2.

TABLE 2.—PROPOSED NO VOLUME LTC–DRG CROSSWALK AND PROPOSED QUINTILE ASSIGNMENT FOR FY 2005—Continued

Proposed LTC–DRG	Description	Proposed cross-walked LTC–DRG	Proposed low-volume quintile assigned.
333	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE 0–17	332	Quintile 2.
334	MAJOR MALE PELVIC PROCEDURES W CC	345	Quintile 4.
335	MAJOR MALE PELVIC PROCEDURES W/O CC	345	Quintile 4.
337	TRANSURETHRAL PROSTATECTOMY W/O CC	306	Quintile 3.
340	TESTES PROCEDURES, NON-MALIGNANCY AGE 0–17	339	Quintile 1.
342	CIRCUMCISION AGE >17	339	Quintile 1.
343	CIRCUMCISION AGE 0–17	339	Quintile 1.
344	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES FOR MALIGNANCY	345	Quintile 4.
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	303	Quintile 4.
357	UTERINE & ADNEXA PROC FOR OVARIAN OR ADNEXAL MALIGNANCY	303	Quintile 4.
358	UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W CC	303	Quintile 4.
359	UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W/O CC	303	Quintile 4.
360	VAGINA, CERVIX & VULVA PROCEDURES	303	Quintile 4.
361	LAPAROSCOPY & INCISIONAL TUBAL INTERRUPTION	149	Quintile 1.
362	ENDOSCOPIC TUBAL INTERRUPTION	149	Quintile 1.
363	D&C, CONIZATION & RADIO-IMPLANT, FOR MALIGNANCY	367	Quintile 1.
364	D&C, CONIZATION EXCEPT FOR MALIGNANCY	367	Quintile 1.
370	CESAREAN SECTION W CC	369	Quintile 3.
371	CESAREAN SECTION W/O CC	367	Quintile 1.
372	VAGINAL DELIVERY W COMPLICATING DIAGNOSES	367	Quintile 1.
373	VAGINAL DELIVERY W/O COMPLICATING DIAGNOSES	367	Quintile 1.
374	VAGINAL DELIVERY W STERILIZATION &/OR D&C	367	Quintile 1.
375	VAGINAL DELIVERY W O.R. PROC EXCEPT STERIL &/OR D&C	367	Quintile 1.
376	POSTPARTUM & POST ABORTION DIAGNOSES W/O O.R. PROCEDURE	367	Quintile 1.
377	POSTPARTUM & POST ABORTION DIAGNOSES W O.R. PROCEDURE	367	Quintile 1.
378	ECTOPIC PREGNANCY	369	Quintile 3.
379	THREATENED ABORTION	367	Quintile 1.
380	ABORTION W/O D&C	367	Quintile 1.
381	ABORTION W D&C, ASPIRATION CURETTAGE OR HYSTEROTOMY	367	Quintile 1.
382	FALSE LABOR	367	Quintile 1.
383	OTHER ANTEPARTUM DIAGNOSES W MEDICAL COMPLICATIONS	367	Quintile 1.
384	OTHER ANTEPARTUM DIAGNOSES W/O MEDICAL COMPLICATIONS	367	Quintile 1.
385	NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY	367	Quintile 1.
386	EXTREME IMMATURITY OR RESPIRATORY DISTRESS SYNDROME, NEONATE	367	Quintile 1.
387	PREMATURITY W MAJOR PROBLEMS	367	Quintile 1.
388	PREMATURITY W/O MAJOR PROBLEMS	367	Quintile 1.
389	FULL TERM NEONATE W MAJOR PROBLEMS	367	Quintile 1.
390	NEONATE W OTHER SIGNIFICANT PROBLEMS	367	Quintile 1.
391	NORMAL NEWBORN	367	Quintile 1.
392	SPLENECTOMY AGE >17	197	Quintile 5.
393	SPLENECTOMY AGE 0–17	197	Quintile 5.
396	RED BLOOD CELL DISORDERS AGE 0–17	399	Quintile 2.
402	LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W/O CC	395	Quintile 4.
405	ACUTE LEUKEMIA W/O MAJOR O.R. PROCEDURE AGE 0–17	404	Quintile 1.
407	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R. PROC W/O CC	408	Quintile 4.
411	HISTORY OF MALIGNANCY W/O ENDOSCOPY	367	Quintile 1.
412	HISTORY OF MALIGNANCY W ENDOSCOPY	367	Quintile 1.
417	SEPTICEMIA AGE 0–17	416	Quintile 3.
422	VIRAL ILLNESS & FEVER OF UNKNOWN ORIGIN AGE 0–17	426	Quintile 1.
432	OTHER MENTAL DISORDER DIAGNOSES	427	Quintile 2.
446	TRAUMATIC INJURY AGE 0–17	445	Quintile 3.
448	ALLERGIC REACTIONS AGE 0–17	447	Quintile 2.
451	POISONING & TOXIC EFFECTS OF DRUGS AGE 0–17	455	Quintile 4.
471	BILATERAL OR MULTIPLE MAJOR JOINT PROCS OF LOWER EXTREMITY	236	Quintile 2.
481	BONE MARROW TRANSPLANT	394	Quintile 3.
482	TRACHEOSTOMY FOR FACE, MOUTH & NECK DIAGNOSES	63	Quintile 4.
484	CRANIOTOMY FOR MULTIPLE SIGNIFICANT TRAUMA	1	Quintile 4.
491	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF UPPER EXTREMITY	209	Quintile 5.
492	CHEMOTHERAPY W ACUTE LEUKEMIA OR W USE OF HI DOSE CHEMOAGENT	410	Quintile 3.
494	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W/O CC	493	Quintile 3.
498	SPINAL FUSION EXCEPT CERVICAL W/O CC	497	Quintile 3.
504	EXTENSIVE BURNS OF FULL THICKNESS BURNS WITH MECH VENT 96+HRS WITH SKIN GRAFT.	468	Quintile 5.
507	FULL THICKNESS BURN W SKIN GRFT OR INHAL INJ W/O CC OR SIG TRAUMA	508	Quintile 3.
516	PERCUTANEOUS CARDIOVASC PROC W AMI	518	Quintile 3.

TABLE 2.—PROPOSED NO VOLUME LTC–DRG CROSSWALK AND PROPOSED QUINTILE ASSIGNMENT FOR FY 2005—Continued

Proposed LTC–DRG	Description	Proposed cross-walked LTC–DRG	Proposed low-volume quintile assigned.
520	CERVICAL SPINAL FUSION W/O CC	497	Quintile 3.
525	OTHER HEART ASSIST SYSTEM IMPLANT	468	Quintile 5.
526	PERCUTNEOUS CARDIOVASULAR PROC W DRUG ELUTING STENT W AMI	517	Quintile 3.
527	PERCUTNEOUS CARDIOVASULAR PROC W DRUG ELUTING STENT W/O AMI	517	Quintile 3.
528	INTRACRANIAL VASCULAR PROC W PDX HEMORRHAGE	1	Quintile 4.
530	VENTRICULAR SHUNT PROCEDURES W/O CC	529	Quintile 4.
534	EXTRACRANIAL PROCEDURES W/O CC	500	Quintile 1.
540	LYMPHOMA & LEUKEMIA W MAJOR OR PROCEDURE W/O CC	399	Quintile 2.

To illustrate this methodology for determining the proposed relative weights for the 170 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 2005 provided above in Table 2:

Example 1: There were no cases in the FY 2003 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 2005 relative weights, would display similar clinical and resource use. Therefore, we assign the same proposed relative weight of proposed LTC–DRG 178 of 0.4964 (Quintile 1) for FY 2005 (Table 11 in the Addendum to this proposed rule) to LTC–DRG 163.

Example 2: There were no LTCH cases in the FY 2003 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 LTC–DRG 91. There were over 25 cases in proposed LTC–DRG 90. Therefore, it would not be assigned to a low-volume quintile for the purpose of determining the LTC–DRG relative weights. However, under our established methodology, proposed LTC–DRG 91, with no LTCH cases, would need to be grouped to a low-volume quintile. We identified that the proposed low-volume quintile with the closest weight to proposed LTC–DRG 90 (0.7368; see Table 11 in the Addendum to this proposed rule) would be proposed low-volume quintile 2 (0.6685; see Table 11 in the Addendum to this proposed rule). Therefore, we assign proposed LTC–DRG 91 a proposed relative weight of 0.6885 for FY 2005.

Furthermore, we are proposing LTC–DRG relative weights of 0.0000 for heart, kidney, liver, lung, pancreas, and simultaneous pancreas/kidney transplants (LTC–DRGs 103, 302, 480, 495, 512, and 513, respectively) for FY 2005 because Medicare will only cover these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified.

Based on our research, we found that most LTCHs only perform minor surgeries, such as minor small and large bowel procedures, to the extent any surgeries are performed at all. Given the extensive criteria that must be met to become certified as a transplant center for Medicare, we believe it is unlikely that any LTCHs would become certified as a transplant center. In fact, in the nearly 20 years since the implementation of the IPPS, there has never been a LTCH that even expressed an interest in becoming a transplant center.

However, if in the future a LTCH applies for certification as a Medicare-approved transplant center, we believe that the application and approval procedure would allow sufficient time for us to determine appropriate weights for the LTC–DRGs affected. At the present time, we would only include these six transplant LTC–DRGs in the GROUPER program for administrative purposes. Since we use the same GROUPER program for LTCHs as is used under the IPPS, removing these LTC–DRGs would be administratively burdensome.

Again, we note that as this system is dynamic, it is entirely possible that the number of 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 LTC–DRGs and to determine the proposed relative weights in this proposed 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 2005.

E. Proposed Add-On Payments for New Services and Technologies

[If you choose to comment on issues in this section, please include the caption ''New Technology Applications'' at the beginning of your comment.]

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that the process must apply to a new medical service or technology if, ''based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.''

The regulations implementing this provision establish three criteria for special treatment. First, § 412.87(b)(2) defines when a specific medical service or technology will be considered new for purposes of new medical service or technology add-on payments. The statutory provision contemplated the special payment treatment for new medical services or technologies until such time as data are available to reflect the cost of the technology in the DRG weights through recalibration. There is a lag of 2 to 3 years from the point a new medical service or technology is first introduced on the market and when data reflecting the use of the medical service or technology are used to calculate the DRG weights. For example, data from discharges occurring during FY 2003 are used to calculate the proposed FY 2005 DRG weights in this proposed rule. Section 412.87(b)(2) provides that a ''medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new medical service or technology (depending on when a new code is assigned and data on the new medical service or technology become

available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion for this section.''

The 2-year to 3-year period would ordinarily begin with FDA approval, unless there was some documented delay in bringing the product onto the market after that approval (for instance, component production or drug production had been postponed until FDA approval due to shelf life concerns). After the DRGs have been recalibrated to reflect the costs of an otherwise new medical service or technology, the special add-on payment for new medical services or technology ceases (§ 412.87(b)(2)). For example, an approved new technology that received FDA approval in October 2003 and entered the market at that time may be eligible to receive add-on payments as a new technology until FY 2006 (discharges occurring before October 1, 2005), when data reflecting the costs of the technology would be used to recalibrate the DRG weights. Because the FY 2006 DRG weights will be calculated using FY 2004 MedPAR data, the costs of such a new technology would likely be reflected in the FY 2006 DRG weights.

Section 412.87(b)(3) further provides that, to receive special payment treatment, new medical services or technologies must be inadequately paid otherwise under the DRG system. To assess whether technologies would be inadequately paid under the DRGs, we establish thresholds to evaluate applicants for new technology add-on payments. In the August 1, 2003 final rule (68 FR 45385), we established the threshold at the geometric mean standardized charge for all cases in the DRG plus 75 percent of 1 standard deviation above the geometric mean standardized charge (based on the logarithmic values of the charges and transformed back to charges) for all cases in the DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant DRGs, if the new medical service or technology occurs in many different DRGs). Table 10 in the Addendum to the August 1, 2003 final rule (68 FR 45648) listed the qualifying threshold by DRG, based on the discharge data that we used to calculate the FY 2004 DRG weights.

However, section 503(b)(1) of Public Law 108–173 amended section 1886(d)(5)(K)(ii)(I) of the Act to provide for ''applying a threshold* * *that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved.'' The provisions of section 503(b)(1) apply to classification for fiscal years beginning with FY 2005. We have updated Table 10 from the October 6, 2003 **Federal Register** correction document, which contains the thresholds that we are using to evaluate applications for new service or technology add-on payments for FY 2005, using the section 503(b)(1) measures stated above, and posted these new thresholds on our Web site at: *www.cms.hhs.gov/providers/hipps/newtech.asp.* The thresholds published in this FY 2005 proposed rule are preliminary thresholds for FY 2006. The final thresholds published in the FY 2005 final rule will be used to evaluate applicants for new technology add-on payments during FY 2006. (Refer to section IV. D. of this preamble for a discussion of a revision of the regulations to incorporate the change made by section 503(b)(1) of Public Law 108–173.)

Section 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits or reduces recovery time compared to the technologies previously available. (*See* the September 7, 2001 final rule (66 FR 46902) for a complete discussion of this criterion.)

The new medical service or technology add-on payment policy provides additional payments for cases with high costs involving eligible new medical services or technologies while preserving some of the incentives under the average-based payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. Under § 412.88, Medicare pays a marginal cost factor of 50 percent for the costs of a new medical service or technology in excess of the full DRG payment. If the actual costs of a new medical service or technology case exceed the DRG payment by more than the 50-percent marginal cost factor of the new medical service or technology, Medicare payment is limited to the DRG payment plus 50 percent of the estimated costs of the new technology.

The report language accompanying section 533 of Public Law 106–554 indicated Congressional intent that the Secretary implement the new mechanism on a budget neutral basis (H.R. Conf. Rep. No. 106–1033, 106th Cong., 2nd Sess. at 897 (2000)). Section 1886(d)(4)(C)(iii) of the Act requires that the adjustments to annual DRG classifications and relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. Therefore, in the past, we accounted for projected payments under the new medical service and technology provision during the upcoming fiscal year at the same time we estimated the payment effect of changes to the DRG classifications and recalibration. The impact of additional payments under this provision was then included in the budget neutrality factor, which was applied to the standardized amounts and the hospital-specific amounts.

Section 503(d)(2) of Public Law 108–173 amended section 1886(d)(5)(K)(ii)(III) of the Act to provide that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, add-on payments for new medical services or technologies for FY 2005 and later years will not be budget neutral. We discuss the regulation change necessary to implement this provision in section IV.H. of this proposed rule.

Applicants for add-on payments for new medical services or technologies for FY 2006 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate the medical service or technology meets the high-cost threshold, no later than early October 2004. Applicants must submit a complete database no later than mid-December 2004. Complete application information, along with final deadlines for submitting a full application, will be available at our Web site after publication of the FY 2005 final rule at: *www.cms.hhs.gov/providers/hipps/default.asp.* To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2006, the Web site will also list the tracking forms completed by each applicant.

2. Other Provisions of Section 503 of Public Law 108–173

Section 503(b)(2) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a new clause (viii) to provide for a mechanism for public input before publication of a notice of proposed rule making regarding whether a medical service or technology represents a substantial improvement or advancement. The revised process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries.
- Make public and periodically update a list of the services and technologies for which an application for add-on payments is pending.
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial improvement.
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to satisfy the requirements of this last provision, we published a notice in the **Federal Register** on February 27, 2004, and held a town meeting at the CMS Headquarters Office in Baltimore, MD, on March 15, 2004. In the announcement notice for the meeting, we stated that the opinions and alternatives provided during the meeting would assist us in our evaluations of applications by allowing public discussions of the substantial clinical improvement criteria for each of the FY 2005 new medical service and technology add-on payment applications before the publication of this FY 2005 IPPS proposed rule.

Approximately 70 participants registered and attended in person, while additional participants listened over an open telephone line. The participants focused on presenting data on the substantial clinical improvement aspect of their products, as well as the need for additional payments to ensure access to Medicare beneficiaries. In addition, we also received many written comments regarding the substantial clinical improvement criterion for the applicants. We have considered these comments in our evaluation of each new application for FY 2005 in this proposed rule. We have summarized these comments, or if applicable, indicated that no comments were received, at the end of the discussion of the individual applications.

Section 503(c) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a new clause (ix) requiring that before establishing any add-on payment for a new medical service or technology, that the Secretary shall seek to identify one or more DRGs associated with the new technology, based on similar clinical or anatomical characteristics and the costs of the technology and assign the new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology. No add-on payment shall be made with respect to such a new technology.

At the time an application is submitted, the DRGs associated with the new technology are identified. We only determine that a new technology add-on payment is appropriate when the reimbursement under these DRGs is not adequate for this new technology. The criterion for this determination is the cost threshold, which we discuss below. We discuss the assignments of several new technologies within the DRG payment system in section II.B. of this preamble.

In this proposed rule, we evaluate whether new technology add-on payments will continue in FY 2005 for the two technologies that currently receive such payments. In accordance with section 503(e)(2) of Public Law 108–173, we also reconsider one application for new technology add-on payments that was denied last year. Finally, we present our evaluations of 10 new applications for add-on payments in FY 2005.

3. FY 2005 Status of Technology Approved for FY 2004 Add-On Payments

a. Drotrecogin Alfa (Activated)—Xigris®

Xigris®, a biotechnology product that is a recombinant version of naturally occurring Activated Protein C (APC), was approved by the FDA on November 21, 2001. In the August 1, 2002 IPPS final rule (67 FR 50013), we determined that cases involving the administration of Xigris®, (as identified by the presence of code 00.11 (Infusion of drotrecogin alfa (activated)) were eligible for additional payments in FY 2003. (The August 1, 2002 final rule contains a detailed discussion of this technology.)

In the August 1, 2003 final IPPS rule (68 FR 45387), we indicated that, for FY 2004, we would continue to make add-on payments for cases involving the administration of Xigris® as identified by the presence of code 00.11. This was because we determined that Xigris® was still within the 2-year to 3-year period before the costs of this new technology would be reflected in the DRG weights.

Xigris® became available on the market at the time of its FDA licensure on November 21, 2001. Early in FY 2005, Xigris® will be beyond the 2-year to 3-year period during which a technology can be considered new. Therefore, we are proposing that Xigris® will not continue to receive new technology add-on payments in FY 2005. During the period of 2 years and 6 months since it came onto the market, Xigris® has been used frequently in the appropriate DRGs. For FY 2005, we analyzed the number of cases involving this technology in the FY 2003 MedPAR file. We found 4,243 cases that received Xigris®, the majority of which fell appropriately into DRGs 415, 416, 475, and 483, with by far the most cases in DRG 416 (Septicemia Age >17). Accordingly, the costs of Xigris® are now well-represented in those DRGs. Therefore, we are proposing that FY 2004 will be the final year for Xigris® to receive add-on payments.

We received no public comments regarding the continuation of add-on payments for Xigris®.

The manufacturer also asked us to consider creating a DRG specifically for severe sepsis. We discuss this request in section II.B.16.c. of this proposed rule.

b. InFUSE™ (Bone Morphogenetic Proteins (BMPs) for Spinal Fusions)

InFUSE™ was approved by FDA for use on July 2, 2002, and became available on the market immediately thereafter. In the August 1, 2003 IPPS final rule (68 FR 45388), we approved InFUSE™ for add-on payments under § 412.88, effective for FY 2004. This approval was on the basis of using InFUSE™ for single-level, lumbar spinal fusion, consistent with the FDA's approval and the data presented to us by the applicant. Therefore, we limited the add-on payment to cases using this technology for anterior lumbar fusions in DRGs 497 (Spinal Fusion Except Cervical With CC) and 498 (Spinal Fusion Except Cervical Without CC). Cases involving InFUSE™ that are eligible for the new technology add-on payment are identified by assignment to DRGs 497 and 498 as a lumbar spinal fusion, with the combination of ICD–9-CM procedure codes 84.51 (Insertion of

interbody spinal fusion device) and 84.52 (Insertion of recombinant bone morphogenetic protein).

Because InFUSE™ was approved by the FDA for use on July 2, 2003, it is still within the 2-year to 3-year period during which a technology can be considered new under the regulations. Therefore, we are proposing to continue add-on payments for FY 2005 for cases receiving InFUSE™ for spinal fusions in DRGs 497 (Spinal Fusion Except Cervical With CC) and 498 (Spinal Fusion Except Cervical Without CC). We are also proposing to continue limiting the add-on payment for cases receiving InFUSE™, to those cases identified by the presence of procedure codes 84.51 and 84.52. However, we are proposing to eliminate add-on payment for the interbody fusion device that is used in combination with this recombinant human bone morphogenetic protein (rhBMP) product (procedure code 84.52). We note that currently add-on payments for InFUSE™ include costs for the interbody fusion device (the LT cage, identified by procedure code 84.51), used in the spinal fusion procedure with the InFUSE™ product. Because this device is not a new technology, but in fact has been in use for 9 years for spinal fusions, we believe that it is inappropriate to pay for this device in conjunction with the genuinely new rhBMP technology. Therefore, we are proposing no longer to pay for the interbody fusion device as bundled in the current maximum add-on payment amount of $4,450 for cases that qualify for additional payment. This proposal would reduce the add-on payment to account for no longer paying for the LT cage. This would reduce the cost of this new technology by $4,990, which results in a total cost of $3,910 for InFUSE™. Therefore, we are proposing a maximum add-on amount of $1,955 for cases that qualify for additional payment. Although we are proposing to eliminate payment for the LT cage, we would still require the presence of procedure code 84.51 (in combination with procedure code 84.52) when making add-on payments for new technology for InFUSE™. This is due to the fact that the LT cage is still required by the FDA when InFUSE™ is used for single level spinal fusions.

We received the following public comments in accordance with section 503(b)(2) of Public Law 108–173 regarding the continuation of add-on payments for this technology.

Comment: Several commenters wrote expressing support for continued add-on payments for this technology. Many of these commenters were physicians who use the device. These commenters noted that the hospitals for which they work did not allow use of the device until the new technology add-on payments began on October 1, 2003. Therefore, they encouraged the continued add-on payment to ensure continued access of the device to patients. They also argued that, because utilization remained low in FY 2003, the DRG recalibration for FY 2005 would not supply adequate payment data for the cases using the device, further jeopardizing patient access to the technology.

Response: As discussed above, we are proposing to continue payments because this technology is still within the 2-year to 3-year period during which a technology can be considered new under the regulation.

4. Reevaluation of FY 2004 Applications That Were Not Approved

Section 503(e)(2) of Public Law 108–173 requires us to reconsider all applications for new medical service or technology add-on payments that were denied for FY 2004. We received two applications for new technologies to be designated eligible for add-on payments for new technology for FY 2004. We approved InFUSE for use in spinal fusions for new technology add-on payments in FY 2004. We denied the application for new technology add-on payments for the GLIADEL® wafer.

GLIADEL® Wafer

Gliablastoma Multiforme (GBM) is a very aggressive primary brain tumor. Standard care for patients diagnosed with GBM includes surgical resection followed by radiation and, in some cases, systemic chemotherapy. According to the manufacturer, the GLIADEL® wafer is indicated for use at the time of surgery in order to prolong survival in patients with GBM. Implanted directly into the cavity that is created when a brain tumor is surgically removed, the GLIADEL® wafer delivers chemotherapy directly to the site where the tumor is most likely to recur.

The FDA gave initial approval for the GLIADEL® wafer on September 23, 1996, for use as an adjunct to surgery to prolong survival in patients with recurrent GBM for whom surgical resection is indicated. In 2003, Guilford Pharmaceuticals submitted an application for approval of the GLIADEL® wafer for add-on payments and stated that the technology should still be considered new for FY 2004, despite its approval by the FDA on September 23, 1996. The manufacturer argued that the technology was still new because it had not been possible to specifically identify cases involving use of the GLIADEL® wafer in the MedPAR data prior to the adoption of a new ICD–9–CM code 00.10 (Implantation of a chemotherapeutic agent) on October 1, 2002. However, as discussed in the September 7, 2001 final rule (66 FR 46914), the determination concerning whether a technology meets this criterion depends on the date of its availability for use in the Medicare population rather than the date a specific code may be assigned. A technology can be considered new for 2 or 3 years after data reflecting the costs of the technology begin to become available. Data on the costs of this technology began to become available in September 1996. As a result, the costs of this technology are currently reflected in the DRG weights. As discussed in the final rule for FY 2004 (68 FR 45391), on February 26, 2003, the FDA approved the GLIADEL® wafer for use in newly diagnosed patients with high-grade malignant glioma as an adjunct to surgery and radiation. However, our understanding is that many newly diagnosed patients were already receiving this therapy. To the extent that this is true, the charges associated with this use of the GLIADEL® wafer were also reflected in the DRG relative weights. Therefore, the GLIADEL® wafer did not meet this criterion for FY 2004.

Section 503(e)(2) of Public Law 108–173 required us to reconsider this application, but did not revise the criterion for determining whether a medical service or technology is new. As stated above, the FDA originally approved the GLIADEL® wafer on September 23, 1996. Therefore, this technology is beyond the period in which it can be considered new. Accordingly, we are proposing to deny this application for new technology add-on payments for FY 2005.

We received no public comments regarding our reconsideration of this application for add-on payments.

Guilford also asked us to consider reclassifying this device into another DRG. We discuss issues relating to the DRG assignment of the GLIADEL® wafer in section II.B.16.c. of this preamble.

5. FY 2005 Applicants for New Technology Add-On Payments

a. InFUSE™ Bone Graft (Bone Morphogenetic Proteins (BMPs) for Tibia Fractures)

Bone Morphogenetic Proteins (BMPs) have been shown to have the capacity to induce new bone formation and, therefore, to enhance healing. Using recombinant techniques, some BMPs

(referred to as rhBMPs) can be produced in large quantities. This has cleared the way for their potential use in a variety of clinical applications such as in delayed unions and nonunions of fractured bones and spinal fusions. One such product, rhBMP–2, is developed for use instead of a bone graft with spinal fusions.

Medtronic Sofamor Danek submitted an application for the InFUSE™ Bone Graft for use in tibia fractures for approval as a new technology eligible for add-on payments in FY 2005. Medtronic submitted a similar application for new technology add-on payments in FY 2004 for InFUSE™ Bone Graft/LT–CAGE Lumbar Tapered Fusion Device. As discussed above, we approved this application for FY 2004, and we are proposing to continue to make new technology payments for FY 2005 for InFUSE™ when used in spinal fusions (refer to section III.E.3.b. of this preamble).

In cases of open tibia fractures, InFUSE™ is applied using an absorbable collagen sponge, which is then applied to the fractured bone in order to promote new bone formation. This use currently represents an off-label use of InFUSE™. The manufacturer contends that this use is severely limited due to the greatly increased costs for treating these cases with InFUSE™ at the time of wound debridement and closure. The manufacturer has conducted a clinical trial and is awaiting FDA approval for the use of InFUSE™ for open tibia fractures. According to the manufacturer, this approval is expected before publication of the final rule. The application for add-on payments for the use of InFUSE for open tibia fractures proposes that such payment would encourage the use of InFUSE™ for treatment of these fractures of grade II or higher (up to and including grade III, which often must be amputated due to the severity of injury). The additional payment, according to the applicant, would encourage more hospitals to use the technology at the time of initial wound closure and would result in reduced rates of infection and nonunion currently associated with the treatment of these injuries.

The manufacturer submitted data on 315 cases using InFUSE™ for open tibia fractures in the FY 2002 MedPAR file, as identified by procedure code 79.36 (Reduction, fracture, open, internal fixation, tibia and fibula) and diagnosis codes of either 823.30 (Fracture of tibia alone, shaft, open) or 823.32 (Fracture of fibula and tibia, shaft, open). The applicant also submitted data for a hospital sample that included 63 cases using the same identifying codes. Based on the data submitted by the applicant, InFUSE™ would be used in four different DRGs: 217 (Wound Debridement and Skin Graft Except Hand, for Musculoskeletal and Connective Tissue Disorders), 218 and 219 (Lower Extremity and Humerus Procedures Except Hip, Foot, Femur Age > 17, With and Without CCs, respectively) and 486 (Other O.R. Procedures for Multiple Significant Trauma). The analysis performed by the applicant resulted in a case-weighted cost threshold of $27,111 for these four DRGs. The average case-weighted standardized charge for cases using InFUSE in these four DRGs would be $46,468. Therefore, the applicant maintains that InFUSE™ for open tibia fractures meets the cost criterion.

InFUSE™ was approved by the FDA for use in open tibia fractures on April 30, 2004. Because FDA approval was not received in time for full consideration of the application in this proposed rule, we are not presenting our full analysis of this application in this proposed rule. However, we have already determined that this technology still qualifies as new in the context of proposing to extend new technology add-on payments for InFUSE™ for single-level spinal fusions. We must still determine whether it is appropriate to approve add-on payments for InFUSE™ in cases of open tibia fractures in light of the cost and substantial improvement criteria. Therefore, we invite comments on whether use of InFUSE™ for open tibia fractures should qualify for add-on payments under these criteria.

We note that, in the September 7, 2001 final rule (66 FR 46915), we stated that if an existing technology was assigned to different DRGs than those in which the technology was initially used, the new use may be considered for new technology add-on payments if it also meets the substantial clinical improvement and inadequacy of payment criteria. Under the policy suggested in that rule, approval of InFUSE™ for tibia fractures would start a new period of add-on payments for the new use of this technology. However, we have some reservations about whether this result would be appropriate. It might be possible, under the policy described in the September 7, 2001 final rule, for a technology to receive new technology add-on payments for many years after it is introduced, provided that use of the technology is continually expanded to treatment of new conditions. We invite comment on whether it would be more appropriate merely to extend the existing approval of InFUSE™ for spinal fusions to cases where InFUSE™ is used for open tibia fractures, without extending the time period during which the technology will qualify for add-on payments.

We note that as part of its application, the applicant submitted evidence on the substantial clinical improvement criterion. The applicant cited data from a prospective, controlled study published on December 12, 2002 in *The Journal of Bone and Joint Surgery* (Govender, S., Crismma, C., Genant, H.K., Valentin-Opran, V., ''Recombinant Human Bone Morphogenetic Protein-2 for Treatment of Open Tibia Fractures,'' Vol. 84–A, No. 12. p. 2123). The study, also known as BESTT study group, involved 49 trauma centers in 11 countries. The study enrolled 450 patients who had sustained an open tibia shaft fracture that normally would be treated by intramedullary nail fixation and soft tissue management. The patients were randomly and blindly assigned to one of three groups: the standard of care as stated above, the standard of care plus implantation an absorbable collagen sponge soaked with .75 mg/ml of rhBmP–2, or the standard of care plus implantation of an absorbable collagen sponge soaked with 1.50 mg/ml of rhBMP–2. The study followed up with 421 (94 percent) of all patients. The applicant stated that the study found that patients who received the standard of care plus an absorbable collagen sponge soaked with 1.50 mg/ml of rhBMP–2 achieved the following results compared to the standard of care without the rhBMP: a 44-percent reduction in the rate of secondary surgery, an average of 39 days reduction in time of clinical healing and lower infection rates. As a result, the applicant maintains that InFUSE™ in tibia fractures represents a substantial clinical improvement over previously available technologies.

We are not presenting a full analysis of this application under the substantial clinical improvement criterion because the technology had not yet received FDA approval for this use in time for consideration in this proposed rule. However, we note that although the cited study does provide some evidence of clinical efficacy, we have some concerns about whether the study conclusively demonstrates substantial clinical improvement over previously available technologies because of its design. (It is important to note, as we stated in the August 1, 2002 **Federal Register** (67 FR 50015), that we do not employ FDA guidelines to determine what drugs, devices, or technologies qualify for new technology add-on payments under Medicare. Our criteria

do not depend on the standard of safety and efficacy that the FDA sets for general use, but on a demonstration of substantial clinical improvement in the Medicare population, particularly patients over age 65.) We will present our full analysis of the evidence regarding clinical improvement in the final rule.

We received no public comments regarding this application for add-on payments.

b. Norian Skeletal Repair System (SRS)® Bone Void Filler

Brigham and Women's Hospital submitted an application for approval of the Norian Skeletal Repair System (SRS)® Bone Void Filler (Norian SRS® Cement), manufactured by Synthes for new technology add-on payments for FY 2005. Synthes has been assisting the applicant with supplemental information and data to help the applicant with the application process. According to the manufacturer, Norian SRS® Cement is an injectable, fast-setting carbonated apatite cement used to fill defects in areas of compromised cancellous bone during restoration or augmentation of the skeleton. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

On December 23, 1998, the FDA approved Norian SRS® for use as an adjunct for fracture stabilization in the treatment of low impact, unstable, metaphyseal distal radius fractures, in cases where early mobilization is indicated. On December 20, 2001, the FDA approved Norian SRS® Cement for use in bony voids or defects that are not intrinsic to the stability of the bony structure. Norian SRS® Cement is intended to be placed or injected into bony voids or gaps in the skeletal system. These defects may be surgically created osseous defects or osseous defects caused by traumatic injury to the bone.

Despite the time that has elapsed since FDA approval, the manufacturer contends that Norian SRS® Cement should still be considered new for several reasons. First, until April 2002, Norian SRS® Cement was hand mixed using a mortar and pestle. Once Norian SRS® Cement was approved by the FDA in December 2001 (for the indication of use in bony voids or defects that are not intrinsic to the stability of the bony structure), the manufacturer issued a new pneumatic mixer. According to the manufacturer, this new pneumatic mixer allows for better preparation, reliability, and ease of use. In addition, a new injection syringe mechanism was developed and made available in May 2002 and replaced the ''Norian Delivery Device''. The manufacturer believes these new procedures for mixing and delivery of the product to the patient should be considered new services as stated in section 1886(d)(5)(k)(ii) of the Act and § 412.87(b)(1) of the regulations. Second, the manufacturer contends that the cement should still be considered new because there is no ICD–9–CM code to uniquely identify Norian SRS® Cement within the DRGs.

Although there have been changes in the way Norian SRS® Cement is mixed and delivered to the patient, we do not believe these changes are significant enough to regard the technology as new. While these changes may enhance the ease with which the technology is used, the product remains substantially the same as when it was initially developed. As we have indicated previously, technology can be considered new only for 2 to 3 years after data reflecting the costs of the technology begin to become available. Data on the costs of this technology began to become available after FDA approval in 1998, and these costs are currently reflected in the DRG weights. As we discussed in the September 7, 2001 final rule (66 FR 46914), the determination concerning whether a technology meets this criterion depends on the date of its availability for use in the Medicare population rather than the date a specific code may be assigned. Therefore, we are proposing that Norian SRS® Cement does not meet the criterion that a medical service or technology be considered new.

Although we are not proposing to approve this application for add-on payments because the technology does not meet the newness criterion, we note that the manufacturer submitted information on the cost criterion and the substantial clinical improvement criterion. The manufacturer submitted 52 Medicare and non-Medicare cases using Norian SRS® Cement. There are currently no ICD–9–CM codes that can distinctly identify Norian SRS® Cement within the MedPAR data; therefore, we cannot track this technology with our own analysis of MedPAR data. Based on the data submitted by the manufacturer, cases using Norian SRS'' Cement were found in 12 DRGs, with 71.1 percent of the cases in DRGs 210, 218, 219, and 225. Based on the 52 cases submitted by the applicant, the case-weighted threshold across all DRGs was $22,493. The average case-weighted standardized charge was $29,032. As a result, the applicant and manufacturer maintain that Norian SRS® Cement meets the cost criterion.

According to the manufacturer, Norian SRS® Cement represents a substantial clinical improvement for the following reasons: It enhances short-term and long-term structural support, improves the rate and durability of healing, decreases donor site morbidity, decreases risk of infection at graft site, lowers the risk of operative complications from shorter operative procedures, lowers the rate of post-treatment hospitalizations and physician visits, and finally, reduces pain.

However, we are not presenting a full evaluation of the application for add-on payments for Norian SRS® Cement under these criteria because the technology does not meet the newness criterion. Therefore, we are proposing to deny add-on payments for this technology.

We received no public comments on this application for add-on payments.

c. InSync® Defibrillator System (Cardiac Resynchronization Therapy with Defibrillation (CRT–D))

Cardiac Resynchronization Therapy (CRT), also known as bi-ventricular pacing, is a therapy for chronic heart failure. A CRT implantable system provides electrical stimulation to the right atrium, right ventricle, and left ventricle to recoordinate or resynchronize ventricular contractions and improve the oxygenated blood flow to the body (cardiac output).

Medtronic submitted an application for approval of the InSync® Defibrillator System, a cardiac resynchronization therapy with defibrillation system (CRT–D), for new technology add-on payments for FY 2005. This technology combines resynchronization therapy with defibrillation for patients with chronic, moderate-to-severe heart failure who meet the criteria for an implantable cardiac defibrillator. Unlike conventional implantable cardiac defibrillators, which treat only arrhythmias, CRT- devices have a dual therapeutic nature intended to treat two aspects of a patient's heart disease concurrently: (1) The symptoms of moderate to severe heart failure (that is, the ventricular dysynchrony); and (2) cardiac arrhythmias, as documented by an electrophysiologic testing or clinical history or both, which would cause sudden cardiac arrest.

InSync® Defibrillation System received FDA approval on June 26, 2002. However, another manufacturer, Guidant, received FDA approval for its CRT–D device on May 2, 2002. Guidant, and another competitor that has yet to receive FDA approval for its CRT–D device, have requested that their devices

be included in any approval of CRT–D for new technology add-on payments. As we discussed in the September 7, 2001 final rule (66 FR 46915), an approval of a new technology for special payment should extend to all technologies that are substantially similar. Otherwise, our payment policy would bestow an advantage to the first applicant to receive approval for a particular new technology.

The applicant contends that, despite the approval of a similar device in May 2002, the InSync® Defibrillator System should still be considered new for several reasons: First, an ICD–9–CM code was only issued in FY 2003, which falls within the 2-year to 3-year range provided in the regulations. Second, the utilization of CRT–Ds is still growing and has not reached full utilization and, therefore, CRT–Ds remain underreported within the FY 2003 MedPAR data that will be used to recalibrate the DRG weights for FY 2005. Finally, the applicant believes reporting of CRT–Ds may be insufficient to accurately recalibrate the DRGs because the new ICD–9–CM codes for CRT–Ds are unlikely to be used consistently and accurately by hospitals in the first year.

We have discussed the relationship between existence of a specific ICD–9–CM code for a technology and our determination of its status as a new technology. As discussed in the September 7, 2001 final rule (66 FR 46914), the determination of whether a technology is new depends on the date of its availability for use in the Medicare population, rather than the date a specific code may be assigned. Because CRT–Ds were available upon the initial FDA approval in May 2002, we consider the technology to be new from this date and not the date a code was assigned.

Using the December 2003 update file to the FY 2003 MedPAR file, we have identified 10,950 cases using CRT–D in the FY 2003 MedPAR database. Of these, 10,694 cases were reported in DRGs 514 and 515 (then Cardiac Defibrillator Implant With and Without Cardiac Catheter, respectively). In DRG 515, we found 3,948 cases with procedure code 00.51 (Implantation of cardiac resynchronization defibrillator, total system (CRT–D)) and 6,746 cases in DRG 514. DRG 514 is no longer valid, effective in FY 2004. In FY 2004, we assigned new cases of defibrillator implants with cardiac catheters from DRG 514 to new DRGs 535 (Cardiac Defibrillator Implant with Cardiac Catheter With Acute Myocardial Infarction (AMI) Heart Failure/Shock) and 536 (Cardiac Defibrillator Implant with Cardiac Catheter Without Acute Myocardial Infarction (AMI) Heart Failure/Shock). Using the 6,746 cases from the FY 2003 MedPAR found in DRG 514, we examined the primary diagnosis codes necessary for assignment to DRG 535 along with procedure code 00.51 and found 3,396 cases of CRT–D for DRG 535. The remaining 3,350 CRT–D cases found in DRG 514 using procedure code 00.51 fall into DRG 536. For FY 2003, the total number of cases of CRT–D found in the FY 2003 MedPAR data for DRGs 514 and 515 were 48,486. Cases reporting CRT–Ds thus represent 22 percent of all cases for these DRGs.

A medical service or technology can no longer be considered new after 2 to 3 years, when data reflecting the costs of the technology begin to become available. Data on the costs of this technology began to become available in May 2002. Our analysis of data from the FY 2003 MedPAR file also shows that the costs of CRT–D are represented by a substantial number of cases within the DRGs. However, as discussed above, the technology still remains within the 2-year to 3-year period during which it can be considered new. Therefore, we are considering whether the CRT–D technology still meets the newness criterion. We welcome comments on this issue as we analyze whether to approve this technology (which would included the InSync® application) in the final rule.

We note that the applicant submitted information on the cost and substantial clinical improvement criteria. The applicant commissioned Navigant Consulting, Inc. to collect charge data on CRT–D. Navigant found 354 Medicare cases among 30 hospitals. Cases were identified using ICD–9–CM procedure code 00.51. Of these 354 cases, 44.1 percent were reported in DRG 515, 23.7 percent were reported in DRG 535, and 32.2 percent were reported in DRG 536. These DRGs result in a case-weighted threshold of $78,674. The average case-weighted standardized charge for the 354 cases mentioned above was $79,163. Based on these data, the manufacturer contends that InSync® Defibrillator System would meet the cost criterion.

In the September 7, 2001 final rule, we stated that the data submitted must be of a sufficient sample size to demonstrate a significant likelihood that the sample mean approximates the true mean across all cases likely to receive the new technology. Using a standard statistical methodology for determining the needed (random) sample size based on the standard deviations of the DRGs identified by the applicant as likely to include cases receiving a CRT–D, we have determined that a random sample size of 354 cases can be reasonably expected to produce an estimate within $3,500 of the true mean.[3] Of course, the data submitted do not represent a random sample of all cases in these DRGs across all hospitals.

The manufacturer also contends that the added capability of the InSync® Defibrillator System device provides significant benefits over and above a conventional defibrillator. The InSync® Defibrillator System device treats both the comorbid conditions of ventricular arrhythmias and moderate to severe heart failure, and takes the place of the existing treatment of drug therapy for heart failure plus a conventional implantable cardiac defibrillator for ventricular arrhythmia. The applicant states this CRT–D is a substantial clinical improvement for patients who remain symptomatic despite drug therapy and have the comorbid condition of heart failure. According to the applicant, some of the improved outcomes that result from using a CRT–D device instead of existing treatments include: improved quality of life, improved exercise tolerance, improved homodynamic performance, and reduced hospitalizations and mortality due to chronic heart failure.

We welcome comments on whether this technology meets these criteria, but especially about whether it meets the newness criterion in the light of the extent to which it is represented cases within the relevant DRGs. We will determine whether to approve this technology in the light of these comments and our continuing analysis.

We received the following public comments in accordance with section 503(b)(2) of Public Law 108–173 regarding this application for add-on payments:

Comment: One commenter noted that CRT–D has had positive clinical outcomes by reversing remodeling of the heart and improving the heart's ability to pump more efficiently. The commenter added that CRT-D has helped decrease hospitalizations and length of stay.

Response: We appreciate the commenters' input on this criterion. We will consider these comments regarding the substantial clinical improvement criterion if we determine that the technology meets the other two criteria.

[3] The formula is $n=4\sigma/B^2$, where σ the standard deviation of the population, and B is the bound on the error of the estimate (the range within which the sample means can reliably predict the population mean). See Statistics for Management and Economics, Fifth Edition, by Mendenhall, W., Reinmuth, J., Beaver, R., and Duhan, D.

d. GliaSite® Radiation Therapy System (RTS)

The Pinnacle Health Group submitted an application for approval of GliaSite® Radiation Therapy System (RTS) for new technology add-on payments. GliaSite® RTS was approved by the FDA for use on April 15, 2001. The system involves several components, including a drug called Iotrex and a GliaSite® catheter. Iotrex is an organically bound liquid form of Iodine ^{125} used in intracavitary brachytherapy with GliaSite® RTS. Iotrex is a single nonencapsulated (liquid) radioactive source. The liquid is a solution of sodium ^{3}-(I^{125}) iodo-4-hydroxybenzenesulfonate and is used to deliver brachytherapy for treatment of brain cancer.

The delivery system for Iotrex is the GliaSite® RTS catheter. Iotrex is administered via injection through a self-sealing port into the primary lumen of the barium-impregnated catheter that leads to the balloon reservoir. After a malignant brain tumor has been resected, the balloon catheter (GliaSite®) is implanted temporarily inside the cavity. The patient is released from the hospital. After a period of 3 days to 3 weeks, the patient is readmitted. During the second admission, the appropriate dose (200 to 600 millicuries) of radiation is then administered. Iotrex is infused into the GliaSite® catheter and intracavitary radiation is delivered to the target area. The gamma radiation emitted by Iotrex is delivered directly to the margins of the tumor bed. After 3 to 7 days, the Iotrex is removed.

GliaSite® RTS was approved by the FDA for use on April 15, 2001. Technology is no longer considered new 2 to 3 years after data reflecting the costs of the technology begin to become available. Because data regarding this technology began to become available in 2001, we have determined that GliaSite® RTS does not meet the criterion that a medical service or technology be considered new. Therefore, we are proposing to deny approval of GliaSite® RTS for new technology add-on payments.

Although we are proposing not to approve this application because GliaSite® does not meet the newness criterion, we note that the applicant submitted information on the cost criterion and substantial clinical improvement criterion. The applicant stated that the number of cases in DRG 7 for FY 2004 was projected to be 14,782, and estimated that 10 percent (or about 1,478) of those patients would be candidates for GliaSite® RTS. The applicant estimated that the standardized charge for all cases using the technology in DRG 7 was $49,406. Based on this calculation, the manufacturer stated in its application that this figure is greater than the cost threshold of $32,115 for DRG 7. Therefore, according to the manufacturer, it appears that GliaSite® would meet the cost criterion.

The applicant also claims this way of delivering brachytherapy to the brain is significantly more patient friendly. The use of a single intracavitary applicator positioned inside the resection cavity during the initial surgery in place of an interstitial-seed implant removes the need for additional invasive procedures and the need for multiple puncture sites (up to 20). In addition, the manufacturer claims that the approach used in the GliaSite® RTS system improves dose-delivery and provides a more practical means of delivering the brachytherapy.

However, as discussed above, GliaSite® does not meet the newness criterion. Therefore, we are proposing to deny add-on payments for this technology in FY 2005.

We received no public comments on this application for add-on payments.

e. Natrecor®—Human B-Type Natriuretic Peptide (hBNP)

Scios, Inc. submitted an application for approval of Natrecor® for new technology add-on payments. Natrecor is a member of a new class of drugs, Human B-type Natriuretic Peptide (hBNP), and it is manufactured from E. coli with recombinant DNA technology. It binds to the particulate guanylate cyclase receptor of vascular smooth muscle endothelial cells, leading to increased intracellular concentrations of guanosine 3′5′-cyclic monophosphate, and therefore to enhance smooth muscle cell relaxation, ultimately causing dilation of arteries and veins. The applicant states that Natrecor® is more potent and relieves symptoms of heart failure more rapidly, while also causing less hemodynamic instability than intravenous nitroglycerin, the most commonly used vasodilator for heart failure.

Natrecor® was approved by the FDA for the treatment of acute congestive heart failure on August 10, 2001. It is indicated for the intravenous treatment of patients with acutely decompensated congestive heart failure (dyspnea). Congestive heart failure is the result of impaired pumping capacity of the heart. It causes a variety of clinical consequences, including water retention, sodium retention, pulmonary congestion, and diminished perfusion of blood to all parts of the body.

The applicant concedes that the FY 2003 MedPAR file includes hospital charge information for patients receiving Natrecor®. The manufacturer contends that Natrecor® should still be considered new for several reasons. The first reason is that these data will not provide an accurate representation of hospital utilization of this product nor an adequate reimbursement rate for hospitals treating acute congestive heart failure patients with Natrecor® in FY 2005. The FY 2003 MedPAR file represents the first full year in which the ICD–9–CM procedure code 00.13 (Injection or infusion of nesiritide) was in effect. Therefore, the manufacturer anticipates a slow increase in the accuracy of coding and billing in FY 2003. In addition, the manufacturer stated that market penetration for this product was 3 percent for FY 2003, but is expected to be significantly higher for FY 2005.

However, technology is no longer considered new 2 to 3 years after data reflecting its costs begin to become available. Because data reflecting the costs of Natrecor® began to become available in 2001, these costs are currently reflected in the DRG weights. In addition, as discussed in the September 7, 2001 final rule (66 FR 46914), the determination of whether a technology is new depends on the date of its availability for use in the Medicare population rather than the date a specific code was assigned. Because Natrecor® was available upon FDA approval, it does not meet the criterion that a medical service or technology be considered new.

Although we are proposing not to approve this application because Natrecor® does not meet the newness criterion, we note that the applicant submitted information on the cost criterion and substantial clinical improvement criterion. Scios commissioned Premier, Inc. to search its database of 196 hospitals for cases in FY 2003 that used Natrecor®. Premier identified 9,811 cases across many DRGs using National Drug Codes from pharmacy databases. The majority of cases (approximately 42 percent) were found in DRG 127 (Heart Failure and Shock), while the remaining cases were found in other DRGs that individually had a maximum of 8 percent of the 9,811 cases identified by Premier. The case-weighted threshold across all DRGs for Natrecor®, using data provided by Premier, was $26,509. (DRGs with less than 25 discharges were not included in this analysis.) The average charge for cases with Natrecor® was $70,137. The average case-weighted standardized charge across all DRGs was $43,422.

Because the average standardized charge is greater than the case-weighted threshold, the applicant stated that Natrecor® meets the cost criterion.

The manufacturer stated that Natrecor® represents a substantial clinical improvement over existing treatments for decompensated congestive heart failure because it provides novel clinical effects, leads to fewer complications, and improves overall clinical outcomes. Specifically, Natrecor® reduces left ventricular preload, afterload, and pulmonary capillary wedge pressure without inducing tachyphylaxis, and it causes a balanced vasodilation of veins, arteries, and coronary arteries that increases cardiac output. It has also been shown to significantly reduce dyspnea, and it blocks the rennin-aldosterone-angiotensin system, thereby reducing sodium retention and enhancing diuresis and natriuresis. In addition, Natrecor® is not pro-arrhythmic; it does not increase cardiac work by causing tachycardia, and it does not cause electrolyte imbalances.

However, as discussed above, Natrecor® does not meet the newness criterion. Therefore, we are proposing to deny add-on payments for this technology in FY 2005.

We received no public comments on this application for add-on payments.

f. Kinetra® Implantable Neurostimulator for Deep Brain Stimulation

Medtronic, Inc. submitted an application for approval of the Kinetra® implantable neurostimulator device for new technology add-on payments. The Kinetra® device was approved by the FDA on December 16, 2003. The Kinetra® implantable neurostimulator is designed to deliver electrical stimulation to the subthalamic nucleus (STN) or internal globus pallidus (GPi) in order to ameliorate symptoms caused by abnormal neurotransmitter levels that lead to abnormal cell-to-cell electrical impulses in Parkinson's Disease and essential tremor. Before the development of Kinetra®, treating bilateral symptoms of patients with these disorders required the implantation of two neurostimulators (in the form of a product called Soletra™ manufactured by Medtronic): One for the right side of the brain (to control symptoms on the left side of the body), the other for the left side of the brain (to control symptoms on the right side of the body). Additional procedures are required to create pockets in the chest cavity to place the two generators required to run the individual leads. The Kinetra® neurostimulator generator, implanted in the pectoral area, is designed to eliminate the need for two devices by accommodating two leads that are placed in both the left and right sides of the brain to deliver the necessary impulses. The manufacturer argues that the development of a single neurostimulator that treats bilateral symptoms provides a less invasive treatment option for patients, and for simpler implantation, followup, and programming procedures for physicians.

The device was approved by the FDA in December 2003. Therefore, it qualifies under the first criterion because it is not yet reflected in the DRG weights. Because there are no data available to evaluate costs associated Kinetra®, we conducted the cost analysis using Soletra™, the predecessor technology used to treat this condition, as a proxy for Kinetra®. The pre-existing technology provides the closest means to track cases that have actually used similar technology and serves to identify the need and use of the new device. The manufacturer informed us that the cost of the Kinetra® device is twice the price of a single Soletra™ device. Since most patients would receive two Soletra™ devices if the Kinetra® device is not implanted, data regarding the cost of Soletra™ give a good measure of the actual costs that will be incurred. Medtronic submitted data for 104 cases that involved the Soletra™ device (26 cases in DRG 1 (Craniotomy Age > 17 With CC), and 78 cases in DRG 2 (Craniotomy Age > 17 Without CC)). These cases were identified from the FY 2002 MedPAR file using procedure codes 02.93 (Implantation, intracranial neurostimulator) and 86.09 (Other incision of skin and subcutaneous tissue). In the analysis presented by the applicant, the mean standardized charges for cases involving Soletra™ in DRGs 1 and 2 were $69,018 and $44,779, respectively. The mean standardized charge for these Soletra™ cases according to Medtronic's data was $50,839.

We used the same procedure codes to identify 187 cases involving the Soletra™ device in DRGs 1 and 2 in the FY 2003 MedPAR file. Similar to the Medtronic data, 53 of the cases were found in DRG 1, and 134 cases were found in DRG 2. The average standardized charges for these cases in DRGs 1 and 2 were $51,163 and $44,874, respectively. Therefore, the case-weighted average standardized charge for cases that included implantation of the Soletra™ device was $46,656. The new cost thresholds established under the revised criteria in Public Law 108–173 for DRGs 1 and 2 are $43,245 and $30,129, respectively. Accordingly, the case-weighted threshold to qualify for new technology add-on payment using the data we identified would be $33,846. Under this analysis, Kinetra® would qualify for the cost threshold.

We note that an ICD–9–CM code was approved for dual array pulse generator devices, effective October 1, 2004, for IPPS tracking purposes. The new ICD–9–CM code that will be assigned to this device is 86.95 (Insertion or replacement of dual array neurostimulator pulse generator), which includes dual array and dual channel generators for intracranial, spinal, and peripheral neurostimulators. The code will not identify cases with this specific device and will only be used to distinguish single versus dual channel-pulse generator devices.

The manufacturer claims that Kinetra® provides a range of substantial improvements beyond previously available technology. These include a reduced rate of device-related complications and hospitalizations or physician visits and less surgical trauma because only one generator implantation procedure is required. Kinetra® has a reed switch disabling function that physicians can use to prevent inadvertent shutoff of the device, as occurs when accidentally tripped by electromagnetic inference (caused by common products such as metal detectors and garage door openers). Kinetra® also provides significant patient control, allowing patients to monitor whether the device is on or off, to monitor battery life, and to fine-tune the stimulation therapy within clinician-programmed parameters. While Kinetra® provides the ability for patients to better control their symptoms and reduce the complications associated with the existing technology, it does not eliminate the necessity for two surgeries. Because the patients who receive the device are often frail, the implantation generally occurs in two phases: The brain leads are implanted in one surgery, and the generator is implanted in another surgery, typically on another day. However, implanting Kinetra® does reduce the number of potential surgeries compared to its predecessor (which requires two surgeries to implant the two single-lead arrays to the brain).

Despite the improvement Kinetra® represents over its immediate predecessor, Soletra™, we have some concerns about whether the device is significantly different in terms of how it achieves its desired clinical result. The stimulation mechanism by which it treats patient symptoms remains substantially the same as the

predecessor device. The enhancements cited by the manufacturer are primarily to features such as control, power, monitoring, and reliability. Nevertheless, these improvements, along with the reduced number of surgeries required, may be sufficient to warrant a determination that the device represents a substantial clinical improvement. We welcome further public comment on the issue of whether the device is sufficiently different from the previously used technology to qualify as a substantially improved treatment of the same patient symptoms.

We also invite comments concerning the cost of the device. If the new device, at twice the cost of the existing technology, merely replaces the costs of two of the previous devices, then the charges for Kinetra® are not substantially different from current charges resulting from the use of either device alone. Because the costs for the predecessor device meet the statutory cost criterion, the successor technology would meet the criterion as well, at least under the manufacturer's assumption that a single Kinetra® costs twice as much as each of the two Soletras™ required to perform the same function. However, since there should be less surgery involved, more patient control, less risk of complications, and fewer office visits as a result of using Kinetra®, the costs for patients who receive the new device would be expected to drop. This suggests that it may not be appropriate to base the cost analysis for Kinetra® on the manufacturer's assumption that total costs for Soletra™ and Kinetra® are substantially the same.

In addition, we also invite public comment concerning the approval of the device for add-on payment, given the uncertainty over the frequency with which the patients receiving the device have the generator implanted in a second hospital stay, and the frequency with which this implantation occurs in an outpatient setting. Any hospital performing the implantation in two separate patient stays, whether they are both inpatient or whether one is inpatient and the second is outpatient, would be paid double for the single device. Therefore, we have some concern about the appropriateness of approving add-on payments for a device that may already receive payment at a nonbundled rate for a high percentage of patients who receive the device. We are currently investigating whether a second hospital stay is needed for implantation of Kinetra®.

Despite these issues, we are still considering whether it is appropriate to approve add-on status for Kinetra® for FY 2005. If approved for add-on payments, the device would be reimbursed up to half of the costs for the device. Since the manufacturer has stated that the cost for Kinetra® would be $16,570, the maximum add-on payment for the device would be $8,285. We will make a final determination in the light of public comments and our continuing analysis.

We received no public comments on this application for add-on payments.

We note that the manufacturer of Kinetra® also submitted an application for pass-through payments under the hospital outpatient payment system (OPPS). This application was denied for pass-through payment in OPPS because the item was already described by a previously existing category of devices for pass-through payment (C1767, Generator, neurostimulator (implantable)). Therefore, no substantial improvement determination was made for that application, although one would have been required for approval if it had met all other criteria. The manufacturer subsequently applied for assignment of deep brain stimulation with Kinetra® neurostimulator to a new technology ambulatory payment classification (APC) under the OPPS. This application is currently under consideration. These special APCs were initiated in OPPS to expedite recognition of and payment for innovative new technologies that do not qualify for pass-through payment. In contrast to the annual decisionmaking under the IPPS, applications for new technology APCs of the OPPS are accepted on an ongoing basis and updates are made quarterly.

g. Intramedullary Skeletal Kinetic Distractor (ISKD)

Orthofix, Inc. submitted an application for approval of the Intramedullary Skeletal Kinetic Distractor (ISKD) Internal Limb Lengthener for new technology add-on payments for FY 2005. The device received FDA marketing approval on May 2, 2001. The ISKD System is a ''closed'' lengthening system. There are no fixation pins exiting the skin, thus eliminating this portal for entry of infectious organisms. The device is implanted in the intramedullary canal. This provides mechanical stability and support to the bone segments during the distraction, regeneration and consolidation phases, thus reducing the opportunity for misalignment.

We reviewed the application and technology, and we have determined that the device is not new and cannot be approved for new technology add-on payments because it came on the market on May 2, 2001. The costs of the device are thus reflected in the FY 2001 MedPAR file, as acknowledged by the manufacturer's data. As a result, the costs of the device are already reflected in the DRG weights.

The manufacturer submitted charge data for cases found in the FY 2001 MedPAR file, as well as data from several hospitals that have used the device. The manufacturer identified cases using ICD–9–CM codes 78.35 (Limb lengthening procedure, femur) and 78.37 (Limb lengthening, tibia/fibula). These procedure codes occur in four DRGs: DRGs 210 and 211 (Hip and Femur Procedures Except Major Joint Procedures Age > 17, With and Without CC, respectively) and DRGs 218 and 219 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur Age > 17, With and Without CC). The average charges for cases involving these procedure codes identified by the applicant were not standardized. The average charges provided for DRGs 210, 211, 218, and 219 were $26,692, $18,187, $32,959 and $20,228, respectively. The manufacturer then added the cost of the device, which the manufacturer states is $6,750. The manufacturer projects that, in FY 2005, there will be 9 cases in DRG 210, 4 cases in DRG 211, 28 cases in DRG 218, and 19 cases in DRG 219, which results in a case-weighted threshold of $22,347. Thus, according to the manufacturer's data, because the case-weighted average standardized charges of $27,003 for the technology are greater than the cost threshold of $22,347 for these projected 60 cases, the ISKD would qualify for new technology add-on payments.

The manufacturer also asserted that the ISKD met the substantial clinical improvement criteria because, in addition to the improvements mentioned above (reduces infection rates and provides mechanical stability), lengthening with the ISKD occurs gradually and with no soft tissue impingement, reducing two factors commonly associated with pain during distraction. The manufacturer also pointed out that with the ISKD, the lengthening procedure is discreet because there are no external pins. There is no cumbersome external frame that may hinder the patient's activities of daily living, or draw further attention to the discrepant limb. In addition, the patient may have partial weight bearing during the lengthening process and resume some activities of normal living.

However, because the device is already captured in our DRG weights, we are proposing to deny the application for the ISKD device for new technology add-on payments for FY 2005.

We received no public comments on this application for add-on payments.

h. Acticon™ Neosphincter

American Medical Systems submitted an application for approval of the Acticon™ Neosphincter for new technology add-on payments for FY 2005. The Acticon™ Neosphincter is a small, fluid-filled prosthesis that is completely implanted within the body. The Acticon™ Neosphincter prosthesis has been developed to treat severe fecal incontinence (the accidental loss of solid or liquid stool at least weekly). It is designed to mimic the natural process of bowel control and bowel movements. The prosthesis consists of three components: a occlusive cuff implanted around the anal canal, a pressure-regulating balloon implanted in the prevesical space, and a control pump with septum implanted in the scrotum. All components are connected with color-coded, kink-resistant tubing.

The FDA approved the Acticon Neosphincter for use on December 18, 2001. A technology can be considered new only 2 to 3 years after data reflecting the costs of the technology begin to become available. Data on the costs of this technology began to become available after the December 2001 FDA approval. As a result, the costs of this technology are currently reflected in the DRG weights. Therefore, we have determined that Acticon™ Neosphincter does not meet this criterion.

Although we are proposing not to approve this application because Acticon™ Neosphincter does not meet the newness criterion, we note that the applicant submitted information on the cost criterion and substantial clinical improvement criterion. The applicant submitted 23 cases (that are indistinguishable as to whether they are Medicare or non-Medicare) using ICD–9–CM procedure codes 49.75 (Implantation or revision of artificial anal sphincter) and 49.76 (Removal of artificial anal sphincter) in order to identify cases where the Acticon™ Neosphincter was used. Of these cases, 9 were in DRG 157 (Anal and Stomal Procedures With CC), and 14 were in DRG 158 (Anal and Stomal Procedures Without CC). The average standardized charge per case was $16,758. The case-weighted threshold for DRGs 157 and 158 (39.1 percent of cases in DRG 157 and 60.1 percent of cases in DRG 158) for this technology is $14, 426. Therefore, according to the applicant, the Acticon™ Neosphincter meets the cost criterion.

The applicant states in its application that the Acticon™ Neosphincter represents a substantial clinical improvement for the following reasons: First, there is no other existing device in the United States that can be used to treat severe fecal incontinence. Second, self-treatment for severe fecal incontinence has proven to be largely unsuccessful and surgical options have historically been more limited, including sphincteroplasty or muscle transposition.

However, since Acticon™ Neosphincter does not meet the newness criterion, we are proposing to deny add-on payments for this new technology. The applicant also requested a DRG reclassification for this technology. In section II.B.4 of the preamble of this proposed rule, we are proposing, in MDC 6 (Diseases and Disorders of the Digestive System) only, to remove codes 49.75 and 49.76 from DRGs 157 and 158, and reassign them to DRGs 146 (Rectal Resection With CC) and 147 (Rectal Resection Without CC). All other MDC and DRG assignments for codes 49.75 and 49.76 would remain the same.

We received the following public comments in accordance with section 50(b)(2) of Pub. L. 108–173 regarding this application for add-on payments.

Comment: One commenter noted that the implant of the Acticon™ Neosphincter avoids the life-altering and disfiguring consequences of a permanent stoma. Another commenter noted that the implant of the Acticon™ Neosphincter avoids the need for a colostomy, which limits a patient's ability to travel and work due to the fact they could have a fecal accident at any time.

Response: We appreciate the commenters' input on this criterion. However, as stated above, the Acticon™ Neosphincter is no longer new. Therefore, we are proposing that it is not eligible for add-on payments for new technologies.

i. TandemHeart™ Percutaneous Left Ventricular Assist System

Brigham and Women's Hospital submitted an application for approval of the TandemHeart™ Percutaneous Ventricular Assist System (PVTA) manufactured by Cardiac Assists, Inc., for new technology add-on payments for FY 2005. Cardiac Assists, Inc. has been assisting the applicant with supplemental information and data to support the application process. According to the manufacturer, the device contains a controller, arterial and venous cannulae and the TandemHeart™ Percutaneous Ventricular Assist Device (pVAD) that works parallel with the left ventricle to provide left ventricular circulatory support. The device is intended for extracorporeal circulatory support using an extracorporeal bypass circuit. The duration of use approved by the FDA is for periods of up to 6 hours.

On November 11, 2000, FDA approved the AB–180 XC Blood Pump (also known as the TandemHeart™ pVAD) as a single use, disposable centrifugal blood pump designed to circulate blood through an extracorporeal circuit. On May 23, 2003, FDA approved the CardiacAssist Transseptal Cannula Set for transseptal catherization of the left atrium via the femoral vein for the purpose of providing a means for temporary (6 hours or less) left ventricular bypass when connected to a suitable extracorporeal blood pump unit that returns blood to the patient via the femoral artery or other appropriate site. The manufacturer stated that, although the TandemHeart™ pVAD was approved in November 2000, this device should still be considered new because the device was not marketed and sold to hospitals until the CardiacAssist Transseptal Cannula Set was approved by FDA in May 2003. We have received confirmation from hospitals that the TandemHeart™ pVAD was indeed not marketed until FDA approved the CardiacAssist Transseptal Cannula Set. Also, only half of a year's worth of data containing the TandemHeart™ pVAD is reflected within the FY 2003 MedPAR file. The manufacturer stated that approximately 60 TandemHeart™ pVADs have been used since FDA approved the Cardiac Arrest Transseptal Cannula Set in May 2003. Therefore, the costs of the TandemHeart™ pVAD are not adequately reflected within the DRGs. As a result, we consider the TandemHeart™ pVAD to be new under our criterion.

As stated above, according to the manufacturer, approximately 60 TandemHeart™ pVADs have been used since FDA approved the Cardiac Assist Transseptal Cannula Set in May 2003 (not all of these have been used in Medicare beneficiaries). However, only two actual cases were submitted by the applicant with an ICD–9–CM code of 37.65 (Implant of an external pulsatile heart assist system) used to identify the device. As stated in the September 7, 2001 final rule (66 FR 46916), data submitted by the applicant must be of a sufficient sample size to demonstrate a significant likelihood that the true mean across all cases likely to receive the technology will exceed the threshold established by CMS. Because we lack a significant sample of data reflecting the costs of this technology,

we cannot accurately determine the average charge per case for the TandemHeart™ pVAD. Neither can we determine whether this technology meets our cost criterion. If we receive sufficient data to complete our analysis in time for inclusion in the final rule, we will assess whether this technology meets the cost criterion.

Although we are not proposing to approve this application because we have insufficient data to determine whether TandemHeart™ pVAD meets the cost criterion, we note that the applicant submitted information on the substantial clinical improvement criterion. The applicant stated in its application that the TandemHeart™ pVAD represents a substantial clinical improvement because, at present, the only alternative to intra-aortic balloon pump support is the surgical implantation of a ventricular assist device. The TandemHeart™ pVAD is the only therapeutic intervention that is capable of achieving effective circulatory support to stabilize cardiogenic shock patients that could be placed via a percutaneous approach. We will present a full analysis of this technology under the significant improvement criterion if we receive sufficient data in time for the final rule to evaluate whether the technology meets the cost criterion.

The applicant also requested an ICD–9–CM code for this technology. We discuss this request in section II.B.3. of the preamble of this proposed rule.

We received no public comments on this application for add-on payments.

j. Aquadex™ System 100 Fluid Removal System (System 100)

CHF Solutions, Inc. submitted an application for the approval of the System 100 for new technology add-on payments for FY 2005. The System 100 is designed to remove excess fluid (primarily excess water) from patients suffering from severe fluid overload through the process of ultrafiltration. Fluid retention, sometimes to an extreme degree, is a common symptom of patients with chronic congestive heart failure. This technology removes excess fluid without causing hemodynamic instability. It also avoids the inherent nephrotoxicity and tachyphylaxis associated with aggressive diuretic therapy, the mainstay of current therapy for fluid overload in congestive heart failure.

The System 100 consists of: (1) An S–100 console; (2) a UF 500 blood circuit; (3) an extended length catheter (ELC); and (4) a catheter extension tubing. The System 100 is designed to monitor the extracorporeal blood circuit and to alert the user to abnormal conditions. Vascular access is established via the peripheral venous system, and up to 4 liters of excess fluid can be removed in an 8-hour period.

On June 3, 2002, FDA approved the System 100 for use with peripheral venous access. On November 20, 2003, FDA approved the System 100 for expanded use with central venous access and catheter extension use for infusion or withdrawal circuit line with other commercial applicable venous catheters. According to the applicant, although the System 100 was first approved by FDA in June 2002, the System 100 was not used by hospitals until August 2002 because it took a substantial amount of time to market and sell the device to hospitals. As a result, the applicant believes that the System 100 should still be considered new. The applicant has presented data and evidence demonstrating that the System 100 was not marketed until August 2002. Therefore, we also believe August 1, 2002 is the relevant date for determining the availability of the System 100.

The applicant estimates that 308 patients (approximately 120 cases per year) have used the System 100 since its inception and the potential population for use of the device is 60,000 cases per year. These 308 cases represent a small percentage of the potential number of cases that can utilize the System 100. Therefore, the System 100 is not adequately reflected within the DRG weights (as discussed in the September 7, 2001 final rule (66 FR 46914)). In addition, the System 100 is within the 2 to 3 year period contemplated under § 412.87(b)(2) of the regulations. Therefore, the System 100 could be considered new. However, the ultrafiltration process that the System 100 employs can also be considered to be a type of hemodialysis, which is an old and well-established technology. We have concerns about whether new technology add-on payments should be extended to a well-established technology, even when a new clinical application is developed for that technology. As discussed above, in the September 7, 2001 final rule (66 FR 46915), we noted that if an existing technology is used for treating patients not expected to be assigned to the same DRG as the patients already receiving the technology, it may be considered for approval if it also meets the other cost and clinical improvement criteria. In this case, the device does treat a different patient population of congestive heart failure than the patient population for renal dialysis. Under the policy described in the September 7, 2001 final rule, this technology may be considered new for the purposes of determining whether it qualifies for add-on payments. However, we have some concerns about whether this is an appropriate result, and about whether technologies that have been in use for many years, in some cases decades, should be able to qualify for add-on payments for new technologies. Therefore, we invite comments on whether this technology should be considered new, and on the general issue of whether existing technologies should be approved for add-on payments when new applications are developed for these technologies and whether special standards regarding, for example, clinical improvement, should be applied in such cases.

The applicant submitted five sets of data to demonstrate that the System 100 meets the cost criterion. Of these five, three sets of data were flawed in the analysis of the cost criterion. Therefore, we will discuss only the data that are most accurate and relevant. It is important to note at the outset of the cost analysis that the console is reusable and is, therefore, a capital cost. Only the circuits and catheters are components that represent operating expenses. Section 1886(d)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act, which makes no mention of any add-on payments for a new medical service or technology. Therefore, it is not appropriate to include capital costs in the add-on payments for a new medical service or technology and these costs should also not be considered in evaluating whether a technology meets the cost criterion. The applicant has applied for add-on payments only for the circuits and catheter, which represent the operating expenses of the device. However, catheters cannot be considered new technology in any sense. As a result, only the UF 500 disposable blood circuit is relevant to the evaluation of the cost criterion.

The applicant commissioned Covance to search the FY 2002 MedPAR file. The applicant used a combination of diagnosis codes to determine which cases could potentially use the System 100. Covance found 27,589 cases with the following combination of ICD–9–CM diagnosis codes: 428.0 through 428.9 (Heart Failure), 402.91 (Unspecified with Heart Failure), or 402.11

(Hypertensive Heart Disease with Heart Failure), in combination with 276.6 (Fluid Overload) and 782.3 (Edema). The 27,589 cases were found among 281 DRGs with 49.4 percent of cases mapped across DRGs 88, 89, 127, 277 and 316. The applicant eliminated those DRGs with less than 150 cases, which resulted in a total of 22,024 cases that could potentially use the System 100. The case-weighted average standardized charge across all DRGs was $14,534. The case-weighted threshold across all DRGs was $17,789. Although the case-weighted threshold is greater than the case-weighted standardized charge, it is necessary to include the standardized charge for the circuits used in each case. In order to establish the charge per circuit, the manufacturer submitted data regarding 51 actual cases that used the System 100. Based on these 51 cases, the standardized charge per circuit was $2,209. The manufacturer also stated that an average of two circuits are used per case. Therefore, adding $4,418 for the charge of the two circuits to the case-weighted average standardized charge of $14,534 results in a total case-weighted standardized charge of $18,952. This is greater than the case-weighed threshold of $17,789. We welcome comments from the public on the charge information submitted by the applicant for the circuits.

Using the FY 2003 MedPAR file, we used the same combination of diagnosis codes to identify 28,660 cases across all DRGs. As in the applicant's analysis, we eliminated those DRGs with less than 150 cases, which resulted in 22,395 cases. The case-weighted average standardized charge for these cases is $15,447. The case-weighted threshold to qualify for new technology add-on payment using the data we identified would then be $18,029. Again, as in the applicant's analysis, it was necessary to include in the charge of $4,418 for the circuits. This results in a total case-weighted average standardized charge of $19,865, which is also greater than the case-weighted threshold of $18,029. Based on these two analyses, the System 100 meets the cost criterion.

The applicant contends that the System 100 represents a substantial clinical improvement for the following reasons: It removes excess fluid without the use of diuretics; it does not lead to electrolyte imbalance, hemodynamic instability or worsening renal function; it can restore diuretic responsiveness; it does not adversely affect the renin-angiotensin system; it reduces hospital length of stay for the treatment of congestive heart failure; and it requires only peripheral venous access.

Although we lack data from a large, multicenter, randomized, prospective clinical trial, we believe the applicant has submitted data that demonstrate the use of this technology in achieving the clinical benefits cited. We believe that there is some basis for concluding that the System 100 represents a substantial clinical improvement over current standard treatment of fluid overload in congestive heart failure. However, we invite comment on whether the data submitted are indeed adequate to demonstrate significant clinical improvement.

Based on the criteria, we believe that the System 100 could be approved for new technology add-on payments for FY 2005. However, we invite comments on this application, and especially on whether the System 100 is really new and on whether it represents a new technology within the meaning of the statute and regulations. If approved for add-on payments, the device would be reimbursed up to half of the costs for the disposable portion of the device. The manufacturer has stated that the cost for the disposable blood circuit and filter would be $900. As stated above, an average two circuits are used per case, which results in a total cost of $1,800 per case. Therefore, the maximum add-on payment for the disposable parts of the device would be $900 per case. We will determine whether to approve this application in the light of the comments we receive and our continuing analysis.

We received the following public comments in accordance with section 503(b)(2) of Pub. L. 108–173 regarding this application for add-on payments.

Comment: Several commenters noted that the System 100 provides physicians a new treatment option for patients with fluid overload who are unresponsive to diuretics and has been documented in clinical studies and other published articles to effectively treat fluid overload. Another commenter noted that patients who have been treated with the System 100 seem to have improved health versus those who have lingered on diuretic therapy or have been treated by hemodialysis. The commenter also noted that the system 100 reduces hospital stays. Other commenters noted that the System 100 is safer for those patients in terms of reduced electrolyte imbalance and renal dysfunction and is a major step forward in the treatment of decompensated heart failure.

Response: As we stated above, we believe that there is some basis for concluding that the System 100 offers substantial clinical improvement. We will consider these comments as we continue to evaluate whether the System 100 meets this criterion.

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 statistical areas established by the Office of Management and Budget (OMB). A detailed discussion of the proposed FY 2005 hospital wage index based on the statistical areas, including OMB's revised definitions of Metropolitan Areas, appears under section III.B of this preamble.

Beginning October 1, 1993, section 1886(d)(3)(E) of the Act requires that we update the wage index annually. Furthermore, this section provides that the Secretary base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. The survey should measure, to the extent feasible, the earnings and paid hours of employment by occupational category, and must exclude the wages and wage-related costs incurred in furnishing skilled nursing services. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The adjustment we are proposing for FY 2005 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed below in section III.G. of this preamble, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating the wage index. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The budget neutrality adjustment we are proposing for FY

2005 is discussed in section II.B. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the initial collection of these data and the occupational mix adjustment that we are proposing to apply beginning October 1, 2004 (the FY 2005 wage index) appears under section III.C. of this preamble.

B. Revised OMB Definitions for Geographical Statistical Areas

[If you choose to comment on issues in this section, please include the caption ''Revised MSAs'' at the beginning of your comment.]

1. Current Labor Market Areas Based on MSAs

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. In accordance with the broad discretion under section 1886(d)(3)(E) of the Act, we currently define hospital labor market areas based on the definitions of Metropolitan Statistical Areas (MSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs) issued by OMB. OMB also designates Consolidated MSAs (CMSAs). A CMSA is a metropolitan area with a population of one million or more, comprising two or more PMSAs (identified by their separate economic and social character). For purposes of the hospital wage index, we use the PMSAs rather than CMSAs because they allow a more precise breakdown of labor costs. If a metropolitan area is not designated as part of a PMSA, we use the applicable MSA.

These different designations use counties as the building blocks upon which they are based. Therefore, hospitals are assigned to either an MSA, PMSA, or NECMA based on whether the county in which the hospital is located is part of that area. For purposes of the IPPS wage index, we combine all of the counties in a State outside a designated MSA, PMSA, or NECMA together to calculate a statewide rural wage index.

2. Core-Based Statistical Areas

OMB reviews its Metropolitan Area (MA) definitions preceding each decennial census. In the fall of 1998, OMB chartered the Metropolitan Area Standards Review Committee to examine the MA standards and develop recommendations for possible changes to those standards. Three notices related to the review of the standards were published on the following dates in the **Federal Register**, providing an opportunity for public comment on the recommendations of the Committee: December 21, 1998 (63 FR 70526); October 20, 1999 (64 FR 56628), and August 22, 2000 (65 FR 51060).

In the December 27, 2000 **Federal Register** (65 FR 82228 through 82238), OMB announced its new standards. According to that notice, OMB defines a Core-Based Statistical Area (CBSA), beginning in 2003, as ''a geographic entity associated with at least one core of 10,000 or more population, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties. The standards designate and define two categories of CBSAs: Metropolitan Statistical Areas and Micropolitan Statistical Areas.'' (65 FR 82235)

According to OMB, MSAs are based on urbanized areas of 50,000 or more population, and Micropolitan Statistical Areas (referred to in this discussion as Micropolitan Areas) are based on urban clusters of at least 10,000 population but less than 50,000 population. Counties that do not fall within CBSAs are deemed ''Outside CBSAs.'' In the past, OMB defined MSAs around areas with a minimum core population of 50,000, and smaller areas were ''Outside MSAs.''

The general concept of the CBSAs is that of an area containing a recognized population nucleus and adjacent communities that have a high degree of integration with that nucleus. The purpose of the standards is to provide nationally consistent definitions for collecting, tabulating, and publishing Federal statistics for a set of geographic areas. CBSAs include adjacent counties that have a minimum of 25 percent commuting to the central counties of the area. This is an increase over the minimum commuting threshold for outlying counties applied in the previous MSA definition of 15 percent.

On June 6, 2003, OMB announced the new CBSAs, comprised of MSAs and the new Micropolitan areas based on Census 2000 data. (A copy of the announcement may be obtained at the following Internet address: *http://www.whitehouse.gov/omb/bulletins/fy04/b04–03.html*.) The new definitions recognize 49 new MSAs and 565 new Micropolitan Areas, and extensively revise the construct of many of the existing MSAs. There are 1,090 counties in MSAs under these new definitions (previously, there were 848 counties in MSAs). Of these 1,090 counties, 737 are in the same MSA as they were prior to the changes, 65 are in a different MSA, and 288 were not previously designated to any MSA. There are 674 counties in Micropolitan Areas. Of these, 41 were previously in an MSA, while 633 were not previously designated to an MSA. There are five counties that previously were designated to an MSA but are no longer designated to either an MSA or a new Micropolitan Area: Carter County, KY; St. James Parish, LA; Kane County, UT; Culpepper County, VA; and King George County, VA.

3. Revised Labor Market Areas

In its June 6, 2003 announcement, OMB cautioned that these new definitions ''should not be used to develop and implement Federal, State, and local nonstatistical programs and policies without full consideration of the effects of using these definitions for such purposes. These areas should not serve as a general-purpose geographic framework for nonstatistical activities, and they may or may not be suitable for use in program funding formulas.''

We have previously examined alternatives to the use of MSAs for the purpose of establishing labor market areas for the Medicare wage index. In the May 27, 1994, proposed rule (59 FR 27724), we presented our latest research concerning possible future refinements to the labor market areas. Specifically, we discussed and solicited comment on the proposal by the Prospective Payment Assessment Commission (ProPAC, a predecessor organization to the Medicare Payment Advisory Commission (MedPAC)) for hospital-specific labor market areas based on each hospital's nearest neighbors, and our research and analysis on alternative labor market areas. Even though we found that none of the alternative labor market areas that we studied provided a distinct improvement over the use of MSAs, we presented an option using the MSA-based wage index but generally giving a hospital's own wages a higher weight than under the current system. We also described for comment a State labor market option, under which hospitals would be allowed to design labor market areas within their own State boundaries.

We described the comments we received in the June 2, 1995 proposed rule (60 FR 29219). There was no consensus among the commenters on the choice for new labor market areas. Many individual hospitals that commented expressed dissatisfaction with all of the proposals. However, several State hospital associations commented that the options merited further study. Therefore, we contacted the association representatives that

participated in our November 1993 meeting on labor market issues in which we solicited ideas for additional types of labor market research to conduct. None of the individuals we contacted suggested any ideas for further research.

Consequently, we have continued to use MSAs to define labor market areas for purposes of the wage index. While we recognize MSAs are not designed specifically to define labor market areas, we believe they do represent a useful proxy for this purpose, and our analysis and discussion here are focused on issues related to adopting the new CBSAs to define labor market areas.

a. New England MSAs

As stated above, we currently use NECMAs to define labor market areas in New England, because these are county-based designations rather than the 1990 MSA definitions for New England, which used minor civil divisions such as cities and towns. Under the previous MSA definitions, NECMAs provided more consistency in labor market definitions for New England compared with the rest of the country, where MSAs are county-based. Under the new CBSAs, OMB has defined the MSAs and Micropolitan Areas in New England on the basis of counties. OMB also established New England City and Town Areas, which are similar to the previous New England MSAs. Therefore, to maintain consistency in the definition of labor market areas between New England and the rest of the country, we are proposing to use the New England MSAs under the new CBSA definition.

b. Metropolitan Divisions

A Metropolitan Division is a county or group of counties within a CBSA that contains a core population of at least 2.5 million, representing an employment center, plus adjacent counties associated with the main county or counties through commuting ties. A county qualifies as a main county if 65 percent or more of its employed residents work within the county and the ratio of the number of jobs located in the county to the number of employed residents is at least .75. A county qualifies as a secondary county if 50 percent or more, but less than 65 percent, of its employed residents work within the county and the ratio of the number of jobs located in the county to the number of employed residents is at least .75. After all the main and secondary counties are identified and grouped, each additional county that already has qualified for inclusion in the MSA falls within the Metropolitan Division associated with the main/secondary county or counties with which the county at issue has the highest employment interchange measure. Counties in a Metropolitan Division must be contiguous. (65 FR 82236)

As noted above, in the past, OMB designated CMSAs as Metropolitan Areas with a population of one million or more and comprising two or more PMSAs. We currently use the PMSAs rather than CMSAs to define labor market areas because they comprise a smaller geographic area with potentially varying labor costs due to different local economies. Similarly, we are proposing to use the Metropolitan Divisions where applicable under the CBSA definitions.

Under the CBSA definitions, there are 11 MSAs containing Metropolitan Divisions: Boston; Chicago; Dallas; Detroit; Los Angeles; Miami; New York; Philadelphia; San Francisco; Seattle; and Washington, D.C. Although these MSAs were also CMSAs under the prior definitions, in some cases their areas have been significantly altered. Under the prior definitions, Boston was a single NECMA. It is now comprised of 4 Divisions. Los Angeles went from 4 PMSAs to 2 Divisions because 2 MSAs became separate MSAs. The New York CMSA went from 15 MSAs down to only 4 Divisions. Five PMSAs in Connecticut now become separate MSAs, and the number of PMSAs in New Jersey goes from 5 to 2, with the consolidation of 2 New Jersey PMSAs (Bergen-Passaic and Jersey City) into the New York-Wayne-White Plains, NY–NJ Division. In San Francisco, only 2 Divisions remain where there were once 6 PMSAs, some of which are now separate MSAs.

Previously, Cincinnati, Cleveland, Denver, Houston, Milwaukee, Portland, Sacramento, and San Juan were all previously designated as CMSAs, but are not any longer. As noted previously, the population threshold to be designated a CMSA was one million. In most of these cases, counties formerly in a PMSA have become a separate, independent MSA, leaving only the MSA for the core area under the new CBSA definitions.

c. Micropolitan Areas

One of the major issues with respect to the new definitions is whether to use Micropolitan Areas to define labor market areas for the purpose of the IPPS wage index. Because the new Micropolitan Areas are essentially a third area definition made up mostly of currently rural areas, but also some or all of current MSAs, how these areas are treated will have significant impacts on the calculation and application of the wage index. Treating Micropolitan Areas as separate and distinct labor market areas would affect both the wage indexes of the hospitals in the Micropolitan Areas and the hospitals in the labor market areas where those hospitals are currently located (both positively and negatively).

Because we currently use MSAs to define urban labor market areas and we group all the hospitals in counties within each State that are not assigned to an MSA together into a statewide rural labor market area, we have used the terms ''urban'' and ''rural'' wage indexes in the past for ease of reference. However, the introduction of Micropolitan Areas complicates this terminology because these areas include so many hospitals that are currently included in the statewide rural labor market areas. In order to facilitate the discussion below, we use the term ''rural'' hospitals to describe hospitals in counties that are not assigned to either an MSA or a Micropolitan Area. This should not be taken to indicate that hospitals in Micropolitan Areas are no longer ''rural'' hospitals. In fact, we are proposing that hospitals in Micropolitan Areas are included in the statewide rural labor market areas, for the reasons outlined below. The reader is referred to section IV.B. of the preamble of this proposed rule for a more specific discussion of the implications of these changes for defining urban and rural areas under § 412.62(f).

Chart 1 below demonstrates the distributions of hospitals by their current and new designations. Approximately 50 percent of hospitals currently designated rural are now in either Micropolitan Areas (691 hospitals) or MSAs (197 hospitals). The vast majority of hospitals currently in MSAs remain in an MSA (2,478, although in some cases the MSAs have been reconfigured), while 2 are now in rural areas and 65 are now in Micropolitan Areas.

CHART 1.—DISTRIBUTION OF HOSPITALS BY CURRENT AND NEW DESIGNATION

Statistical area	Currently rural	Currently MSA.
Rural	861	2
Micropolitan	691	65
MSA	197	2,478
Totals	1,749	2,545

In order to evaluate the impact of these changes, we grouped hospitals based on the county where they are located according to the new MSA and Micropolitan areas using the definitions

on the Census Bureau's Web site: *http://www.census.gov/population/www/estimates/metrodef.html.* We then compared the proposed FY 2004 wage indexes (using data from hospitals' FY 2001 cost reports) calculated based on the current MSAs, without any effects of hospital geographic reclassifications. Consistent with current policy, we applied the rural floor in the case where the statewide rural wage index is greater than the wage index for a particular urban area. We excluded Indian Health Service hospitals from the analysis due to the special characteristics of the prospective payment system for these hospitals. Hospitals in Maryland were excluded from the analysis because they remain excluded from the IPPS under the waiver at section 1814(b)(3) of the Act. Our analysis also does not reflect any changes to the Puerto Rico-specific wage index, which is applicable only to the Puerto Rico standardized amounts (the analysis does include the national wage index values for Puerto Rico hospitals).

Chart 2 below shows the impact on hospitals' wage indexes of recalculating new wage indexes based on the new MSAs, and treating the new Micropolitan Areas as separate labor market areas. Specifically, the table shows the impact of treating the new MSA and Micropolitan Areas as labor market areas and calculating a wage index for each one. The most dramatic impact of this change would be on hospitals that are currently classified as rural. Only 10 currently rural hospitals would experience no changes in their wage indexes after applying the new MSA definitions. Five of these hospitals are in Delaware and Connecticut (three and two hospitals respectively), where the only counties in the State currently considered rural are now part of Micropolitan Areas.

Approximately 62 percent (1,092 out of 1,749) of currently rural hospitals experience decreases in their wage indexes under this change. Among hospitals that remain rural after separately recognizing Micropolitan Areas (those hospitals in counties ''outside CBSAs''), rural hospitals in six States (Arizona, Florida, Idaho, Indiana, Minnesota, and Missouri) experience a positive impact after applying the new MSA definitions. These hospitals benefit because the net effect on their wage index of other hospitals moving into Micropolitan Areas is positive. The majority of the currently rural hospitals (762 out of 1,092) that experience decreases in their wage indexes are hospitals that would remain rural under the new definitions. Moreover, among the 646 rural hospitals whose wage indexes would increase under the new definitions, 547 would now be in an MSA or Micropolitan Area.

Furthermore, in many cases, the magnitude of the changes is quite large. Nearly one-half of all rural hospitals would experience payment changes of at least 5.0 percent, either negatively or positively, if we were to adopt labor market areas based in part on the new Micropolitan Areas.

In contrast, there are 938 currently urban hospitals (37 percent) with wage indexes that are unaffected by the new MSA definitions. These hospitals are in MSAs or PMSAs that are either unchanged (for example, the Austin, Buffalo, Milwaukee, Oakland, Phoenix, San Diego, and Tampa-St. Petersburg MSAs are all unchanged) or include new counties without any hospitals in those counties that are now part of the existing MSA (for example, Atlanta, Denver, Little Rock, Omaha, Portland, Richmond, Toledo, Virginia Beach-Norfolk added counties but not hospitals).

The most significant negative impact (more than a 20-percent decrease) among hospitals currently in an MSA is on those located in counties that become Micropolitan areas or rural areas. Among hospitals with the largest positive impacts (more than a 20-percent increase), the changes appear to be largely due to changes in the counties that are now included (under the CBSAs) in the MSA labor market area.

CHART 2.—IMPACT ON WAGE INDEXES OF NEW MSA, MICROPOLITAN AREAS, AND RURAL LABOR MARKET AREAS

Percent change in area wage index	Number of currently rural hospitals	Number of currently MSA hospitals	Total number of hospitals.
Decrease Greater Than 10.0	99	36	135
Decrease Between 5.0 and 10.0	420	77	497
Decrease Between 2.0 and 5.0	238	95	333
Decrease Between 0 and 02.0	335	585	920
No Change	10	938	948
Increase Between 0 and 2.0	168	495	663
Increase Between 2.0 and 5.0	138	145	283
Increase Between 5.0 and 10.0	203	139	342
Increase Greater Than 10.0	138	35	173
Total	1,749	2,545	4,294

One of the reasons Micropolitan Areas have such a dramatic impact on the wage index is, because Micropolitan Areas encompass smaller populations than MSAs, they tend to include fewer hospitals per Micropolitan Area. Currently, there are only 25 MSAs with one hospital in the MSA. However, under the new definitions, there are 373 Micropolitan Areas with one hospital, and 49 MSAs with only one hospital.

This large number of labor market areas with only one hospital and the increased potential for dramatic shifts in the wage indexes from one year to the next is a problem for several reasons. First, it creates instability in the wage index from year to year for a large number of hospitals. Second, it reduces the averaging effect of the wage index, lessening some of the efficiency incentive inherent in a system based on the average hourly wages for a large number of hospitals. In labor market areas with a single hospital, high wage costs are passed directly into the wage index with no counterbalancing averaging with lower wages paid at nearby competing hospitals. Third, it creates an arguably inequitable system when so many hospitals have wage indexes based solely on their own wages, while other hospitals' wage indexes are based on an average hourly wage across many hospitals.

For these reasons, we are proposing not to adopt Micropolitan Areas as independent labor market areas. Although we considered alternative

approaches that would aggregate Micropolitan Areas in order to reduce the number of one-hospital labor market areas, these approaches created geographically disconnected labor market areas, an undesirable outcome. Therefore, we are proposing to maintain our current policy of defining labor market areas based on the new MSAs (and Divisions, where they exist) using OMB's new criteria and the 2000 Census data.

Chart 3 displays the impacts on hospital wage indexes of this proposed approach. The most apparent difference comparing this chart to Chart 2 is the reduction in the numbers of currently rural hospitals impacted by more than 2.0 percent. Recognizing Micropolitan Areas as independent labor market areas results in negative impacts of more than 2.0 percent for 757 currently rural hospitals, while the comparative number, when recognizing only MSAs, is 256. Conversely, the number of currently rural hospitals positively impacted by more than 2.0 percent declines from 479 to 154.

The greatest negative impacts among hospitals currently designated rural are in Idaho, where the statewide rural wage index falls 6.7 percent as a result of 6 formerly rural hospitals now being included in either new or redefined MSAs. The wage index for rural Utah hospitals declines by 5.7 percent, for similar reasons. Conversely, formerly rural hospitals that are not part of an MSA generally experience positive impacts.

Among hospitals that are currently in MSAs, the number of hospitals with decreases in their wage indexes of at least 10 percent increases under this proposal from 35 to 45. These are primarily hospitals that are now located in Micropolitan Areas that are included in the statewide labor market area. There are 46 counties with 72 hospitals that are currently in an MSA that would be treated as rural under our proposal.

CHART 3.—IMPACT ON WAGE INDEXES OF NEW MSA AND RURAL LABOR MARKET AREAS

Percent change in area wage index	Number of currently rural hospitals	Number of currently MSA hospitals	Total number of hospitals.
Decrease Greater Than 10.0	0	45	45
Decrease Between 5.0 and 10.0	122	60	182
Decrease Between 2.0 and 5.0	134	73	207
Decrease Between 0 and 2.0	588	615	1,203
No Change	160	1,015	1,175
Increase Between 0 and 2.0	591	574	1,165
Increase Between 2.0 and 5.0	32	103	135
Increase Between 5.0 and 10.0	64	25	89
Increase Greater Than 10.0	58	35	93
Total	1,749	2,545	4,294

d. Transition Period

We have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. When we recently removed the wage costs of teaching physicians and residents from the wage index data of teaching hospitals, we spread out the impact over 3 years by blending the hospitals' average hourly wages with and without the data. Similarly, the regulations at § 412.102 provide for a 3-year transition to the standardized amount and DSH adjustment payments to a hospital redesignated from urban to rural.

Given the significant payment impacts upon some hospitals of these changes, we considered options to transition from the current MSAs to the new MSAs. As noted above, the most dramatic negative impacts are among hospitals currently located in an MSA but would become rural under our proposal. Some negative impacts also occur among urban hospitals that remain in MSAs that have been reconfigured. However, these impacts are generally smaller than those among currently urban hospitals that would become rural. To help alleviate the decreased payments for currently urban hospitals that would become rural, we are proposing to allow them to maintain their assignment to the MSA where they are currently located for the 3-year period FY 2005, FY 2006, and FY 2007. Beginning in FY 2008, these hospitals would receive their statewide rural wage index, although they would be eligible to apply for reclassification by the MGCRB, both during this transition period as well as subsequent years.

We also considered the option of allowing a transition to the new MSAs for all hospitals, such as a blend of wage indexes based on the old and new MSAs for some specified period of time. Although this would help some hospitals that are negatively impacted by the changes to the MSAs, it would dampen the payment increases for those hospitals that are positively impacted by the changes. However, we are not proposing a blended transition. We note that OMB in the past has announced MSA changes on an annual basis due to population changes, and we have not transitioned these changes.

C. Proposed Occupational Mix Adjustment to Proposed FY 2005 Index

[If you choose to comment on issues in this section, please include the caption ''Occupational Mix'' at the beginning of your comment.]

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Development of Data for the Occupational Mix Adjustment

In the September 19, 2003 **Federal Register** (68 FR 54905), we published a final notice of intent to collect occupational mix data from hospitals using the Medicare Wage Index Occupational Mix Survey, Form CMS–10079. (The survey and instructions may be accessed at the Web site: *http://cms.hhs.gov/providers/hipps/ippswage.asp.)* The survey requires hospitals to report the number of total paid hours for directly hired and contract employees in occupations that provide the following services: Nursing, physical therapy, occupational therapy, respiratory therapy, medical and clinical laboratory, dietary, and pharmacy. These services each include several standard occupational classifications (SOCs), as defined by the Bureau of Labor Statistics (BLS) on its Occupational Employment Statistics (OES) survey *(http://www.bls.gov/oes/2001/oes_tec.htm)*, that may be used by hospitals in different mixes to provide specific aspects of patient care. CMS decided to use BLS's SOCs to categorize employees for the occupational mix survey in an effort to ease hospitals' reporting burden; most hospitals have had experience with collecting and reporting their employment data according to the SOC definitions. The survey includes a total of 19 SOCs that provide services for the above 7 categories and an ''all other occupations'' category. The hours collected on the survey would be used to determine the proportion of a general service category total that is attributable to each of the category's SOCs, that is, the category's occupational mix.

In order to accurately reflect a hospital's employment, we initially planned to require all hospitals to provide occupational mix data collected from a 1-year period. Several hospitals and their representatives advised us that a 1-year reporting period was feasible because salary and wage data are maintained quarterly for revenue and tax reporting purposes. However, several hospitals expressed concern that their payroll and other personnel accounting systems are typically not set up to collect data on hours for contract employees. The hospitals and their representatives advised us that the approximately 2-month timeframe (*see* dates below) for collecting and submitting the occupational mix data to the fiscal intermediaries would not allow hospitals enough time to develop a year's worth of hours data for contract workers. Therefore, given the short timeframe for collecting the occupational mix data, and to reduce hospitals' reporting burden associated with the initial collection of the data, we decided to allow hospitals the option of providing their hours data for the 19 SOCs either prospectively for a 4-week period beginning on or between December 28, 2003 and January 11, 2004, and ending no later than February 7, 2004, or retrospectively for a 12-month period, that is, calendar year 2003. Although we recognize that using data from only a 4-week period increases our risk of obtaining results that reflect seasonal rather than normal employment trends, we believe that the 4-week prospective reporting period should enable hospitals to plan and provide more accurate data according to our survey instructions and definitions. (*See* the discussion below on the verification and validity of our occupational mix survey results.)

An advance copy of the occupational mix survey was provided to hospitals in mid-December 2003 so that hospitals could begin gathering their data and documentation necessary to complete the survey. The official survey was published as a CMS One-Time Notification (Pub. 100–20, R47OTN) on January 23, 2004. We instructed our fiscal intermediaries to distribute and collect completed occupational mix surveys from any hospital that is subject to IPPS, or any hospital that would be subject to IPPS if not granted a waiver. If a hospital was not an IPPS provider during FY 2001 or, otherwise, did not submit a FY 2001 cost report, the hospital was not required to submit occupational mix data. Consistent with the wage data, CAHs were excluded from the occupational mix survey. In addition, the FY 2005 wage index does not include occupational mix data for hospitals that submitted FY 2001 wage data, but terminated participation in the Medicare program as IPPS providers before calendar year 2003. For such terminated hospitals, there would be no occupational mix data to collect for our survey period.

Hospitals were to submit their completed occupational mix surveys to their fiscal intermediaries by February 16, 2004. Our initial collection of these data was completed by March 1, 2004, the deadline for fiscal intermediaries to submit hospitals' survey data to CMS. We released a public use file containing the data on March 8, 2004 (through the Internet on our Web site at: *http://cms/hhs.gov/providers/hipps/ippswage.asp*. In a memorandum also dated March 8, 2004, we instructed all fiscal intermediaries to inform the IPPS hospitals they service of the availability of the occupational mix data file and the process and timeframe for requesting corrections and revisions. If a hospital wished to request a change to its data as shown in that file, the hospital had to submit the changes to its fiscal intermediary by March 22, 2004. In addition, as this was hospitals' first experience with the occupational mix survey, we provided hospitals another opportunity, if they missed the February 16 filing deadline, to submit their completed surveys. The deadline for this one-time, final opportunity to submit occupational mix data to fiscal intermediaries for the FY 2005 wage index was also March 22, 2004. The final deadline for fiscal intermediaries to submit hospitals' data to CMS was April 16, 2004. (From April 16 until the final rule is published, the process, criteria, and timetable for correcting occupational mix data is the same as for Worksheet S–3 wage data, under Section H.) Occupational mix survey data received by us through March 15, 2004, are used in computing the proposed wage index in this proposed rule. Data received from intermediaries after March 15 through April 16, 2004 will be included in the final rule.

The response rate for the occupational mix survey, as of March 15, 2004, was 89.4 percent. We received occupational mix data from 3,593 hospitals. We expected to receive completed survey data from 4,018 hospitals that submitted cost report wage data for FY 2001 and were still IPPS hospitals during calendar year 2003 or on January 1, 2004. For any hospital that was expected to provide occupational mix data but did not, we are considering using proxy occupational mix data to adjust the hospital's wage data in the final wage index. One option would be to assume that the hospital only has employees in the highest level SOC for each of the general service categories included on the occupational mix survey. Another option would be to assume that such hospitals have the national SOC mix for each general service category. We invite public comment to this proposal. We note that the wage index in this proposed rule does not include proxy data for hospitals that did not complete and submit the occupational mix survey.

As this was the first administration of the occupational mix survey, we did not provide fiscal intermediaries an extensive program for reviewing the hours of data collected. However, hospitals were required to be able to provide any documentation that could be used by the fiscal intermediaries to verify the survey data. In addition, after reviewing the compiled survey data, we contacted fiscal intermediaries to

request corrections from a few hospitals that provided data for reporting periods that were out of range with our specified 12-month or 4-week data collection periods. As the wage index is a relative measure of labor costs across geographic areas, it is important that the data collected from hospitals reflects a common period. We also tested the validity of our occupational mix survey data by comparing our results to those of the 2001 BLS OES survey. As shown in Charts 4 and 5 below, the results of our survey are consistent with the findings of the BLS OES survey.

In addition, to compute the occupational mix adjustment, we collected data on the average hourly rates for the 19 SOCs so that we could derive a weighted average hourly rate for each labor market area. (More details about the occupational mix calculation are included in section III.C.2. of this preamble.) To decrease hospital's reporting burden for this initial collection of the occupational mix data, and to facilitate the timely collection of the data, we did not require hospitals to report data on their total wages or average hourly rates associated with the 19 SOCs. Instead, we used national average hourly rates from the BLS OES *2001 National Industry—Specific Occupational Employment and Wage Estimates, SIC—Hospitals* (accessible at Web site: *http://www.bls.gov/oes/2001/oesi3_806.htm),* as reflected in Chart 4 below.

CHART 4.—BLS NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES FOR HOSPITALS

General service categories	Number of hospital employees	Percent of service category	Percent of total employees	National average hourly wage $
Nursing Services and Medical Assistant Services				
Registered Nurses	1,307,960	68.8	25.88	23.62
Licensed Practical Nurses	194,900	10.2	3.86	14.65
Nursing Aides, Orderlies, & Attendants	351,910	18.5	6.96	10.01
Medical Assistants	47,250	2.5	0.93	11.79
Total	1,902,020	100.0	37.63	
Physical Therapy Services				
Physical Therapists	46,290	61.0	0.92	27.80
Physical Therapist Assistants	17,610	23.2	0.35	17.11
Physical Therapist Aides	12,020	15.8	0.24	10.40
Total	75,920	100.0	1.50	
Occupational Therapy Services				
Occupation Therapists	24,110	75.3	0.48	25.62
Occupation Therapist Assistants	5,690	17.8	0.11	16.81
Occupation Therapist Aides	2,220	6.9	0.04	11.60
Total	32,020	100.0	0.63	
Respiratory Therapy Services				
Respiratory Therapists	68,920	72.8	1.36	19.26
Respiratory Therapy Technicians	25,710	27.2	0.51	16.96
Total	94,630	100.0	1.87	
Pharmacy Services				
Pharmacists	48,630	48.8	0.96	34.58
Pharmacy Technicians	44,270	44.4	0.88	12.30
Pharmacy Assistants/Aides	6,810	6.8	0.13	11.52
Total	99,710	100.0	1.97	
Dietary Services				
Dieticians	16,820	56.4	0.33	20.02
Dietetic Technicians	13,020	43.6	0.26	11.64
Total	29,840	100.0	0.59	
Medical & Clinical Lab Services				
Medical & Clinical Lab Technologists	87,380	57.8	1.73	20.74
Medical & Clinical Lab Technicians	63,900	42.2	1.26	14.90
Total	151,280	100.0	2.99	

CHART 4.—BLS NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES FOR HOSPITALS—Continued

General service categories	Number of hospital employees	Percent of service category	Percent of total employees	National average hourly wage $
Total Nursing, Therapy, Pharmacy, Dietary, and Medical & Clinical Occupations	2,385,420		47.19	
All Other Occupations	2,669,400		52.81	
Total Hospital Employees	5,054,820		100.0	

Source: BLS, OES, 2001 National Industry-Specific Occupational Employment and Wage Estimates, *http://www.bls.gov/oes/2001*

CHART 5.—MEDICARE OCCUPATIONAL MIX SURVEY RESULTS

General Service Categories	Number of employee hours	Percent of service category hours	Percent of total employee hours
Nursing Services and Medical Assistant Services			
Registered Nurses	1,349,683,706.61	70.38	26.23
Licensed Practical Nurses	148,480,984.66	7.74	2.89
Nursing Aides, Orderlies, & Attendants	349,482,222.23	18.22	6.79
Medical Assistants	70,155,219.44	3.66	1.36
Total	1,917,802,132.94	100.00	37.27
Physical Therapy Services			
Physical Therapists	42,728,556.90	60.87	0.83
Physical Therapist Assistants	16,278,842.28	23.19	0.32
Physical Therapist Aides	11,192,122.93	15.94	0.22
Total	70,199,522.11	100.00	1.36
Occupational Therapy Services			
Occupation Therapists	18,016,924.74	76.46	0.35
Occupation Therapist Assistants	3,912,014.51	16.60	0.08
Occupation Therapist Aides	1,635,953.90	6.94	0.03
Total	23,564,893.16	100.00	0.46
Respiratory Therapy Services			
Respiratory Therapists	79,768,909.24	79.96	1.55
Respiratory Therapy Technicians	19,993,236.90	20.04	0.39
Total	99,762,146.14	100.00	1.94
Pharmacy Services			
Pharmacists	52,574,888.83	48.35	1.02
Pharmacy Technicians	51,947,662.82	47.77	1.01
Pharmacy Assistants/Aides	4,219,798.43	3.88	0.08
Total	108,742,350.08	100.00	2.11
Dietary Services			
Dieticians	18,221,465.33	42.23	0.35
Dietetic Technicians	24,929,864.59	57.77	0.48
Total	43,151,329.92	100.00	0.84
Medical & Clinical Lab Services			
Medical & Clinical Lab Technologists	109,938,139.37	52.07	2.14
Medical & Clinical Lab Technicians	101,208,507.21	47.93	1.97
Total	211,146,646.58	100.00	4.10
Total Nursing, Therapy, Pharmacy, Dietary, and Medical & Clinical Occupations	2,474,369,020.92	.....	48.08

CHART 5.—MEDICARE OCCUPATIONAL MIX SURVEY RESULTS—Continued

General Service Categories	Number of employee hours	Percent of service category hours	Percent of total employee hours
All Other Occupations	2,671,751,872.61		51.92
Total Hospital Employees	5,146,120,893.53		100.00

Source: Medicare Wage Index Occupational Mix Survey, Form CMS–10079

2. Proposed Calculation of the Occupational Mix Adjustment Factor and the Proposed Occupational Mix Adjusted Wage Index

The method used to calculate the proposed occupational mix adjusted wage index follows:

Step 1—For each hospital, the percentage of the general service category attributable to an SOC is determined by dividing the SOC hours by the general service category's total hours. Repeat this calculation for each of the 19 SOCs.

Step 2—For each hospital, the weighted average hourly rate for an SOC is determined by multiplying the percentage of the general service category (from Step 1) by the national average hourly rate for that SOC from the 2001 BLS OES survey (*see* Chart 4 above). Repeat this calculation for each of the 19 SOCs.

Step 3—For each hospital, the hospital's adjusted average hourly rate for a general service category is computed by summing the weighted hourly rate for each SOC within the general category. Repeat this calculation for each of the 7 general service categories.

Step 4—For each hospital, the occupational mix adjustment factor for a general service category is calculated by dividing the national adjusted average hourly rate for the category by the hospital's adjusted average hourly rate for the category. (The national adjusted average hourly rate is computed in the same manner as Steps 1 through 3, using instead, the total SOC and general service category hours for all hospitals in the occupational mix survey database.) Repeat this calculation for each of the 7 general service categories. If the hospital's adjusted rate is less than the national adjusted rate (indicating the hospital employs a less costly mix of employees within the category), the occupational mix adjustment factor will be greater than 1.0000. If the hospital's adjusted rate is greater than the national adjusted rate, the occupational mix adjustment factor will be less than 1.0000.

Step 5—For each hospital, the occupational mix adjusted salaries and wage-related costs for a general service category is calculated by multiplying the hospital's total salaries and wage-related costs (from Step 5 of the unadjusted wage index calculation in section F) by the national percentage of total hospital workers attributable to the general service category (from the occupational mix survey data; *see* Chart 5 above) and by the general service category's occupational mix adjustment factor (from Step 4 above). Repeat this calculation for each of the 7 general service categories. The remaining portion of the hospital's total salaries and wage-related costs that is attributable to all other employees of the hospital is not adjusted for occupational mix.

Step 6—For each hospital, the total occupational mix adjusted salaries and wage-related costs for a hospital are calculated by summing the occupational mix adjusted salaries and wage-related costs for the 7 general service categories (from Step 5) and the unadjusted portion of the hospital's salaries and wage-related costs for all other employees. To compute a hospital's occupational mix adjusted average hourly wage, divide the hospital's total occupational mix adjusted salaries and wage-related costs by the hospital's total hours (from Step 4 of the unadjusted wage index calculation in Section F).

Step 7—To compute the occupational mix adjusted average hourly wage for an urban or rural area, sum the total occupational mix adjusted salaries and wage-related costs for all hospitals in the area, then sum the total hours for all hospitals in the area. Next, divide the area's occupational mix adjusted salaries and wage-related costs by the area's hours.

Step 8—To compute the national occupational mix adjusted average hourly wage, sum the total occupational mix adjusted salaries and wage-related costs for all hospitals in the nation, then sum the total hours for all hospitals in the nation. Next, divide the national occupational mix adjusted salaries and wage-related costs by the national hours. The proposed national occupational mix adjusted average hourly wage is 26.2566.

Step 9—To compute the occupational mix adjusted wage index, divide each area's occupational mix adjusted average hourly wage (Step 7) by the proposed national occupational mix adjusted average hourly wage (Step 8).

Step 10—To compute the proposed Puerto Rico specific occupational mix adjusted wage index, follow the Steps 1 through 9 above. The proposed Puerto Rico occupational mix adjusted average hourly wage is 12.2035.

EXAMPLE OF OCCUPATIONAL MIX ADJUSTMENT

General service categories/SOCs	Number of employee hours	Percent of service category hours	Percent of total employee hours	BLS national average hourly wage
NATIONAL—Nursing and Medical Assistant Services				
Registered Nurses	1,349,683,707	70.38	26.23	$23.62.
Licensed Practical Nurses	148,480,985	7.74	2.89	14.65.
Nursing Aides, Orderlies, & Attendants	349,482,222	18.22	6.79	10.01
Medical Assistants	70,155,219	3.66	1.36	11.79 .

EXAMPLE OF OCCUPATIONAL MIX ADJUSTMENT—Continued

General service categories/SOCs	Number of employee hours	Percent of service category hours	Percent of total employee hours	BLS national average hourly wage
Total	1,917,802,133	100.00	37.27	20.01.
Hospital A:				
Registered Nurses	1,642,116	79.84		18.86.
Licensed Practical Nurses	67,860	3.30		0.48.
Nursing Aides, Orderlies, & Attendants	259,177	12.60		1.26
Medical Assistants	87,622	4.26		0.50.
Total	2,056,774	100.00		21.11
Occupational Mix Adjustment				0.9481
Hospital B:				
Registered Nurses	1,510,724	64.44		0.31
Licensed Practical Nurses	159,795	6.82		0.09
Nursing Aides, Orderlies, & Attendants	391,201	16.69		0.08
Medical Assistants	282,728	12.06		2.55
Total	2,344,449	100.00		19.31
Occupational Mix Adjustment				1.0362
NATIONAL—Physical Therapy Services				
Physical Therapists	42,728,557	60.87	0.83	27.80
Physical Therapist Assistants	16,278,842	23.19	0.32	17.11
Physical Therapist Aides	11,192,123	15.94	0.22	10.40
Total	70,199,522	100.00	1.36	22.55
Hospital A:				
Physical Therapists	94,987	61.40		17.07
Physical Therapist Assistants	36,254	23.43		4.01
Physical Therapist Aides	23,460	15.16		1.58
Total	154,701	100.00		22.66
Occupational Mix Adjustment				0.9953
Hospital B:				
Physical Therapists	60,337	57.37		15.95
Physical Therapist Assistants	22,391	21.29		3.64
Physical Therapist Aides	22,444	21.34		2.22
Total	105,173	100.00		21.81
Occupational Mix Adjustment				1.0339
NATIONAL—Occupational Therapy Services				
Occupation Therapists	18,016,925	76.46	0.35	25.62
Occupation Therapist Assistants	3,912,015	16.60	0.08	16.81
Occupation Therapist Aides	1,635,954	6.94	0.03	11.60
Total	23,564,893	100.00	0.46	23.18.
Hospital A:				
Occupation Therapists	40,366	90.06		23.07
Occupation Therapist Assistants	0	0.00		0.00
Occupation Therapist Aides	4,454	9.94		1.15
Total	44,820	100.00		24.23
Occupational Mix Adjustment				0.9568
Hospital B:				
Occupation Therapists	26,547	79.48		20.36
Occupation Therapist Assistants	1,610	4.82		0.81
Occupation Therapist Aides	5,242	15.70		1.82
Total	33,399	100.00		22.99
Occupational Mix Adjustment				1.0081
NATIONAL—Respiratory Therapy Services				
Respiratory Therapists	79,768,909	79.96	1.55	19.26
Respiratory Therapy Technicians	19,993,237	20.04	0.39	16.96
Total	99,762,146	100.00	1.94	18.80

EXAMPLE OF OCCUPATIONAL MIX ADJUSTMENT—Continued

General service categories/SOCs	Number of employee hours	Percent of service category hours	Percent of total employee hours	BLS national average hourly wage
Hospital A:				
Respiratory Therapists	75,339	97.40	.....	18.76
Respiratory Therapy Technicians	2,008	2.60	.....	0.44
Total	77,347	100.00	.....	19.20
Occupational Mix Adjustment	.....	.....	.....	0.9792
Hospital B:				
Respiratory Therapists	73,592	65.62	.....	12.64
Respiratory Therapy Technicians	38,549	34.38	.....	5.83
Total	112,141	100.00	.....	18.47
Occupational Mix Adjustment	.....	.....	.....	1.0179
NATIONAL—Pharmacy Services				
Pharmacists	52,574,889	48.35	1.02	34.58
Pharmacy Technicians	51,947,663	47.77	1.01	12.30
Pharmacy Assistants/Aides	4,219,798	3.88	0.08	11.52
Total	108,742,350	100.00	2.11	23.04
Hospital A:				
Pharmacists	65,863	48.65	.....	16.82
Pharmacy Technicians	69,525	51.35	.....	6.32
Pharmacy Assistants/Aides	0	0.00	.....	0.00
Total	135,388	100.00	.....	23.14
Occupational Mix Adjustment	.....	.....	.....	0.9957
Hospital B:				
Pharmacists	45,856	39.23	.....	13.57
Pharmacy Technicians	64,986	55.60	.....	6.84
Pharmacy Assistants/Aides	6,039	5.17	.....	0.60
Total	116,881	100.00	.....	21.00
Occupational Mix Adjustment	.....	.....	.....	1.0971
NATIONAL—Dietary Services				
Dieticians	18,221,465	42.23	0.35	20.02
Dietetic Technicians	24,929,865	57.77	0.48	11.64
Total	43,151,330	100.00	0.84	15.18
Hospital A:				
Dieticians	13,943	100.00	.....	20.02
Dietetic Technicians	0	0.00	.....	0.00
Total	13,943	100.00	.....	20.02
Occupational Mix Adjustment	.....	.....	.....	0.7582
Hospital B:				
Dieticians	27,458	16.29	.....	3.26
Dietetic Technicians	141,148	83.71	.....	9.74
Total	168,606	100.00	.....	13.00
Occupational Mix Adjustment	.....	.....	.....	1.1676
NATIONAL—Medical & Clinical Lab Services				
Medical & Clinical Lab Technologists	109,938,139	52.07	2.14	20.74
Medical & Clinical Lab Technicians	101,208,507	47.93	1.97	14.90.
Total	211,146,647	100.00	4.10	17.94
Hospital A:				
Medical & Clinical Lab Technologists	166,522	90.82	.....	18.84
Medical & Clinical Lab Technicians	16,841	9.18	.....	1.37
Total	183,363	100.00	.....	20.20
Occupational Mix Adjustment	.....	.....	.....	0.8880
Hospital B:				
Medical & Clinical Lab Technologists	295,516	47.34	.....	9.82
Medical & Clinical Lab Technicians	328,716	52.66	.....	7.85

EXAMPLE OF OCCUPATIONAL MIX ADJUSTMENT—Continued

General service categories/SOCs	Number of employee hours	Percent of service category hours	Percent of total employee hours	BLS national average hourly wage
Total	624,232	100.00		17.66
Occupational Mix Adjustment				1.0156
Total Nursing, Therapy, Pharmacy, Dietary, and Medical & Clinical Occupations	2,474,369,021		48.08	
All Other Occupations	2,671,751,873		51.92	
Total Hospital Employees	5,146,120,894		100.00	

In implementing an occupational mix adjusted wage index based on the above calculation, the wage index values for 18 rural areas (36.7 percent) and 166 urban areas (51.2 percent) would decrease as a result of the adjustment. Nine (9) rural areas (18.4 percent) and 89 urban areas (27.5 percent) would experience a decrease of 1 percent or greater in their wage index values. The largest negative impact for a rural area would be 2.2 percent and for an urban area, 4.5 percent. Meanwhile, 31 rural areas (63.3 percent) and 158 urban areas (48.8 percent) would experience an increase in their wage index values. Although these results show that rural hospitals would gain the most from an occupational mix adjustment to the wage index, their gains may not be as great as might have been expected. Further, it might not have been anticipated that over one-third of rural hospitals would actually fare worse under the adjustment. Overall, a fully implemented occupational mix adjusted wage index would have a redistributive effect on Medicare payments to hospitals.

D. Worksheet S–3 Wage Data for the Proposed FY 2005 Wage Index Update

[If you choose to comment on issues in this section, please include the caption ''Wage Data'' at the beginning of your comment.]

The proposed FY 2005 wage index values (effective for hospital discharges occurring on or after October 1, 2004 and before October 1, 2005) in section VI. of the Addendum to this proposed rule are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2001 (the FY 2004 wage index was based on FY 2000 wage data).

The proposed FY 2005 wage index includes the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty).
- Home office costs and hours.
- Certain contract labor costs and hours (which includes direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services).
- Wage-related costs (The September 1, 1994 **Federal Register** included a list of core wage-related costs that are included in the wage index, and discussed criteria for including other wage-related costs (59 FR 45356)).

Consistent with the wage index methodology for FY 2004, the proposed wage index for FY 2005 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as SNF services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2005 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours and wage-related costs of CAHs are excluded from the wage index, for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397).

Data collected for the IPPS wage index are also currently used to calculate wage indexes applicable to other providers, such as SNFs, home health agencies, and hospices. In addition, they are used for prospective payments to rehabilitation, psychiatric, and long-term care hospitals, and for hospital outpatient services.

E. Verification of Worksheet S–3 Wage Data

[If you choose to comment on issues in this section, please include the caption ''Wage Data'' at the beginning of your comment.]

The wage data for the proposed FY 2005 wage index were obtained from Worksheet S–3, Parts II and III of the FY 2001 Medicare cost reports. Instructions for completing the Worksheet S–3, Parts II and III are in the Provider Reimbursement Manual, Part I, sections 3605.2 and 3605.3. The data file used to construct the proposed wage index includes FY 2001 data submitted to us as of March 15, 2004. As in past years, we performed an intensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our fiscal intermediaries to revise or verify data elements that resulted in specific edit failures. Some unresolved data elements are included in the calculation of the proposed FY 2005 wage index, pending their resolution before calculation of the final FY 2005 index. We instructed the fiscal intermediaries to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than April 16, 2004. 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.

In addition, as part of our editing process, we removed data for 222 hospitals from our database: 147 hospitals became critical access hospitals by the time we published the February public use file, and 75 hospitals were low Medicare utilization hospitals or failed edits that could not be corrected because the hospitals terminated the program or changed ownership. In addition, we removed the wage data for 15 hospitals with incomplete or inaccurate data resulting in zero or negative, or otherwise aberrant, average hourly wages. We have notified the fiscal intermediaries of these hospitals and will continue to work with the fiscal intermediaries to correct these data until we finalize our database to compute the final wage index. As a result, the proposed FY 2005 wage index is calculated based on FY 2001 wage data for 3,954 hospitals.

In constructing the proposed FY 2005 wage index, we include the wage data for facilities that were IPPS hospitals in FY 2001, even for those facilities that have terminated their participation in the program as hospitals, as long as those data do not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period. However, we exclude the wage data for CAHs (as discussed in 68 FR 45397). The proposed wage index in this proposed rule excludes hospitals that are designated as CAHs by February 24, 2004, the date of the latest available Medicare CAH listing at the time we released the proposed wage index public use file on February 27, 2004.

F. Computation of the Unadjusted Wage Index

[If you choose to comment on issues in this section, please include the caption ''Wage Index'' at the beginning of your comment.]

The method used to compute the proposed FY 2005 wage index without an occupational mix adjustment follows:

Step 1—As noted above, we based the proposed FY 2005 wage index on wage data reported on the FY 2001 Medicare cost reports. We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period beginning on or after October 1, 2000 and before October 1, 2001. In addition, we included data from some hospitals that had cost reporting periods beginning before October 2000 and reported a cost reporting period covering all of FY 2001. These data were included because no other data from these hospitals would be available for the cost reporting period described above, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2001 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2001 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2000 and before October 1, 2001), we included wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2—Salaries—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. In calculating a hospital's average salaries plus wage-related costs, we subtracted from Line 1 (total salaries) the GME and CRNA costs reported on lines 2, 4.01, 6, and 6.01, the Part B salaries reported on Lines 3, 5 and 5.01, home office salaries reported on Line 7, and excluded salaries reported on Lines 8 and 8.01 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtracted from Line 1 the salaries for which no hours were reported. To determine total salaries plus wage-related costs, we added to the net hospital salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 9 and 10), home office salaries and wage-related costs reported by the hospital on Lines 11 and 12, and nonexcluded area wage-related costs (Lines 13, 14, and 18).

We note that contract labor and home office salaries for which no corresponding hours are reported were not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 18) are excluded if no corresponding salaries are reported for those employees on Line 4.

Step 3—Hours—With the exception of wage-related costs, for which there are no associated hours, we computed total hours using the same methods as described for salaries in Step 2.

Step 4—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocated overhead costs to areas of the hospital excluded from the wage index calculation. First, we determined the ratio of excluded area hours (sum of Lines 8 and 8.01 of Worksheet S–3, Part II) to revised total hours (Line 1 minus the sum of Part II, Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, and Part III, Line 13 of Worksheet S–3). We then computed the amounts of overhead salaries and hours to be allocated to excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Line 13 of Worksheet S–3, Part III. Next, we computed the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determined the ratio of overhead hours (Part III, Line 13) to revised hours (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, and 7); (2) we computed overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 13, 14, and 18; and (3) we multiplied the computed overhead wage-related costs by the above excluded area hours ratio. Finally, we subtracted the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5—For each hospital, we adjusted the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimated the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2000 through April 15, 2002 for private industry hospital workers from the Bureau of Labor Statistics' *Compensation and Working Conditions.* We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated below.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor.
10/14/2000	11/15/2000	1.07771
11/14/2000	12/15/2000	1.07273
12/14/2000	1/15/2001	1.06767
01/14/2001	02/15/2001	1.06245
02/14/2001	03/15/2001	1.05706
03/14/2001	04/15/2001	1.05168
04/14/2001	05/15/2001	1.04645
05/14/2001	06/15/2001	1.04139
06/14/2001	07/15/2001	1.03638
07/14/2001	08/15/2001	1.03134
08/14/2001	09/15/2001	1.02627
09/14/2001	10/15/2001	1.02133
10/14/2001	11/15/2001	1.01665
11/14/2001	12/15/2001	1.01224
12/14/2001	01/15/2002	1.00803
01/14/2002	02/15/2002	1.00395
02/14/2002	03/15/2002	1.00000
03/14/2002	04/15/2002	0.99610

For example, the midpoint of a cost reporting period beginning January 1, 2001 and ending December 31, 2001 is June 30, 2001. An adjustment factor of 1.03638 would be applied to the wages of a hospital with such a cost reporting period. In addition, for the data for any

cost reporting period that began in FY 2001 and covered a period of less than 360 days or more than 370 days, we annualized the data to reflect a 1-year cost report. Dividing the data by the number of days in the cost report and then multiplying the results by 365 accomplish annualization.

Step 6—Each hospital was assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B) or section 1886(d)(10) of the Act. Within each urban or rural labor market area, we added the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7—We divided the total adjusted salaries plus wage-related costs obtained under both methods in Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8—We added the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the nation and then divided the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage. Using the data as described above, the proposed national average hourly wage is $26.2939.

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 proposed average hourly wage of 12.2038 for Puerto Rico. For each labor market area in Puerto Rico, we calculated the Puerto Rico-specific wage index value by dividing the area average hourly wage (as calculated in Step 7) by the overall Puerto Rico average hourly wage.

Step 11—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. Furthermore, this wage index floor is to be implemented in such a manner as to ensure that aggregate IPPS payments are not greater or less than those that would have been made in the year if this section did not apply. For FY 2005, this change affects 195 hospitals in 51 MSAs. The MSAs affected by this provision are identified by a footnote in Table 4A in the Addendum of this proposed rule.

G. Computation of the Proposed FY 2005 Blended Wage Index

[If you choose to comment on issues in this section, please include the caption ''Wage Index'' at the beginning of your comment.]

For the FY 2005 wage index, we are proposing a blend of the occupational mix adjusted wage index and the unadjusted wage index, in order to minimize the redistributive impact of the occupational mix adjustment (as discussed in section III.C.2. of this preamble) for the first year of its implementation. Specifically, we are proposing to base the FY 2005 wage index on a blend of 10 percent of an average hourly wage, adjusted for occupational mix, and 90 percent of an average hourly wage, unadjusted for occupational mix. Using this blend, the national average hourly wage is 26.2902 and the Puerto Rico specific average hourly wage is 12.2038. We chose this blend for FY 2005 in recognition that this was the first time, for the administration of the occupational mix survey, hospitals had a short timeframe for collecting their occupational mix survey data and documentation, and we could not collect optimum data (that is, wages and hours data from a 1-year period for all hospitals) within the mandatory timeframe for implementing the adjustment, and we had no baseline data to use in developing a desk review program that could ensure the accuracy of the occupational mix survey data.

In addition, we are moving cautiously with implementing the occupational mix adjustment in recognition of changing trends in the hiring of nurses, the largest group in our survey. Since the enactment of section 304(c) of Public Law 106–554, the law requiring the occupational mix adjustment to the wage index, some States have implemented laws that establish floors on the minimum level of registered nurse staffing that hospitals must maintain in order to continue to be licensed and certified by the State. In addition, some rural areas that are facing a shortage of physicians may be hiring more registered nurses as extenders or substitutes for physicians. Such trends may explain why the occupational mix impacts in section III.C.2. of this preamble are not as expected for rural areas in particular.

Further, we are proposing this blend because, although we want to minimize the immediate impact of the occupational mix adjustment on hospitals' wage index values, we do not want to nullify the value and intent of the occupational mix adjustment. We believe that the blended wage index we are proposing satisfies both of these goals. With only 10 percent of the wage index adjusted for occupational mix, the wage index values for 17 rural areas (34.7 percent) and 159 urban areas (49.1 percent) would decrease as a result of the adjustment. However, the decreases would be minimum; the largest negative impact for a rural area would be only 0.22 percent and for an urban area, 0.45 percent. Conversely, 32 rural areas (65.3 percent) and 165 urban areas (50.9 percent) would benefit from this adjustment, but each area's gain would be less than 1 percent. Overall, a wage index that has only 10 percent of the salaries adjusted for occupational mix would have a minimal redistributive effect on Medicare payments to hospitals. (See Appendix A to this proposed rule for further analyses of the impact of the proposed occupational mix adjustment on the FY 2005 wage index.)

The wage index values in Tables 4A, 4B, 4C, 4F, 4G, and 4H and the average hourly wages in Tables 2, 3A, and 3B in the Addendum to this proposed rule include the occupational mix adjustment as proposed. We note that, although we are proposing a blended wage index for FY 2005, at this time we are not proposing an incremental phase-in of the occupational mix adjustment beyond FY 2005. The application of the occupational mix adjustment beyond FY 2005 will be determined and discussed in subsequent IPPS updates.

H. Proposed Revisions to the Wage Index Based on Hospital Redesignation

[If you choose to comment on issues in this section, please include the caption ''Hospital Redesignations'' at the beginning of your comment.]

1. General

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify by September 1 of the year preceding the year during which reclassification is sought.

Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassification to become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in §§ 412.230 through 412.280.

Section 1886(d)(10)(D)(v) of the Act provides that, beginning with FY 2001, a MGCRB decision on a hospital reclassification for purposes of the wage index is effective for 3 fiscal years, unless the hospital elects to terminate the reclassification. Section 1886(d)(10)(D)(vi) of the Act provides that the MGCRB must use the 3 most recent years' average hourly wage data in evaluating a hospital's reclassification application for FY 2003 and any succeeding fiscal year.

Section 304(b) of Public Law 106–554 provides that the Secretary must establish a mechanism under which a statewide entity may apply to have all of the geographic areas in the State treated as a single geographic area for purposes of computing and applying a single wage index, for reclassifications beginning in FY 2003. The implementing regulations for this provision are located at § 412.235.

Section 1886(d)(8)(B) of the Act requires the Secretary to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the MSA to which the greatest number of workers in the county commute if: The rural county would otherwise be considered part of an urban area under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of *all* contiguous MSAs. In light of the new CBSA definitions and the Census 2000 data, we undertook to identify those counties meeting these criteria. The eligible counties are identified below, as well as a discussion of counties that no longer meet the criteria under this provision.

2. Effects of Reclassification

Section 1886(d)(8)(C) of the Act provides that the application of the wage index to redesignated hospitals is dependent on the hypothetical impact that the wage data from these hospitals would have on the wage index value for the area to which they have been redesignated. These requirements for determining the wage index values for redesignated hospitals is applicable both to the hospitals located in rural counties deemed urban under section 1886(d)(8)(B) of the Act and hospitals that were reclassified as a result of the MGCRB decisions under section 1886(d)(10) of the Act. Therefore, as provided in section 1886(d)(8)(C) of the Act,[4] the wage index values were determined by considering the following:

- If including the wage data for the redesignated hospitals would reduce the wage index value for the area to which the hospitals are redesignated by 1 percentage point or less, the area wage index value determined exclusive of the wage data for the redesignated hospitals applies to the redesignated hospitals.
- If including the wage data for the redesignated hospitals reduces the wage index value for the area to which the hospitals are redesignated by more than 1 percentage point, the area wage index determined inclusive of the wage data for the redesignated hospitals (the combined wage index value) applies to the redesignated hospitals.
- If including the wage data for the redesignated hospitals increases the wage index value for the urban area to which the hospitals are redesignated, both the area and the redesignated hospitals receive the combined wage index value. Otherwise, the hospitals located in the urban area receive a wage index excluding the wage data of hospitals redesignated into the area.
- The wage data for a reclassified urban hospital is included in both the wage index calculation of the area to which the hospital is reclassified (subject to the rules described above) and the wage index calculation of the urban area where the hospital is physically located.
- Rural areas whose wage index values would be reduced by excluding the wage data for hospitals that have been redesignated to another area continue to have their wage index values calculated as if no redesignation had occurred (otherwise, redesignated rural hospitals are excluded from the calculation of the rural wage index).
- The wage index value for a redesignated rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located.

3. FY 2005 Issues

Recent policies and decisions that will affect hospitals' geographic classifications for FY 2005 are discussed below. First, we describe decisions by the MGCRB on applications received in accordance with the ongoing reclassification process described in the regulations at §§ 412.230 through 412.280. Second, we describe the implications for reclassification decisions by the MGCRB to be effective during FY 2005 of our proposal to adopt new MSA definitions for the FY 2005 wage index. Third, we discuss the new counties identified under the standards at section 1886(d)(8)(B) of the Act, based on the new CBSAs and the Census 2000 data. Fourth, we discuss the interactions of these changes with reclassifications approved under the one-time appeal process for hospital wage index reclassifications at section 508 of Public Law 108–173. Fifth, we discuss our proposed implementation of section 505 of Public Law 108–173. Under this provision, the Secretary must establish a new process, similar to the current wage index reclassification process, to make adjustments to the hospital wage index, based on commuting patterns of hospital employees.

a. FY 2005 MGCRB Reclassifications

In the August 1, 2003 IPPS final rule, we indicated that hospitals submitting applications for reclassification by the MGCRB for FY 2005 should base those applications on the current (for Medicare payment purposes) MSAs (68 FR 45401). At the time this proposed rule was constructed, the MGCRB had completed its review of FY 2005 reclassification requests. There were 339 hospitals approved for wage index reclassifications by the MGCRB for FY 2005. Because MGCRB wage index reclassifications are effective for 3 years, hospitals reclassified during FY 2003 or FY 2004 are eligible to continue to be reclassified based on prior reclassifications to current MSAs during FY 2005. There were 55 hospitals reclassified for wage index in FY 2003 and 102 hospitals reclassified for wage index in FY 2004.

In the past, hospitals have been able to apply to be reclassified for purposes of either the wage index or the standardized amount. Existing regulations at § 412.230(a)(5)(ii) state

[4] 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 186(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.

that, after 2002, a hospital may not be reclassified for purposes of the standardized amount if the area to which the hospital seeks reclassification does not have a higher standardized amount than the standardized amount the hospital currently receives. Standardized amount reclassifications are only effective for 1 year, so hospitals must reapply every year. At the time the FY 2005 reclassification applications were due, hospitals applied on the basis that the law still provided for a higher standardized amount for hospitals in large urban areas. However, section 401 of Public Law 108–173 established that all hospitals would be paid on the basis of the large urban standardized amount beginning with FY 2004. Consequently, all hospitals will be paid on the basis of the same standardized amount, which effectively makes standardized amount reclassifications moot, at least for purposes of the standardized amount. As a result, the MGCRB denied all applications for standardized amount reclassifications for FY 2005. In light of the fact that all hospitals are now paid on the basis of the same standardized amount, we are proposing to eliminate standardized amount reclassifications (a discussion appears under section IV.C. of this preamble). Although there could still be some benefit in terms of payments for some hospitals under the DSH adjustment for operating IPPS, section 402 of Public Law 108–173 equalized DSH payments for rural and urban hospitals, with the exception that the rural DSH adjustment is capped at 12 percent (except that rural referral centers have no cap) (a detailed discussion appears in section IV.H. of this preamble).

b. Implementation of New MSAs

As discussed above, we are proposing to implement the new CBSAs for FY 2005. Under these new CBSAs definitions, many existing MSAs are reconfigured. Therefore, because hospitals applied for reclassification during FY 2005 on the basis of the MSAs currently used to define labor market areas for FY 2004, the definition of the MSA to which they have been reclassified, or the area where they are located, may have changed under our proposed implementation. Hospitals that have been reclassified for FY 2005 should verify that the reclassified wage index for the labor market area into which they have been reclassified (in Table 4C or 4D in the Addendum to this proposed rule) exceeds the wage index of the labor market area where they are located (in Table 4A or 4B in the Addendum of this proposed rule) after our proposed implementation of the new MSAs. Hospitals may withdraw their FY 2005 reclassifications within 45 days of the publication of this proposed rule.

In some cases, the new CBSA definitions result in previously existing MSAs being divided into two or more separate MSAs. In these situations, we are proposing to assign the hospital to the nearest county in the current MSA, and the hospital's FY 2005 reclassification would be to the new MSA (under the CBSA definitions) that includes that county to which it has been assigned.

For example, the Ann Arbor, MI MSA currently includes the counties of Lenawee, MI; Livingston, MI; and Washtenaw, MI. Under the new CBSA definitions, the Ann Arbor, MI MSA is comprised solely of the county of Washtenaw, MI. Lenawee, MI now comprises the Adrian, MI Micropolitan Area, and Livingston, MI is now in the Warren-Farmington Hills-Troy, MI Metropolitan Division of Detroit. Therefore, a hospital that was reclassified by the MGCRB into Ann Arbor for either FY 2003, FY 2004, or FY 2005, would be assigned to either the Ann Arbor, MI MSA or the Warren-Farmington Hills-Troy, MI Metropolitan Division, depending on whether the hospital was closer to Washtenaw or Livingston (a reclassified hospital located closest to Lenawee County would be assigned to the Ann Arbor MSA, based on Lenawee County's prior inclusion in this MSA).

Reclassified hospitals that have been assigned to a new MSA on this proposed basis are identified in Table 9 in the Addendum of this proposed rule by the identification of the county used to designate them. We have determined the hospital is in closest proximity to the county listed based on mapping data available to us at the time of the preparation of this proposed rule. Hospitals that disagree with our determination of the closest proximate county on which to assign them to a new MSA must submit a comment (as specified under the ''Comment Period'' and **ADDRESSES** sections at the beginning of this proposed rule) indicating the basis for their disagreement. Changes to a hospital's MSA assignment on the basis of a hospital's disagreement will be announced in the final rule.

c. Redesignations Under Section 1886(d)(8)(B) of the Act

Beginning October 1, 1988, section 1886(d)(8)(B) of the Act required us to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the MSA to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area under the standards published in the **Federal Register** on January 3, 1980 (45 FR 956) for designating MSAs (and for designating NECMAs), and if the commuting rates used in determining outlying counties (or, for New England, similar recognized areas) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous MSAs (or NECMAs). Hospitals that met the criteria using the January 3, 1980 version of these OMB standards were deemed urban for purposes of the standardized amounts and for purposes of assigning the wage data index.

Section 402 of Public Law 106–113 provides that, with respect to FYs 2001 and 2002, a hospital may elect to have the 1990 standards applied to it for purposes of section 1886(d)(8)(B) of the Act and that, beginning with FY 2003, hospitals will be required to use the standards published in the **Federal Register** by the Director of OMB based on the most recent decennial census. We implemented section 402 in the August 1, 2001 **Federal Register** (66 FR 39868). However, at that time, updated standards based on the Census 2000 data were not available.

We have used OMB's 2000 CBSA standards and the Census 2000 data to identify counties qualifying under section 1886(d)(8)(B) of the Act for FY 2005. The number of qualifying counties, shown in the following chart, increases from 28 to 97. On the basis of the evaluation of these data, we are proposing that, effective for discharges on or after October 1, 2004, hospitals located in the rural counties listed in the first column of the following table will be redesignated for purposes of assigning the wage index to the urban area listed in the second column.

CHART 6.—COUNTIES REDESIGNATED AS URBAN UNDER SECTION 1886(D)(8)(B) OF THE ACT

[Based on CBSAs and Census 2000 Data]

Rural county	MSA.
Cherokee, AL	Rome, GA.
Macon, AL	Auburn, AL.
Talladega, AL	Anniston, AL.
Hot Spring, AR	Hot Spring, AR.
Litchfield, CT	Hartford, CT.
Windham, CT	Hartford, CT.
Bradford, FL	Gainesville, FL.
Flagler, FL	Deltona-Daytona Beach-Ormond Beach, FL.
Hendry, FL	Miami, FL.
Levy, FL	Gainesville, FL.
Walton, FL	Ft. Walton Beach, FL.
Banks, GA	Gainesville, FL.
Chattooga, GA	Chattanooga, TN–GA.
Jackson, GA	Atlanta, GA.
Lumpkin, GA	Atlanta, GA.
Morgan, GA	Atlanta, GA.
Peach, GA	Macon, GA.
Polk, GA	Atlanta, GA.
Talbot, GA	Columbus, GA–AL.
Bingham, ID	Idaho Falls, ID.
Christian, IL	Springfield, IL.
DeWitt, IL	Bloomington-Normal, IL.
Iroquois, IL	Kankakee, IL.
Logan, IL	Springfield, IL.
Mason, IL	Peoria, IL.
Ogle, IL	Rockford, IL.
Clinton, IN	Lafayette, IN.
Henry, IN	Indianapolis, IN.
Spencer, IN	Evansville, IN–KY.
Starke, IN	Chicago, IL–IN.
Warren, IN	Lafayette, IN.
Boone, IA	Ames, IA.
Buchanan, IA	Waterloo, IA.
Cedar, IA	Iowa City, IA.
Allen, KY	Bowling Green, KY.
Assumption Parish, LA	Baton Rouge, LA.
St. James Parish, LA	Baton Rouge, LA.
Allegan, MI	Holland, MI.
Montcalm, MI	Grand Rapids, MI.
Oceana, MI	Muskegon, MI.
Shiawassee, MI	Lansing, MI.
Tuscola, MI	Saginaw, MI.
Fillmore, MN	Rochester, MN.
Dade, MO	Springfield, MO.
Pearl River, MS	Biloxi-Gulfport, MS.
Caswell, NC	Burlington, NC.
Granville, NC	Durham, NC.
Harnett, NC	Raleigh, NC.
Lincoln, NC	Charlotte NC–SC.
Polk, NC	Spartanburg, NC.
Los Alamos, NM	Sante Fe, NM.
Lyon, NV	Carson City, NV.
Cayuga, NY	Syracuse, NY.
Columbia, NY	Albany, NY.
Genesee, NY	Rochester, NY.
Greene, NY	Albany, NY.
Schuyler, NY	Ithaca, NY.
Sullivan, NY	Poughkeepsie-Newburgh, NY.
Wyoming, NY	Buffalo, NY.
Ashtabula, OH	Cleveland, OH.
Champaign, OH	Springfield, OH.
Columbiana, OH	Youngstown, OH–PA.
Cotton, OK	Lawton, OK.
Linn, OR	Corvalis, OR.
Adams, PA	York, PA.
Clinton, PA	Williamsport, PA.
Greene, PA	Pittsburgh, PA.
Monroe, PA	New York-Newark, NY–NJ–CT.
Schuylkill, PA	Reading, PA.
Susquehanna, PA	Binghamton, NY–PA.

CHART 6.—COUNTIES REDESIGNATED AS URBAN UNDER SECTION 1886(D)(8)(B) OF THE ACT—Continued

[Based on CBSAs and Census 2000 Data]

Rural county	MSA.
Clarendon, SC	Sumter, SC.
Lee, SC	Sumter, SC.
Oconee, SC	Greenville, SC.
Union, SC	Spartanburg, SC.
Meigs, TN	Cleveland, TN.
Bosque, TX	Waco, TX.
Falls, TX	Waco, TX.
Fannin, TX	Dallas-Fort Worth-Arlington, TX.
Grimes, TX	College Station-Bryan, TX.
Harrison, TX	Longview, TX.
Henderson, TX	Dallas-Fort Worth-Arlington, TX.
Milam, TX	Austin, TX.
Van Zandt, TX	Dallas-Fort Worth-Arlington, TX.
Willacy, TX	Brownsville, TX.
Buckingham, VA	Charlottesville, VA.
Floyd, VA	Blacksburg, VA.
Middlesex, VA	Virginia Beach, VA.
Page, VA	Harrisonburg, VA.
Shenandoah, VA	Winchester, VA.
Island, WA	Seattle, WA.
Mason, WA	Olympia-Lacey, WA.
Wahkiakum, WA	Longview, WA–OR.
Jackson, WV	Charleston, WV.
Roane, WV	Charleston, WV.
Green, WI	Madison, WI.
Green Lake, WI	Fond du Lac, WI.
Jefferson, WI	Milwaukee, WI.
Walworth, WI	Chicago, IL–IN.

As in the past, hospitals redesignated under section 1886(d)(8)(B) of the Act are also eligible to be reclassified to a different area by the MGCRB. Affected hospitals should compare the reclassified wage index for the labor market area in Table 4C or 4D in the Addendum of this proposed rule into which they have been reclassified by the MGCRB to the wage index for the area to which they are redesignated under section 1886(d)(8)(B) of the Act. Hospitals may withdraw from an MGCRB reclassification within 45 days of the publication of this proposed rule.

When we apply the OMB 2000 CBSA standards, 16 rural counties no longer meet the qualifying criteria, either because they are now included in a metropolitan area (with the exception of Barry, MI and Cass, MI, most of the counties are now in the metropolitan area in which they were grouped in accordance with section 402) or they fail to meet the 25-percent cumulative out-migration threshold when we apply the new OMB standards. Counties that are now identified as metropolitan are:

Chilton, AL
Macoupin, IL
Piatt, IL
Brown, IN
Carroll, IN
Jefferson, KS
Barry, MI
Cass, MI
Ionia, MI
Hartnett, NC
Preble, PA

Counties that failed to meet the 25-percent threshold are: Marshall, AL; Putnam, FL; Wilson, NC; Van Wert, OH; and Lawrence, PA.

d. Reclassifications Under Section 508 of Public Law 108–173

Under section 508 of Public Law 108–173, a qualifying hospital may appeal the wage index classification otherwise applicable to the hospital and apply for reclassification to another area of the State in which the hospital is located (or, at the discretion of the Secretary, to an area within a contiguous State). Hospitals were required to submit their applications by February 15, 2004. We implemented this process through notices published in the **Federal Register** on January 6, 2004 (69 FR 661) and February 13, 2004 (69 FR 7340). Such reclassifications are applicable to discharges occurring during the 3-year period beginning April 1, 2004 and ending March 31, 2007. Under section 508(b), reclassifications under this process do not affect the wage index computation for any area or for any other hospital and cannot be effected in a budget neutral manner.

The applications submitted under this process were reviewed and decided upon by the MGCRB. The MGCRB issued notifications of its decisions on April 16, 2004. Reclassifications under this one-time appeal process interact with: FY 2005 MGCRB reclassification decisions under the ongoing reclassification process described in the regulations at §§ 412.230 through 412.280; the proposed implementation of the new MSA definitions; and the new redesignations under section 1886(d)(8)(B) of the Act.

In the notices implementing this process, we indicated that, with limited exceptions, hospitals eligible for reclassification under section 508 of Public Law 108–173 are not otherwise reclassified, effective for discharges on or after October 1, 2004. Therefore, aside from the exceptions specified in the notices, hospitals reclassified under this one-time appeal process are not otherwise reclassified by the MGCRB for FY 2005. For those hospitals that were exempted from this requirement and that were granted reclassification under this one-time appeal process, the reclassification under the one-time appeal process takes precedence over any other MGCRB reclassification. We show the reclassifications effective under the one-time appeal process in Table 9B, in the Addendum to this proposed rule.

With regard to the proposed implementation of the new MSAs, we are proposing to apply the reclassified

wage indexes on the basis of the new MSAs. Hospitals reclassified under the one-time appeal process may terminate their reclassifications that would otherwise be effective on or after October 1, 2004, under the normal termination and withdrawal process at § 412.273 (these reclassifications may not be terminated prior to October 1, 2004). Table 9B in the Addendum to this proposed rule shows the areas to which hospitals have been reclassified under the one-time appeal process. Therefore, similar to other hospitals reclassified by the MGCRB under the ongoing reclassification process for FY 2005, hospitals reclassified under the one-time appeal process should verify that the reclassified wage index for the labor market area into which they have been reclassified (in Table 4C or 4D in the Addendum to this proposed rule) exceeds the wage index of the labor market area where they are located (in Table 4A or 4B in the Addendum to this proposed rule) after our proposed implementation of the new MSAs. Affected hospitals may withdraw their one-time appeal process reclassifications within 45 days of the publication of this proposed rule.

As we have discussed above, in some cases, the new CBSA definitions result in the division of previously existing MSAs into two or more separate MSAs. (See the example in section III.H.3.b of this preamble.) In these situations, we are proposing to assign a hospital reclassified under the one-time appeal process to the nearest county in the current MSA, and the hospital's FY 2005 reclassification would be to the new MSA (under the CBSA definitions) that includes that county to which it has been assigned. Hospitals reclassified under the one-time appeals process that have been assigned to a new MSA on this proposed basis are identified in Table 9B, column 7, in the Addendum of this proposed rule. We have determined the county to which a hospital is in closest proximity based on mapping data available to us at the time of the preparation of this proposed rule. Hospitals that disagree with our determination of the closest proximate county must submit a comment (as specified under the ''Comment Period'' and ''Addresses'' sections at the beginning of this proposed rule) indicating the basis for their disagreement. Changes to a hospital's MSA assignment on the basis of a hospital's disagreement will be announced in the final rule.

Similarly, hospitals reclassified under the section 508 one-time appeal process that are also in counties identified under the redesignation process in accordance with section 1886(d)(8)(B) of the Act should compare the wage index applicable to the area to which they were reclassified under section 508 with the wage index applicable to the area to which they are redesignated under section 1886(d)(8)(B) of the Act, if those areas are different. Again, affected hospitals may withdraw their one-time appeal process reclassifications within 45 days of the publication of this proposed rule.

e. Proposed Wage Index Adjustment Based on Commuting Patterns of Hospital Employees (Section 505 of Pub. L. 108–173)

[If you choose to comment on issues in this section, please include the caption ''Out-Migration of Hospital Employees'' at the beginning of your comment.]

Section 505 of Public Law 108–173 established new section 1886(d)(13) of the Act. The new section 1886(d)(13) requires that the Secretary establish a new process to make adjustments to the hospital wage index based on commuting patterns of hospital employees. The process provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county with a higher wage index. Such adjustments to the wage index are effective for 3 years beginning with discharges occurring on or after October 1, 2004. Adjustments under this provision are not subject to the budget neutrality requirements at section 1886(d)(3)(E) or section 1886(d)(8)(D) of the Act.

The Secretary is required to establish criteria to identify ''qualifying counties,'' and hospitals located in such qualifying counties are to receive an adjustment to their wage index. Section 1886(d)(13)(B)(i) of the Act directs the Secretary to establish a threshold percentage difference between the county's wage index and the weighted average of the wage indexes of the surrounding higher wage index area(s) to which hospital employees commute that must be met in order for the county to qualify. Section 1886(d)(13)(B)(ii) of the Act specifies that the Secretary is also to establish the minimum out-migration threshold in order to qualify, which may not be less than 10 percent. Section 1886(d)(13)(iii) of the Act requires that the average hourly wage for all hospitals in the county must be equal to or exceed the average hourly wage for all hospitals in the labor market area. Section 1886(d)(13)(E) of the Act indicates this process may be based on the process used by the MGCRB. This section also gives the Secretary the authority to require hospitals to submit data necessary to implement this provision, or to use other data sources as available.

Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the differences between the wage indexes of the MSA(s) with higher wage indexes and the wage index of the resident county, weighted by the overall percentage of hospital workers residing in the qualifying county who are employed in any MSA with a higher wage index. As discussed below, we have employed the prereclassified wage indexes in making these calculations. The wage index increase is effective for 3 years, unless a hospital requests to waive the application of the payment adjustment. Hospitals that receive this payment adjustment are not eligible for reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

(1) Data

To implement this provision, we analyzed commuting data compiled by the U.S. Census Bureau. The data derive from a special tabulation of Census 2000 journey-to-work data, compiled from responses to the long-form (sample) census survey questions on where people worked. When the Census conducts its decennial survey, each household receives either a short form or a long form. On average, about 1 in every 6 households receive the long form. The results from the long form are used to formulate descriptive population estimates. Thus, the data set is based on the Census 2000 sample and represents estimates of the actual figures that would be obtained from a complete count.

The data provide information about commuting patterns of workers at the county level for residents of the 50 States and the District of Columbia. Each record within the dataset represents a combination of a particular resident county, a workplace county, and a particular industry category. Thus, the record shows the county-of-residence by county-of-work commuter flows. The resident county represents the county where the worker resides, while the workplace county represents the county where the worker works. The industry category associated with workers is based on the 108 Industrial Structure codes developed by the Bureau of Economic Analysis. These Industrial Structure codes break down economic activities by defining industries (such as ''fabricated metal product manufacturing,'' ''legal services,'' and ''gasoline stations''). We

limited the data set to those employees working in the category designated ''hospitals'' (BEA code 622000).

Using these data, we are able to identify the total number of hospital workers who live in each county and the number of workers within that county who commute to hospitals in other counties. For example, the data can be used to determine that, from a sample of 100 hospital employees who live in County A, 50 commute to work at hospitals within County A, 20 commute to work at hospitals within County B, and 30 commute to work at hospitals within County C.

There are some intrinsic limitations to the data. The file shows the weighted worker estimate for flows using a threshold or minimum size of 50 unweighted worker (from all industry codes) records. This means that only county-to-county flows that are comprised of at least 50 unweighted worker records are shown in this file. The Census Bureau omitted all other county-to-county flows from the file for confidentiality reasons. While this could eliminate the workflows of some hospital residents, we believe the eliminations would not have a major impact on the policy.

When Census calculated this special tabulation, the estimates of workers numbering from 1 through 7 have been rounded to 4. Values of 8 or greater have been rounded to the nearest multiple of 5, unless the estimate already ended in 5 or 0, in which case it was not changed. In addition, in this special tabulation, workers are defined as people 16 years and older who were employed and at work during the Census long form reference week. This is the week prior to when the questionnaire was filled out, which was the last week of March 2000 for most people.

In addition, because these data derive from the decennial census, the data file will not change until the census is taken again in 2010. This does not mean that the list of qualifying counties will not change from year to year. The out-migration percentage for each county is a function both of the commuting data and changes in the wage index values. Because the wage indices associated with each work and resident county change each year, a county's out-migration percentages can still vary each year because a higher wage index area in one year, might not be a higher wage index area in the next year. For example, if 100 hospital employees living in County A (wage index 1.00 in FY 2004) commute to County B (wage index 1.10 in FY 2004), then County B would be a higher wage index area for 2004. If in FY 2005, County A's wage index increases to 1.02 and County B's wage index decreases to 1.01, those 100 workers commuting from County A to County B will not be commuting to a higher wage index area for 2005. Consequentially, County A's out-migration percentage would decrease from 100 percent in 2004 to 0 percent in 2005. These normal changes in wage index values could also result in a county not deemed a qualifying county for FY 2005, becoming a qualifying county in FY 2006 or later.

We believe these data provide a useable data source to implement this provision. However, we welcome and encourage comments on the availability and value of alternative data sources. Although the statute authorizes the Secretary to require all hospitals to submit data on the commuting patterns of their employees, such a requirement would be a major undertaking for the hospital industry and CMS. It was not possible to pursue this approach in time to implement the provision by FY 2005. However, in addition to welcoming comments on the merits of relying on the Census data, we welcome comments on the feasibility of surveying hospitals on the residence and commuting patterns of all their hospital employees for purposes of developing future year adjustments.

(2) Qualifying Counties

As noted previously, section 1886(d)(13)(B)(iii) of the Act requires that, to qualify for this commuting wage index adjustment, the average hourly wage for all hospitals in the county must be equal to or exceed the average hourly wage for all hospitals in the labor market area in which the county is located. To determine which counties meet this requirement, we calculated the average of hospitals' 3-year average hourly wages for all hospitals in a given county. We compared this county average 3-year average hourly wage to the 3-year average hourly wage for the labor market area where the county is located. We chose to use the 3-year average hourly wage because we believe it provides a more accurate and stable estimate for the wages paid by a given hospital over a period of time. This statutory requirement limits the number of eligible counties, as counties with a 3-year average hourly wage less than the 3-year average hourly wage of the MSA where the county is located were not considered to meet this requirement.

Some resident counties do not have average hourly wages because either there is no hospital located in the county, or the only hospital in the county is new and has not yet submitted wage data. We did not consider these counties to have met the average hourly wage criteria and thus hospitals in these counties are not yet eligible to receive an increase in wage index. This is consistent with our regulations at 42 CFR 412.230(e)(2)(iii), which require a new hospital to accumulate at least 1 year of wage data, before it is eligible to apply for reclassification.

As noted previously, section 1886(d)(13)(B)(ii) of the Act specifies that the Secretary is to establish the minimum out-migration threshold in order to qualify, which may not be less than 10 percent. To determine the out-migration percentage for each county, we identified higher wage index areas, by comparing 2005 prereclassified wage index of a resident county with the 2005 prereclassified wage index of the MSA or rural statewide area where the work county is located. We use the prereclassified wage index so that hospitals in the county are not disadvantaged by reclassification of other hospitals into the county.

Once we limited the dataset to those county-to-county flows where hospital employees were commuting to a higher wage index area, we calculated the out-migration percentage for resident counties. To calculate the out-migration percentage, we calculated the total number of hospital employees in a resident county who were commuting to a higher wage area as a percentage of the total number of hospital employees residing in the resident county. For example, there are 100 hospital employees who live in County A (wage index 1.0). Of those 100 employees, 50 commute to County B (wage index 1.10), 20 commute to County C (wage index 1.05), and 30 work within County A. Because 70 out of 100 people commute to higher wage areas (assuming County C also qualifies as a higher wage area), County A's out-migration percentage is equal to 70 percent.

To implement section 1886(d)(13)(B)(ii) of the Act, we are proposing that the out-migration threshold to qualify for this adjustment would be the statutory minimum of 10 percent. We believe that this threshold provides an opportunity for a reasonable number of hospitals that would not have recourse to the normal reclassification process to receive an appropriate adjustment to their wage index. We welcome comments on this proposed threshold.

As noted previously, section 1886(d)(13)(B)(i) of the Act directs the Secretary to establish a threshold percentage difference between the county's wage index and the weighted average wage indexes of the higher wage index areas to which hospital

employees commute. However, unlike the threshold for the level of out-migration, the statute does not designate a minimum level for this threshold. Because of the nature of the adjustment provided under this provision, we are proposing to establish that the minimum difference in the wage indexes between the resident county and the work county can be any percentage greater than zero. We are proposing this threshold because the wage index increment for hospitals in qualifying counties under the statutory formula is a function of the differences between that county's wage index and the wage indices of the areas into which resident hospital workers of that county are commuting. In those cases where that difference is very small, the adjustment to the wage index will also be very small. (*See* the discussion of the statutory formula in section III.H.3.e.(3) of this preamble.) Therefore, we believe that a threshold of anything greater than zero is justifiable and consistent with the purposes of this provision.

Our analysis indicates that 224 counties qualify under these proposed criteria. There are 411 hospitals located in these qualifying counties. Hospitals located in qualifying counties are identified in Table 4J in the Addendum to this proposed rule.

(3) The Adjustment

Hospitals located in the qualifying counties identified in Table 4J in the Addendum to this proposed rule that have not already been reclassified for purposes of the wage index would receive the wage index adjustment listed in the table. This increase is equal to the percentage of the hospital employees residing in the qualifying county who are employed in any higher wage area, multiplied by the sum of: the products, for each higher wage index area, of the difference between the wage index for such higher wage index area and the wage index of the qualifying county, and the percentage of hospital employees residing in the qualifying county who are employed in any higher wage index area who are employed in such higher wage index area. This increase in wage index is depicted using the following equation:

$$\text{Adjustment} = A * \Sigma[(B - C) * (D/E)]$$

A is the percentage of hospital employees residing in a qualifying county who are employed in any higher wage index area. B represents the wage index of the higher wage index area. C represents the wage index of the qualifying resident county. D represents the number of hospital employees residing in the qualifying county involved who are employed in such higher wage index area. E represents the total number of hospital employees residing in qualifying county who are employed in any higher wage index area.

For example, County A is identified as a qualifying county. As illustrated before, if 100 hospital employees live in County A (wage index = 1.00), 50 commute to County B (wage index = 1.10), 20 commute to County C (wage index = 1.05); and 30 commute within County A, the out-migration percentage is equal to 70 percent.

The adjustment for hospitals in County A would be:

= .70 * (((1.10 − 1.00)*(50/70)) + ((1.05 − 1.00)*(20/70)))
= .70 * ((.10 * .714) + (.05 * .285))
= .70 * (0.0714 + 0.01428)
= .70 * (0.0856)
= 0.05998

So, hospitals in County A could receive a new wage index of 1.05998, instead of 1.000.

The proposed adjustments calculated for qualifying hospitals are listed in Table 4J in the Addendum to this proposed rule. These proposed adjustments are effective for each county for a period of 3 fiscal years beginning with discharges occurring on or after October 1, 2004. The commuting adjustments for each county will remain static for the 3-year period, after which the county's status as a qualifying county and the adjustment will be recalculated.

(4) Automatic Adjustments

Section 1886(d)(13)(A) of the Act allows the Secretary to establish the process for receiving this increase in wage index through application or otherwise. Listed in Table 4J in the Addendum to this proposed rule are the counties and corresponding hospitals that qualify for an increase in wage index through our proposed implementation of the section. We are proposing that all hospitals located in qualifying counties will automatically receive the increase in wage index, unless the hospital has already been reclassified to another geographic area for purposes of the wage index amount (including reclassifications under section 508 of Pub. L. 108–173). This commuting wage index adjustment will be effective for the county for a period of 3 fiscal years, FY 2005 through FY 2007. As discussed previously, yearly changes in the wage indices associated with areas could result in changes in the out-migration percentage for a given county. Irrespective of these changes, a county will not lose its status as a qualifying county due to wage index changes during the 3-year period, and counties will receive the same wage index increase for those 3 years. However, a county that qualifies in FY 2005 may no longer qualify in FY 2008, or it may qualify but receive a different adjustment level.

We encourage comments on the automatic application of such a wage index adjustment, and whether an application process should be developed under which individual hospitals would have to apply in order to receive the adjustment. We note that, given the short timeframe before implementation of this provision on October 1, 2004, we believe that there is no practical alternative to providing for an automatic adjustment for FY 2005. However, one possibility is to employ an automatic adjustment process this year, and to replace the automatic process with an application process for future years. We invite comments on whether to establish the automatic process permanently, or to devise an application process for future years. We also invite comments on whether any application process should be the responsibility of the MGCRB or some other entity.

Hospitals receiving this wage index increase under section 1886(d)(13)(F) of the Act are not eligible for reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act. As previously noted, the wage index increase is effective for 3 years, unless a hospital elects to waive the application of the wage index adjustment. Hospitals that wish to waive the application of this wage index adjustment must notify CMS within 45 days of the publication of this proposed rule. Waiver notifications should be sent to the following address: Centers for Medicare & Medicaid Services, Center for Medicare Management, Attention: Wage Index Adjustment Waivers, Division of Acute Care, C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850. However, consistent with § 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**. Hospitals that have been reclassified by the MGCRB (including reclassifications under section 508 of the MMA) may terminate an existing 3-year reclassification within 45 days of the publication of this proposed rule in order to receive the wage index adjustment under this provision. Hospitals that are eligible for this adjustment and that withdraw their application for reclassification will then

automatically receive the wage index adjustment listed in Table 4J in the Addendum 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 2005 must be received by the MGCRB within 45 days of the publication of this proposed rule. Hospitals should carefully review the wage index adjustment that they would receive under this provision (as listed in Table 2 in the Addendum to this proposed rule) in comparison with the wage index that they would receive under MGCRB reclassification (Table 9 in the Addendum to this proposed rule).

4. Proposed FY 2005 Reclassifications

The proposed wage index values for FY 2005 (except those for hospitals receiving wage index adjustments under section 505 of Pub. L. 108–173) are shown in Tables 4A, 4B, 4C, and 4F in the Addendum to this proposed rule. Hospitals that are redesignated will be required to use the wage index values shown in Table 4C. Areas in Table 4C may have more than one wage index value because the wage index value for a redesignated urban or rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located. Therefore, those areas with more than one wage index shown have hospitals from more than one State reclassified into them, and the rural wage index for a State in which at least one hospital is physically located is higher than the wage index for the area to which the hospital is reclassified.

Tables 3A and 3B in the Addendum to this proposed rule list the 3-year average hourly wage for each labor market area before the redesignation of hospitals, based on FYs 1999, 2000, and 2001 cost reporting periods. Table 3A lists these data for urban areas and Table 3B lists these data for rural areas. In addition, Table 2 in the Addendum to this proposed rule includes the adjusted average hourly wage for each hospital from the FY 1999 and FY 2000 cost reporting periods, as well as the FY 2001 period used to calculate the proposed FY 2005 wage index. The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its average hourly wage for the 3-year period is calculated based on the data available during that period.

At the time this proposed wage index was constructed, the MGCRB had completed its review of FY 2005 reclassification requests. We are including in the Addendum of this proposed rule Table 9A, which shows hospitals that have been reclassified under either section 1886(d)(8) or section 1886(d)(10)(D) of the Act. This table includes 400 hospitals reclassified for FY 2005 by the MGCRB (for wage index purposes), as well as hospitals that were reclassified for the wage index in either FY 2003 53 or FY 2004 102 and are, therefore, in either the second or third year of their 3-year reclassification. This table also includes hospitals located in urban areas that have been redesignated rural in accordance with section 1886(d)(8)(E) of the Act (17). In addition, it includes rural hospitals redesignated to urban areas under section 1886(d)(8)(B) of the Act for purposes of the wage index (98).

Under § 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of 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 2004 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 not 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 for FY 2006 reclassifications are due to the MGCRB by September 1, 2004. We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under § 412.273(d). Applications and other information about MCGRB reclassifications may be obtained, beginning in mid-July 2004, via the CMS Internet Web site at: *http://cms.hhs.gov/providers/prrb/mgcinfo.asp,* or by calling the MCGRB at (410) 786–1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244–2670.

I. Process for Requests for Wage Index Data Corrections

[If you choose to comment on issues in this section, please include the caption ''Wage Data Corrections'' at the beginning of your comment.]

1. Worksheet S–3 Wage Data

In the August 1, 2003 final rule (68 FR 27194), we revised the process and timetable for application for development of the wage index, beginning with the FY 2005 wage index. The preliminary and unaudited Worksheet S–3 wage data file was made available on October 8, 2003 through the Internet on CMS's Web site at: *http://cms.hhs.gov/providers/hipps/ippswage.asp.* In a memorandum dated October 10, 2003, we instructed all Medicare fiscal intermediaries to inform the IPPS hospitals they service of the availability of the wage data file and the process and timeframe for requesting revisions (including the specific deadlines listed below). We also instructed the fiscal intermediaries to advise hospitals that these data are also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in that wage data file, the hospital was to submit corrections along with complete, detailed supporting documentation to its intermediary by November 24, 2003. Hospitals were notified of this deadline and of all other possible deadlines and requirements, including the requirement to review and verify their data as posted on the preliminary wage data file on the Internet, through the October 10, 2003 memorandum referenced above.

The fiscal intermediaries notified the hospitals in early February of any changes to the wage data as a result of the desk reviews and the resolution of the hospitals' early November change requests. The fiscal intermediaries also submitted the revised data to CMS in early February. CMS published the proposed wage index public use file that included hospitals' revised wage data on February 27, 2004. In a memorandum also dated March 1, 2004, we instructed fiscal intermediaries to notify all hospitals regarding the availability of the proposed wage index public use file and the criteria and process for requesting corrections and revisions to the wage data. Hospitals had until March 12, 2004 to submit requests to the fiscal intermediaries for reconsideration of adjustments made by the fiscal intermediaries as a result of the desk review, and to correct errors due to CMS's or the intermediary's mishandling of the wage data. Hospitals were also required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, fiscal intermediaries are to submit additional revisions resulting from the hospitals' reconsideration requests by April 16, 2004. The deadline for hospitals to request CMS intervention in cases where the hospital disagrees with the fiscal intermediary's policy interpretations is April 23, 2004.

Hospitals should also examine Table 2 in the Addendum to this proposed rule. 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 2001 data used to construct the proposed FY 2005 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 by March 15, 2004.

We will release a final wage data file in early May to hospital associations and the public on the Internet at *http://www.cms.hhs.gov/providers/hipps/ippswage.asp.* The May 2004 public use file 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 16, 2004). If, after reviewing the May 2004 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 11, 2004. 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, C4–08–06, 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 2004 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 16, 2004.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the March 1, 2004 wage data file (or the March 8 occupational mix data; see section III.H.2. of this preamble).
- Requests to revisit factual determinations or policy interpretations made by the intermediary or CMS during the wage index data correction process.

2. Occupational Mix Data

The process and criteria for requesting corrections to the occupational mix survey data are described in section III.C.1 of this preamble. As stated in that section, from April 16, 2004 forward, the process for correcting the final occupational mix survey data is the same, and on the same schedule, as described above for correcting the final Worksheet S–3 wage data.

3. All FY 2005 Wage Index Data

Verified corrections to the wage index received timely (that is, by June 11, 2004) will be incorporated into the final wage index in the final rule to be published by August 1, 2004, and to be effective October 1, 2004.

We created the processes described above to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2005 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage data corrections or to dispute the intermediary's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to challenge later, before the Provider Reimbursement Review Board, the failure of CMS to make a requested data revision (*See W. A. Foote Memorial Hospital* v. *Shalala,* No. 99–CV–75202–DT (E.D. Mich. 2001), also *Palisades General Hospital* v. *Thompson,* No. 99–1230 (D.D.C. 2003)).

Again, we believe the wage index data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage data to the fiscal intermediaries' attention. Moreover, because hospitals will have access to the final wage index data by early May 2004, 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 2005 wage index by August 1, 2004, and the implementation of the FY 2005 wage index on October 1, 2004. 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: (1) That the intermediary or CMS made an error in tabulating its data; and (2) that the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of FY 2005 (that is, by the June 11, 2004 deadline). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index. As described earlier, 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 2005 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.

J. Proposed Revision of the Labor-Related Share of the Wage Index

[If you choose to comment on issues in this section, please include the caption ''Labor-Related Share'' at the beginning of your comment.]

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related: ''The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. * * *'' The portion of hospital costs attributable to wages and wage-related costs is referred to as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index. In the past, we have defined the labor-related share for prospective payment acute care hospitals as the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share for the acute care hospital inpatient prospective payment system has been calculated as the sum of the weights for wages and salaries, fringe benefits, nonmedical professional fees, contract labor, postage, and labor-intensive services.

In its June 2001 Report to Congress, MedPAC recommended that the Secretary ''should reevaluate current assumptions about the proportion of providers'' costs that reflect resources purchased in local and national markets.'' (Report to the Congress: Medicare in Rural America, Recommendation 4D, page 80.) MedPAC recommended that the labor-related share include the weights for wages and salaries, fringe benefits, contract labor, and other labor-related costs for locally purchased inputs only. MedPAC noted that this would likely result in a lower labor share, which would decrease the amount of the national base payment amount adjusted by the wage index. As a result, hospitals located in low-wage markets (those with a wages index less than 1.0) would receive higher payments, while those located in high-wage labor markets would receive lower payments.

In our proposed and final regulations updating the IPPS for FY 2003 (67 FR 31404, May 9, 2002 and 67 FR 49982, August 1, 2002), we discussed the methodology that we have used to determine the labor-related share. We noted that, at that time, the results of employing that methodology suggested that an increase in the labor-related share (from 71.066 percent to 72.495 percent) was warranted. However, we decided not to propose such an increase in the labor-related share until we conducted further research to determine whether a different methodology for determining the labor-related share should be adopted. The labor-related share has thus remained 71.066 percent.

Section 403 of Pub. L. 108–173 amended sections 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this ''would result in lower payments than would otherwise be made.'' However, this provision of Pub. L. 108–173 did not the change the legal requirement that the Secretary estimate ''from time to time'' the proportion of hospitals'' costs that are ''attributable to wages and wage-related costs.'' In fact, section 404 of Pub. L. 108–173 requires the Secretary to develop a frequency for revising the weights used in the hospital market basket, including the labor share, to reflect the most current data more frequently than once every 5 years. This reflects Congressional intent that hospitals will receive payment based on a 62-percent labor share, or the labor share estimated from time to time by the Secretary, whichever is higher.

Section 404 further requires us to include in the final IPPS rule for FY 2006 an explanation of the reasons for, and options considered, in determining the frequency for revising the weights used in the hospital market basket, including the labor share. In the meantime, we are also continuing our research into the assumptions employed in calculating the labor-related share. Our research involves analyzing the compensation share separately for urban and rural hospitals, using regression analysis to determine the proportion of costs influenced by the area wage index, and exploring alternative methodologies to determine whether all or only a portion of professional fees and nonlabor intensive services should be considered labor-related. We will present our analysis and conclusions regarding the frequency and methodology for updating the labor share in the proposed and final rules for FY 2006.

In section IV.F. of this preamble, we discuss our proposal to incorporate the requirements of section 403 of Pub. L. 108–173 in a new § 412.64(h) of the regulations.

As discussed above, the Secretary had determined, prior to the enactment of Pub. L. 108–173, that the labor-related share would be 71.066 percent. As a result, application of a 62-percent labor share would result in lower payments for any hospital with a wage index greater than 1.0. Therefore, we are modifying our payment system software for FY 2005 to apply wage indexes greater than 1.0 to 71.066 percent of the standardized amount, and to apply wage indexes less than or equal to 1.0 to 62 percent of the standardized amount.

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

A. Postacute Care Transfer Payment Policy (§ 412.4)

[If you choose to comment on issues in this section, please include the caption ''Postacute Care Transfers'' at the beginning of your document.]

1. Background

Existing regulations at § 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines transfers from one acute care hospital to another, and § 412.4(c) defines transfers to certain postacute care providers. Our policy provides that, in transfer situations, full payment is made to the final discharging hospital and each transferring hospital is paid a per diem rate for each day of the stay, not to exceed the full DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full DRG payment by the geometric mean length of stay for the DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy provides for payment that is double the per diem amount for the first day (§ 412.4(f)(1)). Transfer cases are also eligible for outlier payments. The outlier threshold for transfer cases is equal to the fixed-loss outlier threshold for nontransfer cases, divided by the geometric mean length of stay for the DRG, multiplied by the length of stay for the case, plus one day.

Medicare adopted its IPPS transfer policy because, if the program were to pay the full DRG payment regardless of

whether a patient is transferred or discharged, there would be a strong incentive for hospitals to transfer patients to another IPPS hospital early in the patients' stay in order to minimize costs while still receiving the full DRG payment. The transfer policy adjusts the payments to approximate the reduced costs of transfer cases.

Previously, when a patient chose to depart from a hospital against the medical opinion of treating physicians, the case was treated as a left against medical advice (LAMA) discharge and coded as discharge status ''07-Left Against Medical Advice (LAMA)'' on the inpatient billing claim form. Because, by definition, LAMA discharges were assumed not to involve the active participation of the hospital administration, our policy had been to treat LAMA cases as discharges. This policy applied even if the patient was admitted to another hospital on the date of the LAMA discharge. Consequently, until FY 2004, we made a full DRG payment for any discharge coded as a LAMA case.

Last year, in response to an Office of Inspector General (OIG) report issued in March 2002 (A–06–99–00045), we became concerned that some hospitals were incorrectly coding transfers as LAMA cases. Therefore, in the August 1, 2003 final IPPS rule (68 FR 45405), we expanded our definition of a transfer under § 412.4(b) to include all patients who are admitted to another IPPS hospital on the same day that the patient is discharged from an IPPS hospital, unless the first (transferring) hospital can demonstrate that the patient's treatment was completed at the time of discharge from that hospital. In other words, unless the same-day readmission is to treat a condition that is unrelated to the condition treated during the original admission (for example, the beneficiary is in a car accident later that day), any situation where the beneficiary is admitted to another IPPS hospital on the same date that he or she is discharged from an IPPS hospital would be considered a transfer, even if the patient left against medical advice from the first hospital.

Hospitals are now allowed to report a patient as left against medical advice only if they have no knowledge that the patient has been admitted to another hospital on the same day. If a hospital later leans that a patient was admitted to another facility on the same day, the hospital must resubmit the claim and correctly code the patient as a ''transfer.'' This change prohibits payment of two claims for the same patient on the same day. Therefore, if a hospital believes a claim has been wrongly denied, the original discharging hospital must resubmit the claim with documentation that the discharge was appropriate and unrelated to the subsequent same-day admission.

2. Proposed Changes to DRGs Subject to the Postacute Care Transfer Policy (§§ 412.4(c) and (d))

Under section 1886(d)(5)(J) of the Act, a ''qualified discharge'' from one of 10 DRGs selected by the Secretary to a postacute care provider is treated as a transfer case beginning with discharges on or after October 1, 1998. This section required the Secretary to define and pay as transfers all cases assigned to one of 10 DRGs selected by the Secretary, if the individuals are discharged to one of the following postacute care settings:

- A hospital or hospital unit that is not a subsection 1886(d) hospital. (Section 1886(d)(1)(B) of the Act identifies the hospitals and hospital units that are excluded from the term ''subsection (d) hospital'' as psychiatric hospitals and units, rehabilitation hospitals and units, children's hospitals, long-term care hospitals, and cancer hospitals.)
- A SNF (as defined at section 1819(a) of the Act).
- Home health services provided by a home health agency, if the services relate to the condition or diagnosis for which the individual received inpatient hospital services, and if the home health services are provided within an appropriate period (as determined by the Secretary).

In the July 31, 1998 IPPS final rule (63 FR 40975 through 40976), we specified the appropriate time period during which we would consider a discharge to postacute home health services to constitute a transfer as within 3 days after the date of discharge. In addition, in the July 31, 1998 final rule, we did not include in the definition of postacute care transfer cases patients transferred to a swing-bed for skilled nursing care (63 FR 40977).

Section 1886(d)(5)(J) of the Act directed the Secretary to select 10 DRGs based upon a high volume of discharges to postacute care and a disproportionate use of postacute care services. As discussed in the July 31, 1998 final rule, these 10 DRGs were selected in 1998 based on the MedPAR data from FY 1996. Using that information, we identified and selected the first 20 DRGs that had the largest proportion of discharges to postacute care (and at least 14,000 such transfer cases). In order to select 10 DRGs from the 20 DRGs on our list, we considered the volume and percentage of discharges to postacute care that occurred before the mean length of stay and whether the discharges occurring early in the stay were more likely to receive postacute care. We identified 10 DRGs to be subject to the postacute care transfer rule starting in FY 1999.

Section 1886(d)(5)(J)(iv) of the Act authorizes the Secretary to expand the postacute care transfer policy beyond 10 DRGs for FY 2001 or subsequent fiscal years. In the FY 2004 IPPS final rule (68 FR 45412), we expanded the postacute care transfer policy to include additional DRGs. We established the following criteria that a DRG must meet, for both of the 2 most recent years for which data are available, in order to be added to the postacute care transfer policy:

- At least 14,000 postacute care transfer cases;
- At least 10 percent of its postacute care transfers occurring before the geometric mean length of stay;
- A geometric mean length of stay of at least 3 days; and
- If a DRG is not already included in the policy, a decline in its geometric mean length of stay during the most recent 5 year period of at least 7 percent.

We identified 21 new DRGs that met these criteria. We also determined that one DRG from the original group of 10 DRGs (DRG 263) no longer met the volume criterion of 14,000 transfer cases. Therefore, we removed DRGs 263 and 264 (DRG 264 is paired with DRG 263) from the policy and the postacute care transfer policy to include payments for transfer cases in the new 21 DRGs, effective October 1, 2003. As a result, a total of 29 DRGs were subject to the postacute care transfer policy in FY 2004.

We indicated in last year's rule that we would review and update this list periodically to assess whether additional DRGs should be added or existing DRGs should be removed. We have analyzed the available data from the FY 2003 MedPAR file. For the 2 most recent years of available data (FY 2002 and FY 2003), we have found that no additional DRGs qualify under the four criteria set forth in the IPPS final rule for FY 2004. We have also analyzed the DRGs included under the policy for FY 2004 to determine if they still meet the criteria to remain under the policy. In addition, we have analyzed the special circumstances arising from a change to one of the DRGs included under the policy in FY 2004.

As discussed in section II.B.9. of this preamble, we are proposing to eliminate DRG 483. The cases that would have been placed into DRG 483 would now be split into two proposed new DRGs, 541 (Tracheostomy With Mechanical

Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses With Major O.R. Procedure) and 542 (Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses Without Major O.R. Procedure). This would be done by subdividing the cases in the existing DRG 483 based on the presence of a major O.R. procedure, in addition to the tracheotomy code that is currently required to be assigned to this DRG. Therefore, if the patient's case involves a major O.R. procedure (a procedure whose code is included on the list that is assigned to DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), except for tracheostomy codes 31.21 and 31.29), the case would be assigned to the proposed new DRG 541. If the patient does not have an additional major O.R. procedure (that is, there is only a tracheotomy code assigned to the case), the case would be assigned to proposed new DRG 542.

Neither of the proposed new DRGs 541 and 542 would have enough cases to meet the first criterion for inclusion in the postacute care transfer policy. DRG 483 had 44,788 total cases with 15,520 transfer cases in FY 2002, and 44,618 total cases with 20,034 transfer cases in FY 2003. These cases would now split between proposed new DRG 541 (20,812 total cases) and proposed new DRG 542 (23,387 total cases). As a result, neither of these proposed new DRGs would meet the existing threshold of 14,000 transfer cases (6,779 projected transfer cases for proposed DRG 541, and 8,570 projected transfer cases for proposed DRG 542). Nevertheless, we believe the cases that would now be incorporated into these two proposed new DRGs remain appropriate candidates for application of the postacute care transfer policy. The proposed new DRGs 541 and 542 would contain the same cases that were included in existing DRG 483, which qualified for inclusion in the postacute care transfer policy. Furthermore, many of the cases in the proposed new DRGs 541 and 542 would continue to require postacute care.

When we analyzed the cases that we projected would fall into the two proposed new DRGs in the FY 2003 GROUPER Version 22.0, we found that a high proportion of cases in both the proposed new DRGs are projected to be transfer cases: 33 percent of all cases in proposed DRG 541, and 37 percent in proposed DRG 542. In addition, a high proportion of the transfer cases in these proposed new DRGs, based on the data from cases in DRG 483 in the FY 2003 MedPAR file, are projected to fall into the short-stay transfer category: 41 percent of transfer cases in proposed new DRG 541 and 42 percent of transfer cases in proposed new DRG 542 are projected to occur before the geometric mean length of stay for these proposed new DRGs. By contrast, among all DRGs, approximately 15 percent of transfer cases are short-stay transfer cases. The percentage of transfer cases that are short-stay cases that would be in both proposed new DRGs 541 and 542 would be more than 2 standard deviations above the mean percentage of short-stay cases across all DRGs. (Two standard deviations above the mean across all DRGs is 37 percent for FY 2005.) Therefore, we believe this proposed subdivision of DRG 483 should not change the original application of the postacute care transfer policy to the cases once included in that DRG. We do not believe that it is appropriate for these cases to fall outside the scope of this policy solely because of the proposed revision to the DRG structure that was driven by policy reasons unrelated to the postacute care transfer provision. The high proportion of transfer cases among all cases that would be assigned to these proposed new DRGs, along with the unusually high proportion of short-stay cases among those transfer cases, provide solid reasons for considering whether alternate criteria might better address the special circumstances that can arise from changes in DRGs unrelated to the postacute care transfer policy.

Therefore, we are proposing alternate criteria to be applied in cases where DRGs do not satisfy the existing criteria, for discharges occurring on or after October 1, 2004. These proposed new criteria are designed to address situations such as those posed by the proposed split of DRG 483, where there remain substantial grounds for inclusion of cases within the postacute care transfer policy, although one or more of the original criteria may no longer apply. Therefore, we are proposing to examine DRGs for inclusion within the policy against two sets of criteria, first, the original four criteria, and then, the proposed alternate set of criteria. DRGs that do not satisfy the first set of criteria would still be included if they satisfy the second set. Specifically, a DRG would still be subject to the postacute care transfer policy under the alternative set of criteria if, for the 2 most recent years for which data are available, there are at least 5,000 total transfers to postacute care among the cases included in the DRG, and if, among the cases included in the DRG, the percentage of transfer cases that are short-stay transfer cases is at least 2 standard deviations above the geometric mean length of stay across all DRGs (which is 37 percent for FY 2005). We would also continue to require a geometric mean length of stay of at least 3 days among the cases included in the DRG. Finally, we would require that, if a DRG is not already included in the policy, it either experienced a decline in its geometric mean length of stay during the most recent 5 year period of at least 7 percent or contains only cases that would have been included in a DRG to which the policy applied in the prior year.

Under these proposed alternate criteria, DRGs 430, 541, and 542 would qualify for inclusion in the postacute care transfer policy. DRG 430 meets the proposed threshold of 5,000 transfer cases in both of the 2 most recent years, with 11,973 transfer cases and 46 percent short-stay transfer cases in FY 2002, and 12,202 transfer cases and 38 percent short-stay transfers in FY 2003. In addition, DRG 430 experienced a 7-percent decline in length of stay from FY 2000 to FY 2004. DRG 430 also had a 5.8 day average length of stay during those years. As discussed above, the cases that would be included in proposed new DRGs 541 and 542 contain a sufficient number of transfers to meet the first alternate criterion, and among the cases that would be included in these DRGs, the percentages of transfer cases occurring before the geometric mean length of stay for these two proposed new DRGs exceed 2 standard deviations above the geometric mean length of stay for all DRGs. The average lengths of stay for the cases that would be included in proposed new DRGs 541 and 542 are 37.7 days and 28.9 days, respectively.

We are proposing to revise the regulations governing the postacute transfer policy to include the alternative criteria described above (§ 412.4(d)). We are also proposing that DRG 430 and proposed new DRGs 541 and 542 would be included in the postacute care transfer policy.

We would also like to call attention to the data concerning DRG 263, which was subject to the postacute care transfer policy until FY 2004. We removed DRG 263 from the postacute care transfer policy last year because it did not have the minimum number of cases (14,000) transferred to postacute care (13,588 transfer cases in FY 2002, with more than 50 percent of transfer cases being short-stay transfers). The FY 2003 MedPAR data show that there were 15,602 transfer cases in the DRG in FY 2003, of which 46 percent were short-stay transfers. Because we

removed the DRG from the postacute care transfer policy in FY 2004, it must meet all criteria to be included under the policy in subsequent fiscal years. Because the geometric mean length of stay for DRG 263 shows only a 6-percent decrease since 1999, DRG 263 does not qualify to be added to the policy for FY 2005 under the existing criterion that was included in last year's rule. However, DRG 263 would qualify under the volume threshold and percent of short-stay transfer cases under the proposed new alternate criteria in this proposed rule, but it still does not meet the proposed required decline in length of stay to qualify to be added to the policy in FY 2005.

The table below displays the 31 DRGs that we are proposing to include in the postacute care transfer policy, effective for discharges occurring on or after October 1, 2004. These 31 DRGs include the effects of dropping DRG 483, which we are proposing to delete from the DRG list, and adding the two proposed new DRGs 541 and 542 that would now incorporate the cases formerly assigned to DRG 483. They also include the proposed addition of DRG 430 to the list. These DRGs meet the criteria specified above during both of the 2 most recent years available prior to the publication of the FY 2005 IPPS proposed rule (FYs 2002 and 2003), as well as their paired-DRG if one of the DRGs meeting the criteria includes a CC/no-CC split.

DRG	DRG title.
12	Degenerative Nervous System Disorders.
14	Intracranial Hemorrhage and Stroke with Infarction.
24	Seizure and Headache Age > 17 With CC.
25	Seizure and Headache Age > 17 Without CC.
88	Chronic Obstructive Pulmonary Disease.
89	Simple Pneumonia and Pleurisy Age > 17 With CC.
90	Simple Pneumonia and Pleurisy Age > 17 Without CC.
113	Amputation for Circulatory System Disorders Except Upper Limb and Toe.
121	Circulatory Disorders With AMI and Major Complication, Discharged Alive.
122	Circulatory Disorders With AMI Without Major Complications Discharged Alive.
127	Heart Failure & Shock.
130	Peripheral Vascular Disorders With CC.
131	Peripheral Vascular Disorders Without CC.
209	Major Joint and Limb Reattachment Procedures of Lower Extremity.
210	Hip and Femur Procedures Except Major Joint Age > 17 With CC.
211	Hip and Femur Procedures Except Major Joint Age > 17 Without CC.
236	Fractures of Hip and Pelvis.
239	Pathological Fractures and Musculoskeletal and Connective Tissue Malignancy.
277	Cellulitis Age > 17 With CC.
278	Cellulitis Age > 17 Without CC.
294	Diabetes Age > 35.
296	Nutritional and Miscellaneous Metabolic Disorders Age > 17 With CC.
297	Nutritional and Miscellaneous Metabolic Disorders Age > 17 Without CC.
320	Kidney and Urinary Tract Infections Age > 17 With CC.
321	Kidney and Urinary Tract Infections Age > 17 Without CC.
395	Red Blood Cell Disorders Age > 17.
429	Organic Disturbances and Mental Retardation.
430	Psychoses.
468	Extensive O.R. Procedure Unrelated to Principal Diagnosis.
Proposed 541	Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses With Major O.R. Procedure.
Proposed 542	Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses Without Major O.R. Procedure.

Section 1886(d)(5)(J)(i) of the Act recognizes that, in some cases, a substantial portion of the costs of care is incurred in the early days of the inpatient stay. Similar to the policy for transfers between two acute care hospitals, the transferring hospital in a postacute care transfer receives twice the per diem rate for the first day of treatment and the per diem rate for each following day of the stay before the transfer, up to the full DRG payment. However, three of the DRGs subject to the postacute care transfer policy exhibit a disproportionate share of costs very early in the hospital stay in postacute care transfer situations. For these DRGs, hospitals receive 50 percent of the full DRG payment plus the single per diem (rather than double the per diem) for the first day of the stay and 50 percent of the per diem for the remaining days of the stay, up to the full DRG payment.

In previous years, we determined that DRGs 209 and 211 met this cost threshold and qualified to receive this special payment methodology. Because DRG 210 is paired with DRG 211, we include payment for cases in that DRG for the same reason we include paired DRGs in the postacute care transfer policy (to eliminate any incentive to code incorrectly in order to receive higher payment for those cases). The FY 2003 MedPAR data show that DRGs 209 and 211 continue to have charges on the first day of the stay that are higher than 50 percent of the average charges in the DRGs. Therefore, we are proposing to continue the special payment methodology for DRGs 209, 210, and 211 for FY 2005.

B. Payments for Inpatient Care in Providers That Change Classification Status During a Patient Stay (§§ 412.2(b)(3) and 412.521(e))

[If you choose to comment on issues in this section, please include the caption ''Crossover Patients'' at the beginning of your document.]

Different Medicare payment systems apply to care furnished to Medicare beneficiaries during inpatient stays, depending on the classification status of the provider. For example, payments made to an acute care hospital for inpatient services are made under the IPPS on a per discharge basis, using a

DRG classification system. Payments to LTCHs that are classified under section 1886(d)(1)(B)(iv)(I) and (II) of the Act are made under the LTCH PPS on a per discharge basis, using a LTC–DRG classification system. The main difference between a LTCH that is classified under section 1886(d)(1)(B)(iv)(I) of the Act and an acute care hospital is the average length of stay at the hospital. Specifically, section 1886(d)(1)(B)(iv)(I) hospitals must have a greater than 25 day average Medicare inpatient length of stay. (section 1886(d)(1)(B)(iv)(II) hospitals, among other requirements, must have a greater than 20 day Medicare and non-Medicare inpatient length of stay to qualify as LTCHs.) Situations occur in hospital inpatient care settings in which a Medicare provider changes its Medicare payment classification status during a patient's stay, for example, an acute care hospital changes to a LTCH. (We refer to the patients in these situations as ''crossover patients.'')

Questions have arisen as to how Medicare should pay for an inpatient stay in a hospital when the hospital changes its classification status during the course of the beneficiary's single hospital stay. Specifically, how should Medicare pay for an inpatient stay when a patient is in an acute care hospital and the acute care hospital changes to a LTCH during the beneficiary's hospitalization. In other words, how does Medicare pay for the first part of the stay that occurs before the change in classification status and how does Medicare pay for the part of the stay that occurs after the change in classification status. Although the situation may occur in other settings, this payment issue is most prevalent for services furnished to crossover patients in a newly established LTCH. This is because all new LTCHs begin as other provider types, generally as acute care hospitals, and generally after at least 5 months of experience showing an average length of stay in excess of 25 days, and are then paid as LTCHs. Therefore, as explained further below, we are currently addressing this problem in the context of crossover patients discharged from LTCHs.

To address payment for inpatient care for such crossover patients, we had issued instructions for hospital billing purposes (paper-based manual, Hospital Manual, HCFA Pub. 10, section 404, which has been replaced by the Medicare Claims Processing Manual, Pub. 100–4, Chapter 3, section 100.4.1) that were in effect prior to the implementation of the PPS for LTCHs (that is, prior to October 1, 2002). The manual instructed hospitals as follows: ''The hospital must submit a discharge bill with the old provider number and an admission notice with the new provider number. The date of discharge and the date of admission are the same date, which is the first day of the new fiscal period. All subsequent billings are submitted under the new provider number.''

It is important to note that at the time this manual provision was written, IPPS-excluded hospitals, including LTCHs, were reimbursed under the reasonable cost-based (TEFRA) payment system, not under other PPSs that pay on a per discharge basis. Thus, under the manual instructions, if a patient was in an acute care hospital and the hospital converted to a LTCH during the patient's stay, Medicare would then make payment for what was, in reality, only one episode of care as if it were two episodes. Specifically, the days of the stay while the facility was certified as an acute care hospital generate a full DRG payment under the IPPS; and the services provided from the time the facility was certified as a LTCH were reimbursed under the reasonable cost-based payment system. We are proposing to revisit the issue of Medicare payment for crossover patients now that there has been a fundamental change in the Medicare payment system for LTCHs. LTCHs are now paid under the discharge-based LTCH PPS which was effective for LTCHs for cost reporting periods beginning on or after October 1, 2002.

Under the LTCH PPS for crossover patients, under the existing manual instructions, Medicare makes a full DRG payment under the IPPS to the acute care hospital for the ''first portion'' of the inpatient stay, and when the acute care hospital converts to an LTCH, Medicare makes a second PPS payment under the LTCH PPS for the ''second portion'' of the stay. We believe that this results in excessive Medicare payments and results in the inappropriate use of the Medicare Trust Fund. We believe the results described above are contrary to a basic premise of a PPS, which is that a single discharge-based PPS payment is adequate and appropriate reimbursement for the entire bundle of services that a hospital provides during the course of a patient's stay. We believe the care provided prior to and after the conversion to a LTCH is really one bundle of services provided during a single hospitalization. The ''discharge'' from the acute care hospital and ''admission'' to the LTCH has only been a ''paper discharge'' that was triggered solely by a change in the Medicare payment classification of the hospital treating the inpatient. In the instant case, the beneficiary, by mere coincidence, just happened to be an inpatient of the acute care hospital when it changed status—the acute care hospital does not drastically change the medical care it provides a beneficiary during his or her single hospitalization because its classification as an acute care hospital ends on one day and changes to LTCH classification on the next day, nor does the ''discharge'' signify the completion of a discrete period of care. Under the existing manual instructions, the hospital is receiving not one payment, but two PPS payments for a bundle of services that, in fact, was furnished during a single inpatient hospital stay and should have been adequately and properly reimbursed by a single PPS payment.

In addition, presently, if the DRG assigned to the ''discharge'' from the acute care hospital for a crossover patient falls within one of the DRGs covered by the postacute care transfer policy at § 412.4(c), the provider will receive a payment under the postacute care transfer policy as if the patient, who in fact has not moved, was transferred to a postacute care provider. Payment under the postacute care transfer policy is triggered when a discharge bill with the old provider number and an admission notice with the new provider number is submitted and processed by the Medicare standard bill processing systems as a transfer. Because the patient is, in reality, at the ''same'' facility (an acute care hospital that had met the LTCH designation criteria) and is in one episode of care, we do not believe the application of the existing transfer policy is the appropriate methodology for dealing with this situation. Under the postacute care transfer policy, the payment to the transferring hospital is only affected if the patient is discharged prior to the day before the geometric mean length of stay for the DRG. Where the patient is discharged by the day before the geometric mean length of stay, the ''discharging'' acute care hospital will receive the equivalent of the full IPPS DRG payment and the LTCH hospital will also receive a full LTCH PPS payment.

Accordingly, we are proposing to revise our regulations to provide for only one Medicare program payment for LTCH crossover patients. After reconsidering the current payment policy for crossover patients, we do not believe it is appropriate to make two separate discharge-based payments under Medicare for what, in reality, is a single inpatient hospital stay. In fact, when a patient under existing policy is deemed discharged from an acute care

hospital that has met the LTCH designation requirements during the patient's stay and has now changed its classification to LTCH status, we believe the patient has been receiving one consistent course of treatment throughout his or her stay. An acute care hospital that has become a LTCH prior to being paid as a LTCH has been admitting and treating patients with the multi-cormorbidities that result in longer hospital stays that are characteristic of the patient census at a LTCH, as required by § 412.23(e). Invariably, at the time the acute care hospital becomes a LTCH, there will be patients who were admitted to the acute care hospital and who remain in the facility when it converts to a LTCH and are ultimately discharged from the LTCH. An acute care hospital's change in payment classification status to a LTCH at the start of its first cost reporting period should have no impact on the course of treatment that is already underway for the patient in what is now a LTCH and not an acute care hospital. Accordingly, we believe that only one Medicare payment should be made for the entire stay.

Therefore, we are proposing a more appropriate payment policy for crossover patients that would provide one Medicare payment for what has been treated, for payment purposes under Medicare, to be two stays, but is, in reality, one continuous and uninterrupted period of inpatient hospital care. Consistent with the authority granted to the Secretary in both section 123 of the BBRA (Pub. L. 106–113) and section 307 of the BIPA (Pub. L. 106–554) to develop a LTCH PPS DRG-based system, we are proposing, effective for a patient stay in which a patient is in an acute care hospital and that hospital is designated as a LTCH on or after October 1, 2004, to make only one LTCH payment based on the PPS of the facility that is actually discharging the patient. Under this approach, we would include those days of care and costs incurred by the hospital for the crossover patient before the facility met the LTCH status criteria, in determining payments to the LTCH for that patient under the LTCH PPS. Under this proposed policy, for example, if an acute care hospital admits a patient on December 28 and the hospital converts to a LTCH on January 1 when its cost reporting period begins, and the patient is physically discharged from the LTCH on February 5, a single Medicare payment would be made for this entire stay (December 28 through February 5), and payment would be made to the LTCH based on the LTCH–DRGs under the LTCH PPS. We are proposing to count the crossover patient's entire hospitalization (that is, all days and costs of the patient stay in the facility that occurred prior to and after conversion) in determining the applicable payment under the LTCH PPS. This proposed provision would also count all the days of the inpatient stay, that is, prior to and after conversion, as LTCH days for purposes of determining whether the facility continues to meet the average length of stay regulations for LTCH. We believe that this proposed policy is consistent with the discretionary authority granted to the Secretary at section 1886(d)(1)(B)(iv)(I) of the Act for determining average lengths of stay for LTCHs. Specifically, section 1886(d)(1)(B)(iv)(I) of the Act provides that a LTCH is a hospital that has an average length of stay (as determined by the Secretary) of greater than 25 days. Thus, the Secretary determines how a LTCH's average length of stay is to be determined.

We are also using the broad discretionary authority provided in section 1871 of the Act to not count the days of the patient's stay in the acute care hospital prior to conversion as acute care days. In addition, we are using the broad authority in section 1871 of the Act to not pay for the days of the patient's stay in the acute care hospital as acute days. Section 1871 of the Act authorizes the Secretary to promulgate regulations that are necessary to carry on the administration of the Medicare program.

In addition, we believe counting all days for the patient's stay is consistent with the policy at recently revised § 412.23(e)(3), which provides that if a LTCH patient is admitted in one cost reporting period and discharged in a second cost reporting period, all of the days of the patient's stay, even those from prior fiscal years, are counted in the cost reporting period in which the patient is discharged. In the example of a crossover patient cited above, including the days in December may result in a full LTC–DRG payment rather than the lower payment under the short-stay outlier policy (§ 412.529) based on the length of the stay. (Under the short-stay policy, we would adjust (lower) the Federal prospective payment if the payment is for a length of stay that is up to and including five-sixths of the geometric average length of stay for the LTC–DRG assigned to the case.)

Accordingly, we are proposing to add a new § 412.2(b)(3), applicable to acute care hospitals, and a new § 412.521(e), applicable to LTCHs, that specify that Medicare would make only one LTCH PPS payment for a crossover patient to the LTCH that is discharging the patient based on the entire stay, both prior to the change to LTCH status and after the change. Medicare considers all days of the patient stay in the facility (days prior to and after conversion to the LTCH status) to be a single episode of LTCH care. Medicare will not make any payment under 42 CFR Part 412, Subpart H for any part of the hospitalization. In addition, for purposes of determining the beneficiary LTCH length of stay, the days prior to and after conversion to LTCH status are included. In order to implement the proposed policy, we would create systems adjustments that would enable the single claim generated by the discharging provider to include patient days under the initial provider number. We note that our proposal to define and pay for crossover patient stays as one episode of care based on the PPS of the discharging provider is consistent with existing regulations that establish that payment under the per discharge PPS constitutes ''payment in full'' for acute care hospitals at § 412.2(b) under the IPPS and for LTCHs, at § 412.521(b) under the LTCH PPS.

In this proposal, we have specifically addressed only the situation of a crossover patient that was in an acute care hospital that meets the requirements to be paid as a LTCH. However, we believe the policy may be equally applicable to other crossover situations. For example, an acute care hospital may meet the requirements to be paid as an inpatient rehabilitation facility (under the IRF PPS) and there could be rehabilitation patients who were admitted to the acute care hospital who were not discharged from the hospital until after the facility was designated as an IRF. At this time, we are not proposing to make a change to the existing payment policy in situations other than the LTCH crossover patient. We have only addressed the LTCH crossover patient because, based on the statutory and regulatory qualifying criteria, every LTCH must first be certified as a hospital before it can meet the LTCH criteria. However, the same is not true for other hospital certifications. For example, an inpatient rehabilitation hospital can be certified as an IRF without first being certified and paid as an acute care hospital for inpatient services. However, we intend to revisit the existing crossover policy as it affects other crossover situations in the future. We also welcome comments on how Medicare payment policy should address those situations.

C. Geographic Reclassifications—Definitions of Urban and Rural Areas (§ 412.63(b) and Proposed New § 412.64(b))

[If you choose to comment on issues in this section, please include the caption ''Urban and Rural Areas Definitions'' at the beginning of your document.]

As discussed in section III.B. and III.G. of this proposed rule, we are proposing how we would implement OMB's revised standards for defining MSAs and our plan to use the New England MSAs established by OMB. These proposals relate to our policies in established regulations under § 412.63(b) governing geographic classification of hospitals for purposes of the wage index and the standardized amounts in determining the Federal rates for inpatient operating costs. In this section, we define the geographic areas for purposes of reclassification of hospitals. Therefore, consistent with our proposed changes to reflect the new definitions of CBSAs based on the Census 2000 data, effective for discharges occurring on or after October 1, 2004, we are proposing to revise § 412.63(b) and add a new § 412.64(b) to reflect the existing geographic classification definitions.

D. Equalization of Urban and Rural Standardized Amounts (§ 412.63(c) and Proposed New § 412.64)

[If you choose to comment on issues in this section, please include the caption ''Standardized Amounts'' at the beginning of your document.]

Sections 1886(d)(2)(D) and (d)(3) of the Act previously required the Secretary to compute two average standardized amounts for discharges occurring in a fiscal year: one for hospitals located in large urban areas and one for hospitals located in other areas. In addition, under sections 1886(d)(9)(B)(iii) and (d)(9)(C)(i) of the Act, the average standardized amount per discharge was determined for hospitals located in large urban and other areas in Puerto Rico. In accordance with section 1886(b)(3)(B)(i) of the Act, prior to April 1, 2003, the large urban average standardized amount was 1.6 percent higher than the other area average standardized amount. The two standardized amounts are currently equal, as discussed in the following paragraphs.

Section 402(b) of Pub. L. 108–7 required that, effective for discharges occurring on or after April 1, 2003, and before October 1, 2003, the Federal rate for all IPPS hospitals would be based on the large urban standardized amount. Subsequently, Pub. L. 108–89 extended section 402(b) of Pub. L. 108–7 to discharges occurring on or after October 1, 2003, and before April 1, 2004. Finally, section 401(a) of Pub. L. 108–173 required that, beginning with FY 2004 and thereafter, an equal standardized amount is to be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. This provision in effect makes permanent the equalization of the standardized amounts at the level of the previous standardized amount for large urban hospitals. Section 401(c) also equalizes the Puerto Rico-specific urban and other area rates.

Accordingly, we are providing in this proposed rule for a single national standardized amount and a single Puerto Rico standardized amount for FY 2005 and thereafter, as discussed in detail in the Addendum to this proposed rule. We are proposing to revise existing § 412.63 that includes the provisions related to computation of the standardized amount to make it applicable to fiscal years through FY 2004 and to establish a new § 412.64 that will include the provisions applicable to the single national standardized amount applicable for FY 2005 and subsequent years. Similarly, we are proposing to revise existing § 412.210 for Puerto Rico to make it applicable to fiscal years through FY 2004 and adding a new § 412.211 for FY 2005 and subsequent years for the Puerto Rico standardized amount. We are also proposing to make conforming changes to various other sections of the regulations to reflect the single standardized amount for the States and for Puerto Rico.

E. Reporting of Hospital Quality Data for Annual Hospital Payment Update (Proposed New § 412.64(d))

[If you choose to comment on issues in this section, please include the caption ''Hospital Quality Data'' at the beginning of your document.]

1. Background

Section 501(b) of Pub. L. 108–173 amended section 1886(b)(3)(B) of the Act to add a new subclause (vii) to revise the mechanism used to update the standardized amount for payment for inpatient hospital operating costs. Specifically, the amendment provides that the update percentage increase (also known as the market basket update) for each of FYs 2005 through 2007 will be reduced by 0.4 percentage point for any ''subsection (d) hospital'' that does not submit data on a set of 10 quality indicators established by the Secretary as of November 1, 2003. (The statutory reference to a ''subsection (d) hospital'' restricts the application of this provision to hospitals paid under the IPPS. Therefore, the provision does not apply to hospitals and hospital units excluded from the IPPS, nor to payments to hospitals under other systems such as the outpatient hospital PPS.) The statute also provides that any reduction will apply only to the fiscal year involved, and will not be taken into account in computing the applicable percentage increase for a subsequent fiscal year. This measure establishes an incentive for IPPS hospitals to submit data on the quality measures established by the Secretary.

We are proposing to implement the provisions of section 501(b) as described at the CMS Web site: *http://www.cms.hhs.gov/quality/hospital.*

At a press conference on December 12, 2002, the Secretary of HHS announced a series of steps that HHS and its collaborators are taking for public reporting of hospital quality information. These collaborators include the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, the Joint Commission on Accreditation of Healthcare Organizations, the National Quality Forum, the American Medical Association, the Consumer-Purchaser Disclosure Project, the American Association of Retired Persons, the American Federation of Labor-Congress of Industrial Organizations and the Agency for Healthcare Research and Quality, as well as CMS, QIOs, and others.

CMS began the public reporting initiative in July 2003 with a professional Web site that provides data intended for health care professionals. The professional Web site will be followed by a consumer Web site. The information on the consumer Web site will include the data from the professional Web site but in an easy-to-use format for consumers. It is intended to be an important tool for individuals to use in making decisions about their health care coverage. This information will assist beneficiaries by providing comparison information for consumers who need to select a hospital. It will also serve as a way of encouraging hospitals to adopt quality improvement strategies.

The 10 measures that were employed in this voluntary initiative as of November 1, 2003, are:

- Heart Attack (Acute Myocardial Infarction)

  Was aspirin given to the patient upon arrival to the hospital?

Was aspirin prescribed when the patient was discharged?
Was a beta-blocker given to the patient upon arrival to the hospital?
Was a beta-blocker prescribed when the patient was discharged?
Was an ACE inhibitor given for the patient with heart failure?

- Heart Failure
  Did the patient get an assessment of his or her heart function?
  Was an ACE inhibitor given to the patient?
- Pneumonia
  Was an antibiotic given to the patient in a timely way?
  Had a patient received a pneumococcal vaccination?
  Was the patient's oxygen level assessed?

These measures have been endorsed by the National Quality Forum (NQF) and are a subset of the same measures currently collected for the JCAHO by its accredited hospitals. Many hospitals are currently participating in the Department's National Voluntary Hospital Reporting Initiative (NVHRI) and are already submitting data to the QIO Clinical Warehouse. The Secretary adopted collection of data on these 10 quality measures in order to: (1) Provide useful and valid information about hospital quality to the public; (2) provide hospitals a sense of predictability about public reporting expectations; (3) begin to standardize data and data collection mechanisms; and (4) foster hospital quality improvement.

2. Requirements for Hospital Reporting of Quality Data

For the hospital reporting initiative for the Medicare annual payment update provided for under section 501(b) of Public Law 108–173, we will be collecting data on the 10 clinical measures for all patients. We refer to this program as the Reporting Hospital Quality Data for the Annual Payment Update (RHQDAPU) program to distinguish it from the continuing NVHRI.

The procedures for participating in the RHQDAPU can be found on the QualityNet Exchange at the Web site: *http://qnetexchange.org* in the ''Reporting Hospital Quality Data for Annual Payment Update Reference Checklist.'' This checklist also contains all of the forms to be completed by hospitals participating in the program. In order to participate in the RHQDAPU, hospitals must follow the following steps:

- The hospital must identify a QualityNet Exchange administrator who follows the registration process and submits the information through the QIO. This must be done, regardless of whether the hospital uses a vendor for transmission of data.
- All participants must first register with the QualityNet Exchange, regardless of the method used for data submission. If a hospital is currently participating in the voluntary reporting initiative, re-registration on the QualityNet Exchange is unnecessary. However, registration includes completion of the RHQDAPU Notice of Participation form. All hospitals must send the RHQDAPU form to their QIOs no later than August 1, 2004, for the FY 2005 update.
- The hospital must collect data for all 10 measures and submit the data to the QIO Clinical Warehouse either using the CMS Abstraction & Reporting Tool (CART), the JCAHO Oryx Core Measures Performance Measurement System (PMS), or another third-party vendor who has met the measurement specification requirements for data transmission to the QualityNet Exchange. The QIO Clinical Warehouse will submit the data to CMS on behalf of the hospitals. The submission will be done through QualityNet Exchange, which is a secure site that voluntarily meets or exceeds all current Health Insurance Portability and Accountability Act (HIPAA) requirements, while maintaining QIO confidentiality as required by law. The information in the Clinical Warehouse is considered QIO data, and therefore, is subject to the stringent confidentiality regulations in 42 CFR part 480.

Hospitals must begin the submission of data under the provisions of section 1886(b)(3)(B)(vii)(II) of the Act, as added by section 501(b) of Public Law 108–173, by July 1, 2004. Because section 501(b) of Public Law 108–173 grants a 30-day grace period for submission of data with respect to FY 2005, we are proposing to allow hospitals until August 1, 2004, for completed submissions to be successfully accepted into the QIO Clinical Warehouse. Hospitals would be required to submit data for the first calendar quarter of 2004 discharges in order to meet the requirements for the FY 2005 payment update. Hospitals participating in the NVHRI that submit the required 10 measures for the fourth calendar quarter of 2003 by the CMS-established deadline of May 15, 2004, and that meet the registration requirements for the market basket update, would be given until August 15, 2004, to submit data for the first calendar quarter of 2004. There will be no chart-audit validation criteria in place for the FY 2005 payment update beyond the CART edits, currently in force, applied to data entering the QIO Clinical Warehouse. In addition, we will estimate the minimum number of discharges anticipated to be submitted by a hospital using Medicare administrative data. We will use this anticipated minimum number to establish our expectations of the number of cases for each hospital. Hospitals that do not treat a condition or have very few discharges would not be penalized and would receive the full annual payment update if they submit all the data they do possess. New hospitals should begin collecting and reporting data immediately and complete the registration requirements for the market basket update. The same standards that are applied to established hospitals will be applied to new hospitals when determining the expected number of discharges for the calendar quarters covered for each fiscal year.

The annual payment updates will be based on the successful submission of data to CMS via the QIO Clinical Warehouse by the established deadlines. Hospitals may withdraw from RHQDAPU at any time up to August 1, 2004. Hospitals withdrawing from the program will not receive the full market basket update. Instead, they will receive a 0.4 percentage point reduction in the update. By law, a hospital's actions each fiscal year will not affect its update in a subsequent fiscal year. Therefore, a hospital must meet the requirements for RHQDAPU each fiscal year the program is in effect, and failure to receive the full update in one fiscal year will not affect its update in a succeeding fiscal year.

3. Submission of Hospital Data for FYs 2006 and 2007

For FYs 2006 and 2007, we will require hospitals to submit data quarterly, starting August 15, 2004. Eligibility for the full annual payment update will be based on the most recent four quarters of data. These data would be submitted on the same schedule for data transmission currently in force for CART data. That is, data must be submitted to the QIO Clinical warehouse no later than 15 calendar days after the fourth month following the end of the calendar quarter. This schedule is available at *http://www.qnetexchange.org*. We will establish validation requirements for submitted data for FYs 2006 and 2007. Submissions would, at a minimum, need to be accurate, timely, and complete. That is—

- The hospital-submitted data must meet minimum levels of reliability through chart audit re-abstractions over all topics. At the data element level, there must be an 80 percent agreement

between the original abstraction and the re-abstraction using the CART tool.

• The submitted data must be on schedule, pass all warehouse edits, and be successfully accepted into the warehouse.

• Completeness of submitted data will be assessed to ensure the number of submitted cases corresponds to the number of bills submitted by the hospital to CMS.

We are planning to publish the most recent 12 months of discharge data (4 quarters) for all data accepted into the warehouse and passing all validation requirements. For FY 2005, we will publish as much data as we have available. Hospitals will have the opportunity to review the information prior to posting on the CMS Web site. However, there will be no opportunity to withhold the publication of the information. The preview will only be to correct obvious errors.

4. Proposed Regulation Change

We are proposing to establish a new § 412.64(d)(2) to provide that, for FYs 2005, 2006, and 2007, the applicable percentage change is reduced by 0.4 percentage point in the case of any subsection (d) hospital that does not submit data to CMS on the 10 quality indicators established by the Secretary as of November 1, 2003. Any reduction will apply only to the fiscal year involved, and will not be taken into account in computing the applicable percentage increase for a subsequent fiscal year. We will be modifying our payment software to apply the correct updates to hospitals, depending on whether they submit the requisite data on the 10 quality indicators. We show the different standardized amounts that apply to hospitals that submit the requisite quality data, and to hospitals that do not, in the Addendum to this proposed rule.

F. Proposed Revision of the Labor-Related Share for the Hospital Wage Index (§ 412.64(h))

[If you choose to comment on issues in this section, please include the caption ''Labor-Related Share'' at the beginning of your document.]

As discussed in section III. of the preamble of this proposed rule, section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related. The portion of hospital costs attributable to wages and wage-related costs is referred to as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index. In the past, we have defined the labor-related share for prospective payment acute care hospitals as the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share for the acute care hospital inpatient prospective payment system has been calculated as the sum of the weights for wages and salaries, fringe benefits, nonmedical professional fees, contract labor, postage, and labor-intensive services. For FY 2004, the labor share of the hospital wage index was established at 71.066 percent.

Section 403 of Pub. L. 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must use 62 percent as the labor-related share unless application of this percentage ''would result in lower payments than would otherwise be made.'' However, this provision of Pub. L. 108–173 did not change the legal requirement that the Secretary estimate ''from time to time'' the proportion of hospitals' costs that are ''attributable to wages and wage-related costs.'' In fact, section 404 of Pub. L. 108–173 requires the Secretary to develop a frequency for revising the weights used in the hospital market basket, including the labor share, to reflect the most current data more frequently than once every 5 years. Section 404 further requires us to include in the final IPPS rule for FY 2006 an explanation of the reasons for, and options considered, in determining such frequency.

Under section III. of this preamble, we discuss our proposed implementation of section 1886(d)(3)(E) of the Act, as amended by section 403, as it applies to the development of the proposed FY 2005 wage index. In this section IV.F. of the preamble, we are proposing to incorporate the provisions of section 403 of Pub. L. 108–173 under a new § 412.64(h). Specifically, we are proposing to specify that CMS will adjust the proportion of the Federal rate for inpatient operating costs that are attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS based on survey data) reflecting the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined the regulations) of the hospital compared to the national average level of hospital wages and wage-related costs. The wage index would continue to be updated annually. In addition, we are proposing to specify that CMS will determine the proportion of the Federal rate that is attributable to wages and labor-related costs from time to time, employing a methodology that is described in the annual regulation updating the system of payment for inpatient hospital operating costs. However, CMS would employ 62 percent as the proportion of the rate that is adjusted for the relative level of hospital wages and wage-related costs, unless employing that percentage would result in lower payments for the hospital than employing the proportion determined under the methodology described in the preceding sentence.

G. Wage Index Adjustment for Commuting Patterns of Hospital Employees (Proposed New § 412.64(i))

[If you choose to comment on issues in this section, please include the caption ''Out-Migration of Hospital Employees'' at the beginning of your document.]

As discussed in section III.G.2.e. of this preamble, section 505 of Pub. L. 108–173 established new section 1886(d)(13) of the Act. The new section 1886(d)(13) requires that the Secretary establish a new process to make adjustments to the hospital wage index based on commuting patterns of hospital employees. The process provides for an increase in the wage index for hospitals located in certain counties that have a high percentage of hospital employees who reside in the county but work in a different area with a higher wage index. These adjustments to the wage index are effective for 3 years beginning with discharges occurring on or after October 1, 2004. Adjustments under this provision are not subject to the budget neutrality requirements at section 1886(d)(3)(E) or section 1886(d)(8)(D) of the Act.

Under section III.G.3.e of this preamble, we discuss the proposed implementation of the provisions of section 505 in developing the proposed FY 2005 wage index and the proposed applicable adjustments to that index. We are proposing in this section IV.G. of the preamble to incorporate the provisions of section 505 in the regulations by adding a new § 412.64(i).

The Secretary is required to establish criteria to identify ''qualifying counties,'' and hospitals located in the qualifying counties are to receive an adjustment to their wage index. To implement this provision, we are proposing to use commuting data compiled by the U.S. Census Bureau based on a special tabulation of Census 2000 journey-to-work data. This

information is gathered from responses to the Census long-form (sample) questions on where people worked. The resulting county-of-residence by county-of-work commuter flow file uses 108 Industrial Structure codes, developed by the Bureau of Economic Analysis. Using these data, we are able to identify the total number of hospital workers who live in each county and the number of workers within that county who commute to hospitals in other counties.

Section 1886(d)(13)(B)(i) of the Act directs the Secretary to establish a threshold percentage difference between the county's wage index and a weighted wage index of the surrounding higher wage index areas that must be met in order for the county to qualify. We are proposing to establish this threshold at any percentage greater than zero, such that any increase in the wage index resulting from this provision that is greater than zero percent would be recognized. Section 1886(d)(13)(B)(ii) of the Act specifies that the Secretary is to establish the minimum out-migration threshold in order to qualify, which may not be less than 10 percent. We are proposing to establish the out-migration threshold at the minimum 10 percent.

Section 1886(d)(13)(B)(iii) of the Act requires that the average hourly wage for all hospitals in the county must be equal to or exceed the average hourly wage for all hospitals in the labor market area. Section 1886(d)(13)(E) of the Act indicates this process may be based on the process used by the MGCRB. This section also gives the Secretary the authority to require hospitals to submit data necessary to implement this provision, or to use other data sources as available. To compute this requirement, we are proposing to determine the average of hospitals' 3-year average hourly wage for all hospitals in a given county. We would compare this county average hourly wage to the 3-year average hourly wage for the labor market area where the county is located. We are proposing to use the 3-year average hourly wage because we believe it gives a better estimate for the wages paid by a given hospital over a period of time. This statutory requirement limits the number of eligible counties.

Section 1886(d)(13)(A) of the Act allows the Secretary to establish the process through application or otherwise for this adjustment to the wage index. We are proposing not to use an application process. Rather, all hospitals located in qualifying counties would automatically receive the increase in wage index, unless the hospital has already been reclassified to another geographic area for purposes of wage index or standardized amount. This wage index increase would be effective for a period of 3 fiscal years, FY 2005 through FY 2007.

Hospitals receiving this wage index increase under section 1886(d)(13)(F) of the Act are not eligible for reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act. Therefore, consistent with § 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. Hospitals that withdraw their application for reclassification would then automatically receive the commuting wage index adjustment. The request for withdrawal of an application for reclassification or termination of an existing 3-year reclassification that would be effective in FY 2005 must be received by the MGCRB within 45 days of the publication of this proposed rule.

H. Additional Payments for New Medical Services and Technology: Proposed Policy Changes (§§ 412.87 and 412.88)

[If you choose to comment on issues in this section, please include the caption ''New Technology Threshold'' at the beginning of your document.]

As discussed in section II.D. of this proposed rule, sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies under the IPPS, effective for discharges beginning on or after October 1, 2001. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that the process must apply to a new medical service or technology if, ''based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.'' Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered ''new'' if it meets criteria established by the Secretary after notice and opportunity for public comment.

Sections 1886(d)(5)(K)(ii) through (d)(5)(K)(vi) of the Act further provide—

- For an additional payment for new medical services and technology in an amount beyond the DRG prospective payment system payment rate that adequately reflects the estimated average costs of the service or technology.
- That the requirement for an additional payment for a new service or technology may be satisfied by means of a new technology group (described in section 1886(d)(5)(L) of the Act), an add-on payment, a payment adjustment, or any other similar mechanism for increasing the amount otherwise payable with respect to a discharge.
- For the collection of data relating to the cost of a new medical service or technology for not less than 2 years and no more than 3 years after an appropriate inpatient hospital services code is issued. The statute further provides that discharges involving new services or technology that occur after the collection of these data will be classified within a new or existing DRG group with a weighting factor derived from cost data collected for discharges occurring during such period.

Section 412.87(b)(1) of our existing regulations provides that a new technology will be an appropriate candidate for an additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries (see the September 7, 2001 final rule (66 FR 46902)). Section 412.87(b)(3) provides that, to receive special payment treatment, new technologies meeting this clinical definition must be demonstrated to be inadequately paid otherwise under the DRG system.

In the August 1, 2003 final IPPS rule, we revised the threshold amount for determining if payment for a new technology or medical service is inadequate, effective for FY 2005 and subsequent fiscal years (68 FR 45392). We lowered the previously established threshold of 1 standard deviation to 75 percent of 1 standard deviation (based on the logarithmic values of the charges) beyond the geometric mean standardized charges for all cases in the DRG to which the new technology is assigned (or the case-weighted average of all relevant DRGs, if the new technology occurs in many different DRGs), transformed back to charges.

Section 503(b) of Pub. L. 108–173 amended section 1886(d)(5)(K)(ii)(I) of the Act to specify that in determining whether payments for a new technology or medical service are inadequate, the Secretary is to determine and apply a threshold amount that is the ''lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of 1 standard deviation for the DRG involved.'' As a result of enactment of section 503(b), we are proposing to revise our regulations at § 412.87(b)(3)

to incorporate the revised threshold amount.

The report language accompanying section 533 of Pub. L. 106–554 indicated Congressional intent that the Secretary implement the new mechanism on a budget neutral basis (H.R. Conf. Rep. No. 106–1033, 106th Cong., 2nd Sess., at 897 (2000)). Section 1886(d)(4)(C)(iii) of the Act requires that the adjustments to annual DRG classifications and relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. Therefore, in the past, we accounted for projected payments under the new medical service and technology provision during the upcoming fiscal year at the same time we estimated the payment effect of changes to the DRG classifications and recalibration. The impact of additional payments under this provision was then included in the budget neutrality factor, which was applied to the standardized amounts and the hospital-specific amounts.

To balance appropriately the Congressional intent to increase Medicare payments for eligible new technologies with concern that the total size of those payments not result in significantly reduced payments for other cases, we set a target limit for estimated add-on payments for new technology under the provisions of sections 1886(d)(5)(K) and (L) of the Act at 1.0 percent of estimated total operating prospective payments. In accordance with § 412.88(c) of the regulations, if the target limit was exceeded, we would reduce the level of payments for approved technologies across the board, to ensure estimated payments did not exceed the limit.

Section 503(d)(1) of Pub. L. 108–173 amended section 1886(d)(5)(K)(ii)(III) of the Act to remove the budget neutrality provision for add-on payments for a new medical service or technology. Section 503(d)(2) specifies that ''There shall be no reduction or other adjustment to payments under section 1886 of the Social Security Act because an additional payment is provided'' for new technology. Accordingly, as a result of the enactment of section 503(d) of Pub. L. 108–173, we will no longer include the impact of additional payments for new medical services and technologies in the budget neutrality factor. In addition, we are proposing to delete § 412.88(c) of the regulations.

I. Rural Referral Centers (§ 412.96)

[If you choose to comment on issues in this section, please include the caption ''Rural Referral Centers'' at the beginning of your document.]

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center. For discharges occurring before October 1, 1994, rural referral centers received the benefit of payment based on the other urban standardized amount rather than the rural standardized amount. Although the other urban and rural standardized amounts are the same for discharges occurring on or after October 1, 1994, rural referral centers continue to receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Pub. L. 108–173 raised the DSH adjustment for other rural hospitals with less than 500 beds and rural referral centers. Other rural hospitals with less than 500 beds are subject to a 12–percent cap on DSH payments. Rural referral centers are not subject to the 12.0 percent cap on DSH payments that is applicable to other rural hospitals (with the exception of rural hospitals with 500 or more beds). Rural referral centers are not subject to the proximity criteria when applying for geographic reclassification, and they do not have to meet the requirement that a hospital's average hourly wage must exceed 106 percent of the average hourly wage of the labor market area where the hospital is located.

As discussed in **Federal Register** documents at 62 FR 45999 and 63 FR 26325, under section 4202 of Pub. L. 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 median case-mix index value for FY 2005 includes all urban hospitals nationwide, and the proposed regional values for FY 2005 are the median values of urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals receiving indirect medical education payments as provided in § 412.105). These proposed values are based on discharges occurring during FY 2003 (October 1, 2002 through September 30, 2003) and include bills posted to CMS' records through December 2003.

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, 2004, rural hospitals with fewer than 275 beds must have a case-mix index value for FY 2003 that is at least—

- 1.3550; or
- The median case-mix index value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 412.105) calculated by CMS for the census region in which the hospital is located.

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)	1.2400
2. Middle Atlantic (PA, NJ, NY)	1.2387
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.3249
4. East North Central (IL, IN, MI, OH, WI)	1.2661
5. East South Central (AL, KY, MS, TN)	1.2777
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.1787
7. West South Central (AR, LA, OK, TX)	1.3043
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.3527
9. Pacific (AK, CA, HI, OR, WA)	1.3095

The preceding numbers will be revised in the final rule to the extent required to reflect the updated FY 2001 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 2001 (that is, October 1, 2000 through September 30, 2001), which is the latest available cost report data we have at this time. In last year's final rule we inadvertently indicated that we relied upon data regarding discharges occurring during FY 2002. However, we have now determined that our values were based upon data regarding discharges occurring during FY 2000.

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, 2004, must have as the number of discharges for its cost reporting period that began during FY 2001 a figure that is at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located, as indicated in the following table:

Region	Number of discharges.
1. New England (CT, ME, MA, NH, RI, VT)	8,212
2. Middle Atlantic (PA, NJ, NY)	9,574
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,303
4. East North Central (IL, IN, MI, OH, WI)	8,684
5. East South Central (AL, KY, MS, TN)	7,624
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	6,789
7. West South Central (AR, LA, OK, TX)	6,485
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,489
9. Pacific (AK, CA, HI, OR, WA)	6,274

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

We reiterate that if an osteopathic hospital is to qualify for rural referral center status for cost reporting periods beginning on or after October 1, 2004, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2001.

J. Additional Payments to Hospitals With High Percentage of End-Stage Renal Disease (ESRD) Discharges (§ 412.104)

[If you choose to comment on issues in this section, please include the caption ''ESRD Discharges'' at the beginning of your document.]

Under existing regulations at § 412.104(a), CMS provides for additional Medicare payments to a hospital for inpatient dialysis provided to Medicare beneficiaries with end-stage renal disease (ESRD) if the hospital's ESRD Medicare beneficiary discharges are 10 percent or more of its total Medicare discharges. This provision states that discharges classified into DRG 302 (Kidney Transplant), DRG 316 (Renal Failure), or DRG 317 (Admit for Renal Dialysis) are excluded for purposes of determining a hospital's eligibility for this special payment. We have been informed that, under this provision, hospitals may be counting all discharges of ESRD Medicare beneficiaries towards determining the 10 percent factor rather than counting only those discharges where the ESRD beneficiary received inpatient dialysis.

When we established this regulation in the August 31, 1984 final rule (49 FR 34747), we stated that this special payment was intended to ameliorate those circumstances in which the concentration of ESRD beneficiaries receiving inpatient dialysis may be such that the hospital would not be able to absorb the entire expense with revenue from other less costly cases. We further stated that we believed those few hospitals most extremely impacted by the ESRD beneficiary population should be afforded some protection against the chance of encountering inpatient dialysis expenses that could not be offset by revenue from cases in which the DRG payment was greater than the hospital's cost. Because this special payment is intended to limit the adverse impact on hospitals delivering inpatient dialysis services to ESRD beneficiaries, we firmly believe that only those

discharges of beneficiaries who receive dialysis services during an inpatient stay should be counted in determining a hospital's eligibility for the additional payment. After a careful review of § 412.104(a), we acknowledge that hospitals may require additional guidance in appropriately determining their eligibility for this special payment. Therefore, we are proposing to revise § 412.104(a) to make it clear that, in determining a hospital's eligibility for the additional Medicare payment, only discharges involving ESRD Medicare beneficiaries who have received a dialysis treatment during an inpatient hospital stay are to be counted. This proposed change would be applied prospectively, effective for cost reporting periods beginning on or after October 1, 2004.

K. Indirect Medical Education (IME) Adjustment (§ 412.105)

[If you choose to comment on issues in this section, please include the caption ''IME Adjustment'' at the beginning of your document.]

1. IME Adjustment Factor Formula Multipliers (Section 502(a) of Public Law 108–173 and Existing § 412.105(d)(3)(vii) and Proposed § 412.105(d)(3)(viii) Through (d)(3)(xii) of the Regulations)

Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals that have residents in an approved graduate medical education (GME) program receive an additional payment to reflect the higher indirect costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment, known as the indirect medical education (IME) adjustment, are located at § 412.105. The IME adjustment is based in part on the applicable IME adjustment factor. The IME adjustment factor is calculated using a hospital's ratio of residents to beds, which is represented as r, and a formula multiplier, which is represented as c, in the following equation: $c \times [\{1 + r\}^{.405} - 1]$. The formula is traditionally described in terms of a certain percentage increase in payment for every 10-percent increase in the resident-to-bed ratio.

Section 502(a) of Pub. L. 108–173 modified the formula multiplier c to be used in the calculation of the IME adjustment. Prior to enactment of Pub. L. 108–173, the formula multiplier was fixed at 1.35 for discharges occurring during FY 2003 and thereafter. Section 502(a) modifies the formula multiplier beginning midway through FY 2004 and provides for a new schedule of formula multipliers for FYs 2005 and thereafter as follows:

- For discharges occurring on or after April 1, 2004, and before October 1, 2004, the formula multiplier is 1.47.
- For discharges occurring during FY 2005, the formula multiplier is 1.42.
- For discharges occurring during FY 2006, the formula multiplier is 1.37.
- For discharges occurring during FY 2007, the formula multiplier is 1.32.
- For discharges occurring during FY 2008 and fiscal years thereafter, the formula multiplier is 1.35.

We are proposing to revise § 412.105(d)(3)(vii) and add § 412.105(d)(3)(viii) through (d)(3)(xii) to incorporate these changes in the formula multipliers.

2. IME Adjustment Formula Multiplier for Redistributed FTE Resident Slots (Section 422(b)(1)(C) of Pub. L. 108–173)

Under new section 1886(h)(7)(B) of the Act, added by section 422(a) of Pub. L. 108–173, a hospital may receive an increase in its FTE resident cap as a result of the agency's redistribution of unused resident positions. (This provision is discussed in detail in section IV.J.2. of the preamble of this proposed rule.) Section 422(b)(1)(C) of Pub. L. 108–173 amended section 1886(d)(5)(B) of the Act to add a new subclause (ix) to provide that, for discharges occurring on or after July 1, 2005, for a hospital whose FTE resident cap is increased as a result of a redistribution of unused resident positions, the IME adjustment factor is to be calculated using a formula multiplier of 0.66 with respect to any additional residents counted by the hospital as a result of that increase in the hospital's FTE resident cap. Thus, we are proposing that a hospital that counts additional residents as a result of an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act would receive IME payments based on the sum of two different IME adjustment factors: (1) An IME adjustment factor that is calculated using the schedule of formula multipliers described in section IV.G.1. of this preamble established by section 502(a) of Pub. L. 108–173, and which also uses the hospital's number of FTE residents, not including residents attributable to an FTE cap increase under section 1886(h)(7)(B) of the Act, in the numerator of the resident-to-bed ratio; and (2) an IME adjustment factor that is calculated using the formula multiplier of 0.66, and the additional number of FTE residents that are attributable to the increase in the hospital's FTE resident cap under section 1886(h)(7)(B) of the Act in the numerator of the resident-to-bed ratio. (The number of available beds used in the denominator would be the same for both IME adjustments.)

We note that section 422(b) of Pub. L. 108–173, which addresses the application of the IME adjustment to the residents counted as a result of an increase in a hospital's FTE resident cap under section 422(a), makes no reference to section 1886(d)(5)(B)(vi) of the Act. That is, the statute does not provide for an exclusion from application of the cap on the resident-to-bed ratio at section 1886(d)(5)(B)(vi)(I) of the Act or from application of the rolling average count at section 1886(d)(5)(B)(vi)(II) of the Act for residents added as a result of FTE cap increases under section 1886(h)(7)(B). There is no specific pronouncement in section 422 exempting residents counted as a result of the FTE resident cap increases under section 422(a) from the cap on the resident-to-bed ratio and the rolling average, and we see no apparent reason to treat those residents differently for purposes of these two provisions. Therefore, we are proposing to require that if a hospital increases its IME FTE count of residents as a result of section 1886(h)(7)(B) of the Act, those FTE residents are immediately subject to the cap on the resident-to-bed ratio and the rolling average calculation. Furthermore, we believe that, given potentially significant shifts of FTE positions among hospitals as a result of the new section 1886(h)(7) of the Act, the inclusion of FTE residents added as a result of section 1886(h)(7)(B) of the Act in the cap on the resident-to-bed ratio and in the rolling average introduces a measure of stability and predictability, and mitigates radical shifts in IME payments from period to period. Thus, a hospital's increase in IME payment may be delayed for one year to the extent that the resident-to-bed ratio for the current cost reporting period is capped by the resident-to-bed ratio for the previous cost reporting period. Further, the additional FTE residents would be phased in over a 3-year period in the hospital's FTE count because they are immediately included in the rolling average calculation.

The following illustrates how the IME payment would be calculated for a hospital that receives an increase to its FTE resident cap as a result of section 1886(h)(7)(B) of the Act. For example, Hospital A has a fiscal year end (FYE) of September 30, and a 1996 IME FTE cap of 20 FTEs. During its FYEs September 30, 2003, September 30, 2004, and September 30, 2005, Hospital A trains 25 FTE residents. Effective July 1, 2005, under section 1886(h)(7)(B) of

the Act, Hospital A receives an increase to its IME 1996 cap of 5 FTEs, for a total adjusted IME cap of 25 FTEs. Hospital A has maintained an available bed count of 200 beds in FYE September 30, 2004 and throughout FYE September 30, 2005. For the FYE September 30, 2005 cost report, the IME adjustment factor is calculated as follows:

Step 1. For discharges occurring on October 1, 2004, through September 30, 2005 for residents NOT counted pursuant to section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: 20+20+20/3 = 20.
- Current year resident-to-bed ratio: 20/200 = .10.
- Cap on resident-to-bed ratio (from prior year): 20/200 = .10.
- Compare, and use the lower of, prior year resident-to-bed ratio and current year resident-to-bed ratio: .10 = .10.
- Compute IME adjustment factor: $1.42 \times [\{1 + .10\}^{.405} - 1] = 0.0559$.

Step 2. For discharges occurring on July 1, 2005 through September 30, 2005 for residents counted pursuant to section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: 25+20+20/3 = 21.7.
- Resident-to-bed ratio for 7/1/05–9/30/05: 21.7/200 = .11.
- Cap on resident-to-bed ratio (from prior year): 20/200 = .10.
- Compare, and use the lower of, prior year resident-to-bed ratio and resident-to-bed ratio for 7/1/05–9/30/05: .10 < .11. Capped by prior year ratio of .10.
- Compute IME adjustment factor: $0.66 \times [\{1 + 0\}^{.405} - 1] = 0.0$.

In this example, the addition of 5 FTE residents under section 1886(h)(7)(B) caused Hospital A's resident-to-bed ratio for discharges occurring on July 1, 2005, through September 30, 2005, to exceed the resident-to-bed ratio of .10 from the prior year. Since the multiplier of 0.66 is to be used for determining IME payment ''insofar as an additional payment amount * * * is attributable to resident positions redistributed to a hospital * * *'' under section 1886(d)(5)(B)(v) of the Act, as amended by section 422(b)(1)(C) of Pub. L. 108–173, Hospital A does not receive any IME payment attributable to the 5 FTE residents added as a result of section 1886(h)(7)(B) of the Act for discharges occurring on July 1, 2005, through September 30, 2005. As shown under the fifth bullet point in Step 2 of the example above, a resident-to-bed ratio of zero is used to compute the IME adjustment for FTE residents attributable to increases in the FTE resident cap under section 1886(h)(7)(B) of the Act for discharges occurring on or after July 1, 2005 and on or before September 30, 2005. The ratio of .10 would not be used to compute the IME adjustment for FTE residents attributable to an increase in the FTE resident cap under section 1886(h)(7)(B) because the ratio of .10 is attributable to the 20 FTE residents from the prior year, and is not related to residents added under section 1886(h)(7)(B) of the Act. (We note that a hospital's resident-to-bed ratio in the current year might decrease despite residents added as a result of section 1886(h)(7)(B) of the Act, due to an increase in the number of available beds in the denominator of the current year resident-to-bed ratio. In such a case, because the current year ratio would be less than the prior year ratio, the hospital's resident-to-bed ratio would not be capped by the prior year resident-to-bed ratio, and, therefore, the hospital could receive an IME payment in the current year (that is, there would not be a 1-year delay) relating to residents added under section 1886(h)(7)(B) of the Act).

However, an increase in the resident-to-bed ratio in the current period may establish a higher cap for the following period, and, all other things being equal, a hospital could then receive IME payment for FTE residents added as a result of section 1886(h)(7)(B) of the Act after a 1-year lag. In the example above, Hospital A would receive an IME payment for residents added as a result of section 1886(h)(7)(B) of the Act in its cost reporting period ending September 30, 2006, as follows:

Step 1. For residents NOT counted pursuant to section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: 20+20+20/3 = 20.
- Current year resident-to-bed ratio: 20/200 = .10.
- Cap on resident-to-bed ratio (from prior year): 20/200 = .10.
- Compare, and use the lower of, prior year resident-to-bed ratio and current year resident-to-bed ratio: .10 = .10.
- Compute IME adjustment factor: $1.37 \times [\{1 + .10\}^{.405} - 1] = 0.0559$.

Step 2. For 5 FTE residents counted pursuant to with section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: 25+25+20/3 = 23.3.
- Resident-to-bed ratio for FYE 9/30/06: 23.3/200 = .12.
- Cap on resident-to-bed ratio (from prior year): 25/200 = .13.
- Compare, and use the lower of, prior year resident-to-bed ratio and current year resident-to-bed ratio: .13 >.12. Current year ratio of .12 is the lower of the two.
- Take the difference between the rolling average count of FTE residents counted as a result of section 1886(h)(7)(B) of the Act, and the rolling average count of FTE residents *not* counted as a result of section 1886(h)(7)(B) of the Act, (rolling average count under step 2 minus rolling average count under step 1): 23.3 − 20 = 3.3.
- Compute current year resident-to-bed ratio attributable to residents added under section 1886(h)(7)(B): 3.3/200 = 0.02.
- Compute IME adjustment factor: $0.66 \times [\{1 + .02\}^{.405} - 1] = 0.0053$.

Step 3. Compute IME payment for FYE September 30, 2006: [Total DRG payments for discharges occurring on October 1, 2005 through September 30, 2006] × [0.0592] (that is, 0.0539 + 0.0053).

We are proposing to revise § 412.105 to incorporate these changes under proposed new paragraph (d)(4), proposed new paragraph (e)(2), proposed new paragraph (f)(1)(iv)(B), and proposed added new last sentence of paragraph (f)(1)(v).

3. Technical Changes

- In § 412.105(a)(1), introductory text, we include a cross-reference to ''paragraph (f) and (h)'' of § 412.105. Paragraph (h) no longer exists in this section. Therefore, we are proposing to remove the cross-reference to paragraph (h).
- In § 412.105(f)(1)(i)(A), we reference national organizations listed in § 415.200(a). The cross-reference to § 415.200(a) is incorrect. We are proposing to correct the cross-reference to read ''§ 415.152.''
- In section IV.O. of this preamble, we discuss our proposal to redesignate existing § 413.86 governing payments for direct costs of GME to nine separate sections. Many of the paragraphs in the existing § 413.86 are cited in § 412.105 governing the IME adjustment. We are proposing to make changes to the cross-reference in § 412.105 to conform them to these proposed redesignated separate sections.

L. Payment to Disproportionate Share Hospitals (DSHs) (Section 402 of Pub. L. 108–173 and § 412.106 of Existing Regulations)

[If you choose to comment on issues in this section, please include the caption ''DSH Adjustment'' at the beginning of your document.]

1. Enhanced DSH Adjustment for Rural Hospitals and Urban Hospitals With Fewer Than 100 Beds

Section 1886(d)(5)(F) of the Act provides for additional payments to subsection (d) hospitals that serve a disproportionate share of low-income patients. The Act specifies two methods for a hospital to qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to indigent patients. These hospitals are commonly known as ''Pickle hospitals.'' The second method, which is also the most commonly used method for a hospital to qualify, is based on a complex statutory formula under which payment adjustments are based on the level of the hospital's DSH patient percentage, which is the sum of two computations. 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 payment adjustments for urban hospitals with 100 or more beds and rural hospitals with 500 or more beds, hospitals that qualify as RRCs or SCHs, and other hospitals.

Effective April 1, 2004, section 402 of Public Law 108–173 amended section 1886(d)(5)(F) of the Act to revise the formulae used to calculate DSH payment adjustments for certain hospitals that qualify for the adjustments under the second method. Specifically, under the new section 1886(d)(5)(F)(xiv), added by section 402, for hospitals that are not large urban or large rural hospitals, DSH payments are calculated using the same DSH adjustment formula used for large urban hospitals. However, the DSH payment adjustment for most of these categories of hospitals, except for hospitals classified as RRCs, including RRCs that are also SCHs, is capped at 12 percent. In addition, the formula for large urban hospitals with 100 beds or more, and large rural hospitals with 500 beds or more, has not been revised by section 402. Finally, Pickle hospitals are not affected by this change; they will continue to receive a DSH adjustment under the alternative formula.

Effective for discharges occurring on or after April 1, 2004, the following DSH payment adjustment formulae apply for the following specified categories of hospitals:

- For urban hospitals with fewer than 100 beds and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent: (Disproportionate patient percentage − 15 percent) (65 percent) + 2.5 percent.
- For urban hospitals with fewer than 100 beds and whose disproportionate patient percentage is greater than 20.2: (Disproportionate patient percentage − 20.2 percent) (82.5 percent) + 5.88 percent.

For urban hospitals with fewer than 100 beds, the maximum DSH payment adjustment is 12 percent.

- For rural hospitals that are SCHs and are not RRCs and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent: (Disproportionate patient percentage − 15 percent) (65 percent) + 2.5 percent.
- For rural hospitals that are SCHs and are not RRCs and whose disproportionate patient percentage is greater than 20.2 percent: (Disproportionate patient percentage − 20.2 percent) (82.5 percent) + 5.88 percent.

For rural hospitals that are SCHs and are not RRCs, the maximum DSH payment adjustment is 12 percent.

- For RRCs whose disproportionate patient percentage is greater than or equal to 15 percent and less than or equal to 20.2 percent: (Disproportionate patient percentage − 15 percent) (65 percent) + 2.5 percent.
- For RRCs whose disproportionate patient percentage is greater than 20.2 percent: (Disproportionate patient percentage − 20.2 percent) (82.5 percent) + 5.88 percent.
- For rural hospitals that are both RRCs and SCHs and whose disproportionate patient percentage is greater than or equal to 15 percent and less than or equal to 20.2 percent: (Disproportionate patient percentage − 15 percent) (65 percent) + 2.5 percent.
- For rural hospitals that are both RRCs and SCHs whose disproportionate patient percentage is greater than 20.2 percent: (Disproportionate patient percentage − 20.2 percent) (82.5 percent) + 5.88 percent.
- For rural hospitals with fewer than 500 beds and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent: (Disproportionate patient percentage − 15 percent) (65 percent) + 2.5 percent.
- For rural hospitals with fewer than 500 beds and whose disproportionate patient percentage is greater than 20.2 percent: (Disproportionate patient percentage − 20.2 percent) (82.5 percent) + 5.88 percent.

For rural hospitals with fewer than 500 beds, the maximum DSH payment adjustment is 12 percent.

These revised formulae, which became effective for discharges occurring on or after April 1, 2004, were implemented through a CMS One-Time Notification (CR 3158), issued on March 26, 2004. The notice describes the changes required by section 402 of Public Law 108–173. In this proposed rule, we are proposing to revise §§ 412.106 (d)(2)(ii), (d)(2)(iii), and (d)(2)(iv) of the regulations to reflect these statutory revisions.

The following DSH formulae were not affected by the changes made by section 402 of Pub. L. 108–173 and remain in effect:

- For urban hospitals with 100 beds or more and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent: (Disproportionate patient percentage − 15 percent) (65 percent) + 2.5 percent.
- For urban hospitals with 100 beds or more and whose disproportionate patient percentage is greater than 20.2 percent: (Disproportionate patient percentage − 20.2 percent) (82.5 percent) + 5.88 percent.
- For rural hospitals with 500 beds or more and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent: (Disproportionate patient percentage − 15 percent) (65 percent) + 2.5 percent.
- For rural hospitals with 500 beds or more and whose disproportionate patient percentage is greater than 20.2 percent: (Disproportionate patient

percentage −20.2 percent) (82.5 percent) + 5.88 percent.

2. Proposals for Available Beds and Patient Days for the DSH Adjustment

In our May 19, 2003 IPPS proposed rule for FY 2004 (68 FR 27201), we proposed changes to our policy on counting available beds and patient days for the purposes of the DSH adjustment. For the available beds policy we proposed changes to counting unoccupied beds and observation beds. In regard to patient days, we proposed changes to counting dual-eligible and Medicare+Choice (M+C) days. Due to the number and nature of the public comments received, we did not respond to the public comments on these proposals in the final rule for FY 2004 (68 FR 45415). We indicated that we would address those public comments in a separate document. We plan to address the comments regarding unoccupied beds, observation beds, dual eligible days, and M+C days in the IPPS final rule for FY 2005.

M. Payment Adjustments for Low-Volume Hospitals (Proposed New § 412.101)

[If you choose to comment on issues in this section, please include the caption ''Low-Volume Hospital Adjustment'' at the beginning of your document.]

Section 406 of Pub. L. 108–173 amended section 1886(d) of the Act to add a new subclause (12) to provide for a new payment adjustment to account for the higher costs per discharge of low-volume hospitals under the IPPS. Section 1886(d)(12)(C)(i) of the Act, as added by section 406, defines a low-volume hospital as a ''subsection (d) hospital . . . that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year.'' Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term ''discharge'' refers to total discharges, and not merely to Medicare discharges. Specifically, the term refers to the ''inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under part A.'' Finally, the provision requires the Secretary to determine an applicable percentage increase for these low-volume hospitals based on the ''empirical relationship'' between ''the standardized cost-per-case for such hospitals and the total number of discharges of these hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.'' The statute thus mandates the Secretary to develop an empirically justifiable adjustment formula based on the relationship between costs and discharges for these low-volume hospitals. The statute also limits the adjustment to no more than 25 percent.

MedPAC has published an analysis of the financial performance and cost profiles of low-volume hospitals (MedPAC June 2001 Report to Congress, page 66). Its analysis indicated that hospitals with 500 discharges or less generally have negative Medicare margins. Specifically, hospitals with 200 discharges or less have margins of −16.4 percent, and hospitals with 201 to 500 discharges have margins of −2.1 percent. MedPAC's analysis further revealed that hospitals with a small volume of discharges have higher costs per discharge than larger facilities, after controlling for the other cost factors recognized in the payment system. MedPAC's analysis thus indicates that low-volume providers are disadvantaged by payment rates based on average volume. In analyzing the relationship between costs per case and discharges, MedPAC also found that this relationship begins to level off and reaches zero variation at around 500 discharges. Therefore, MedPAC recommended an adjustment formula in the form of:

1.25 = (.0005*D), if D<500 discharges

Where 1.25 represents the maximum 25-percent add-on, .0005 is the payment adjustment per case (derived by dividing .25 by 500 discharges) and ''D'' is the number of discharges.

Using FY 2001 cost report data, we found an even larger disparity than MedPAC found between low-volume providers and their higher-volume counterparts. Although Medicare margins remain healthy overall at 9.32 percent, the Medicare margin for providers with 200 or less discharges is −46.26 percent, and the margin for providers with 201 to 500 discharges is −11.74 percent. We employed a bivariate regression analysis to determine the fit between total hospital discharges and operating costs from FY 2001. For the final rule, we plan to conduct more detailed multivariate analyses. We have some concerns about whether we have sufficient information (for example, total hospital case-mix) to support valid multivariate analyses. We are continuing to examine this in preparation for the final rule.

We found a very strong correlation between costs and the total number of discharges. We then examined the variation in cost-per-case among subsection (d) hospitals, using both log and nonlog functions. When the analysis was limited to hospitals with fewer than 1,000 discharges, we found a strong relationship between cost per case and low volume. We found that the greatest variation from the mean costs per case exists between 1 and 150 discharges, indicating (as MedPAC also found) that hospitals with the lowest case volume generally experience greater costs per case than hospitals with higher volume. However, after about 150 discharges, the trend line begins to level off rapidly. The trend line reaches zero variation from mean cost per case at approximately 450 discharges (cost per case in log form) or 500 discharges (nonlog form). Immediately after that point, the trend line in both forms becomes negative, while still maintaining a very smooth line. Both because of where the trend line crosses zero and because there is very little variation from the mean after this point, we believe that 500 discharges is the appropriate cutoff for an add-on payment under this provision.

Based on these results, we are proposing to adopt a slightly revised version of MedPAC's recommended formula for an add-on payment to low-volume hospitals:

Adjustment = 1.25 − (.0005*D), if 0<D≤ 500 discharges

Where 1.25 represents the maximum 25 percent add-on, .0005 is the payment adjustment per case (derived by dividing .25 by 500 discharges) and ''D'' is the number of discharges. We are proposing to revise the MedPAC recommended formula by adding the condition that ''D>0'' in order to avoid the anomalous result that a hospital without any discharges would qualify for the maximum 25-percent adjustment.

We note that, under this formula, some hospitals that meet the statutory definition of low-volume hospital would receive no adjustment. Specifically, hospitals with more than 500 but fewer than 800 total discharges for the year would receive no adjustment under this formula. Despite the statutory definition of a low-volume hospital as a subsection (d) hospital that has less than 800 discharges during the fiscal year, the statutory provision mandating this adjustment also requires the Secretary to determine the empirical relationship between the standardized cost-per-case, the total number of discharges, and the amount of incremental costs associated with the number of discharges. In addition, the provision requires that the applicable percentage increase shall be ''based upon such relationship in a manner that

reflects * * * such incremental costs.'' We believe that the statutory language thus gives the Secretary the flexibility to set the percentage increase at zero for a given number of discharges if the empirical evidence shows that hospitals experience no higher incremental costs when they reach that number of discharges. In other words, the statute does not require the Secretary to provide an adjustment in the absence of empirical evidence that an adjustment is warranted by higher incremental costs.

While the statute defines low-volume hospitals in terms of total inpatient acute care discharges and mandates that the adjustment be based upon the amount of incremental costs associated with the number of discharges, it does not specify whether the count of discharges, either for purposes of the definition or the payment adjustment formula, should be based on the payment year or some previous year. Specifically, the statute defines low-volume hospital as ''for *a fiscal year,* a subsection (d) hospital * * * [that] has less than 800 discharges during *the fiscal year'' (emphasis added).*

We believe that this statutory language gives us the flexibility to define which fiscal year to use in determining the number of discharges, both for purposes of the definition of ''low-volume hospital'' and the payment adjustment formula. Prospective payment systems place substantial value on providing hospitals with predictability regarding payments. If the determination of whether hospitals qualify for low-volume payment adjustments and the computation of the payment adjustment amount are based on the number of discharges in the current fiscal year, neither CMS nor the hospital will know with certainty whether a hospital qualifies for the adjustment, or what the amount of the adjustment would be, until after the end of the payment year (probably not until the time of final cost report settlement for the year). In such circumstances, CMS could be faced with the prospect of recouping large overpayments in some cases or reimbursing for large underpayments in others. Hospitals would face similar uncertainties. On the other hand, if these determinations are based on discharge counts from a prior fiscal year, hospitals will know in advance whether they will be receiving a payment adjustment and what the size of the adjustment will be. Both hospitals and CMS will be able to plan accordingly.

Therefore, we are proposing to base the count of discharges, for purposes both of meeting the qualifying definition and determining the amount of the payment adjustment, on the number of inpatient acute care discharges occurring during the cost reporting period for the most recent submitted cost report. We recognize that this policy may temporarily disadvantage certain hospitals. For example, a hospital that had more than 500 discharges in its most recent submitted cost report may have fewer than 500 discharges during the first fiscal year in which this low-volume payment adjustment is available. Such a hospital would not qualify for the low-volume adjustment during the first fiscal year of the adjustment under the policy that we are proposing, but it would qualify under alternative policy of basing the discharge count on the fiscal year for which payment is made. However, even in such cases, the hospital would not be certain about whether it would receive an adjustment until its cost report for the payment year is settled. In addition, under the policy we are now proposing, the hospital would still be certain of receiving a low-volume adjustment for any fiscal year in which it had 500 or fewer discharges. The hospital would receive the adjustment during the fiscal year after the cost report is submitted for any fiscal year in which the hospital had 500 discharges or less.

A further implication of this proposed policy is that a new hospital would not receive an adjustment during its first year of operation, even if it has fewer than 500 total discharges during that year. While this approach is somewhat disadvantageous for hospitals in their first year of existence, we believe that it is justified in order to avoid setting up a settlement process to finalize payments under this new proposed adjustment. Therefore, we are proposing that new hospitals that meet the distance requirement would not be eligible for the adjustment until data become available to determine that the annual number of discharges is 500 or less. Under this approach, new hospitals would not receive a low-volume adjustment during at least the first 2 years of their existence. (This is generally the amount of time that elapses before submission of a cost report.) This treatment is consistent with the treatment of some existing hospitals, for example, hospitals that have declining numbers of discharges, and would not be eligible for the adjustment until their data show 500 or fewer discharges.

As we noted above, the statute defines a low-volume hospital as a subsection (d) hospital that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year. In order to enforce the requirement that a qualifying hospital must be located more than 25 miles from another PPS hospital, we are proposing that a hospital that wishes to qualify for the adjustment must provide its fiscal intermediary with evidence that it meets this distance requirement. The intermediary will then certify, on the basis of the evidence presented by the hospital and any other relevant evidence that it may be able to develop, that the hospital meets this requirement. Other relevant evidence may include maps, mapping software, and inquiries to State and local police, transportation officials, or other government officials.

We are proposing to add a new § 412.101 to incorporate the provisions of section 406 of Public Law 108–173.

N. Medicare Geographic Classification Review Board (MGCRB) Reclassifications (§§ 412.230, 412.234, and 412.236)

[If you choose to comment on issues in this section, please include the caption ''Hospital Reclassifications'' at the beginning of your document.]

1. Background

With the creation of the MGCRB, beginning in FY 1991, under section 1886(d)(10) of the Act, hospitals could request reclassification from one geographic location to another for the purpose of using the other area's standardized amount for inpatient operating costs or the wage index value, or both (September 6, 1990 interim final rule with comment period (55 FR 36754), June 4, 1991 final rule with comment period (56 FR 25458), and June 4, 1992 proposed rule (57 FR 23631)). Implementing regulations in Subpart L of Part 412 (§§ 412.230 *et seq.*) set forth criteria and conditions for redesignations for purposes of the wage index or the average standardized amount, or both, from rural to urban, rural to rural, or from an urban area to another urban area, with special rules for SCHs and rural referral centers.

Effective with reclassifications for FY 2003, section 1886(d)(10)(D)(vi)(II) of the Act provides that the MGCRB must use the average of the 3 years of hourly wage data from the most recently published data for the hospital when evaluating a hospital's request for reclassification. The regulations at § 412.230(e)(2)(ii) stipulate that the wage data are taken from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes. To evaluate applications for wage index reclassifications for FY 2005, the

MGCRB used the 3-year average hourly wages published in Table 2 of the August 1, 2003 IPPS final rule (68 FR 50135). These average hourly wages are taken from data used to calculate the wage indexes for FY 2002, FY 2003, and FY 2004, based on cost reporting periods beginning during FY 1998, FY 1999, and FY 2000, respectively.

2. Standardized Amount Reclassification Provisions

As specified in § 412.230(d)(1), to be reclassified to an adjacent area for the purpose of using that area's standardized amount, an individual hospital seeking redesignation must demonstrate that its incurred costs are comparable to hospital costs in the adjacent area (that is, hospitals must demonstrate that their costs exceed their current payments by 75 percent of the additional payments they would receive through reclassification) and that it has the necessary close proximity to that area (that is, an urban hospital must be no more than 15 miles and a rural hospital no more than 35 miles from the adjacent area; or at least 50 percent of the hospital's employees must reside in the adjacent area).

Under section 402(b) of Public Law 108–7, Congress provided that all inpatient PPS hospitals be paid at the large urban average standardized amount for discharges occurring on or after April 1, 2003 and before October 1, 2003. Under Public Law 108–89, Congress extended section 402(b) of Public Law 108–7 to discharges occurring through March 31, 2004. Section 401 of Public Law 108–173 further extended the equalization of urban and rural operating standardized payment amounts. (*See* section IV.B. of this preamble for a more detailed discussion.) Section 401 also equalized the Puerto Rico-specific urban and other area rates by requiring that the Puerto Rico-specific urban and other area rates be made retroactive to October 1, 2003. The Puerto Rico-specific equalization of the urban and rural operating standardized amounts became effective for discharges beginning on or after April 1, 2004.

As a result of these legislative changes, the standardized amount reclassification criterion is no longer necessary or appropriate. Therefore, we are proposing to revise § 412.230 and § 412.234 to remove all standardized amount criteria provisions. We are proposing to remove the provisions of ''§ 412.230(d)'' (existing paragraph (e) would be redesignated as paragraph (d)), and to remove § 412.234(c) and (d)(2) (existing paragraph (d)(1) would be redesignated as paragraph (c) and revised), which contain the criterion requiring individual hospitals and urban hospital groups to demonstrate that their costs are more comparable to the average amount they would be paid if they were reclassified than the amount they would be paid under their current classification.

With the implementation of the equalization of the national adjusted operating standardized amount for large urban and other areas provision of Public Law 108–173, we also are proposing the following technical revisions to several sections under Subpart L of Part 412, which set forth the criteria and conditions for redesignations.

- We are proposing to delete the cross-reference to ''§ 412.230(d)(2)'' cited in § 412.230(a)(4) and to make redesignation changes for the existing cross-reference changes to paragraph (e), which is proposed to be redesignated as paragraph (d).
- We are proposing to delete § 412.230(a)(5)(ii) (the existing paragraphs (a)(5)(iii), (a)(5)(iv), and (a)(5)(v) would be redesignated as paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(5)(iv), respectively. Under existing § 412.230(a)(5)(ii), we defined, for fiscal years 1997, 1998, and 2002, the limitation for redesignation for purposes of the standardized amount. Our policy has been that a hospital may not be redesignated for purposes of the standardized amount to an area that does not have a higher standardized amount than the standardized amount the hospital currently receives.

We are proposing to delete existing § 412.236. Section 412.236 sets forth the redesignation criteria for hospitals in a NECMA. Under the new CBSAs, OMB has defined the MSAs and Micropolitan areas in New England on the basis of counties. As discussed in section III.B. of this proposed rule, to maintain consistency in the definition of labor market areas between New England and the rest of the country, we are proposing to use the New England MSAs under the new CBSA definition. Proposing to adopt the New England MSAs requires not only that we delete the reference to NECMAs in existing definitions, but that we also delete reference to criteria applicable to hospitals located in a NECMA that apply for reclassification. In keeping with the proposal to define labor market areas as MSAs, including those in New England, the criteria and conditions for redesignation set forth in § 412.230 will be applicable to New England hospitals seeking to reclassify.

In an effort to refine the reclassification guidelines, we established §§ 412.234 and 412.236 in the existing guidelines to allow for reclassification of urban groups and New England groups, respectively (56 FR 25458). Under § 412.232(a) and § 412.234(a), we set forth similar criteria for rural and urban hospitals to be reclassified as a group, respectively. Prior to the implementation of legislation to eliminate the differential in the standardized amount, urban county groups that were interested in applying for purposes of the wage index submitted applications to the MGCRB for consideration. Many urban county group applications were unable to reclassify solely because they failed to meet the standardized amount criteria. In light of the fact that the standardized amount criteria are no longer appropriate, we believe it would be appropriate to make an adjustment to the hospital's wage index by assigning, to hospitals that were unable to reclassify in applications for both FY 2004 and FY 2005, the wage index for the MSA requested in the FY 2004 and FY 2005 group application. Section 1886(d)(5)(I)(i) of the Act provides the Secretary with broad authority to make adjustments and exceptions under the IPPS. Specifically, the section provides that the ''Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate.'' Under this unique circumstance, we are proposing to exercise the broad authority under section 1886(d)(5)(I)(i) of the Act, to make an exception to the assignment of wage index value for certain hospitals that failed to reclassify as a group under § 412.234 for FY 2004 and FY 2005. Specifically, effective with discharges occurring during the 3-year period beginning October 1, 2004 through September 30, 2007, any hospital whose urban county group application under § 412.234 would have been approved by the MGCRB but for the failure to meet the requirements in § 412.234(c), would be assigned the wage index for the MSA identified in the FY 2004 and FY 2005 group application (in cases where the group identified more than one preference, the hospital would be assigned the wage index that is most advantageous). Hospitals that wish to receive the wage index of the area identified in their FY 2004 and FY 2005 group applications under this provision need only notify CMS in writing, at the address provided under the Addresses section of this proposed rule, before the close of the comment period. The notification should only contain:

- The hospital's name and street address.
- The hospital's provider number.

- The name, title, and telephone number of a contact person for communications.
- The area (name and MSA number) identified in their FY 2005 group application.
- Copies of any and all MGCRB decision notification letters for FY 2004 and FY 2005.

3. Reclassification of Urban Rural Referral Centers

Under existing regulations at § 412.230(e)(3), rural referral centers (RRCs) (including hospitals that were ever RRCs) are exempt from one of the average hourly wage criteria that apply to other hospitals seeking reclassification. Specifically, an RRC is exempt from the requirement under § 412.230(e)(1)(iii) that the hospital's 3-year average hourly wage meet a threshold percentage in relation to the average hourly wage of all the hospitals in the area in which the hospital is located. These threshold percentages are 108 percent for hospitals located in urban areas, and 106 percent for hospitals located in rural areas. However, an RRC is not exempt from another threshold requirement, namely the requirement under § 412.230(e)(1)(iv) that the hospital's 3-year average hourly wage must meet a threshold percentage of the 3-year average hourly wage of the hospitals located in the area to which the hospital seeks reclassification. As in the case of the first threshold, this threshold percentage is different for urban and rural hospitals. An urban hospital's 3-year average hourly wage must be at least 84 percent of the average hourly wage of the hospitals located in the area to which the hospital seeks reclassification, while a rural hospital's 3-year average hourly wage must be at least 82 percent of the average hourly wage of the hospitals located in the area to which the hospital seeks reclassification.

It has come to our attention that the requirement of § 412.230(e)(1)(iv) places RRCs located in urban areas on a different footing than RRCs located in rural areas. In some cases, urban RRCs that have been denied reclassification because they failed to meet the 84-percent threshold would have been able to meet the 82-percent threshold that would have applied if they were located in a rural area. RRCs play a significant role in treating Medicare beneficiaries from rural areas, whether or not a particular RRC is physically located in a rural area or an urban area. Thus, we believe that it would be more appropriate for all RRCs, whether they are actually located in urban or rural areas, to be treated on an equal basis with respect to the qualifications for geographic reclassification. Therefore, we are proposing to revise § 412.230(e)(1)(iii) of the regulations to provide that RRCs, including RRCs located in urban areas, must meet the 82-percent threshold that applies to rural hospitals rather than the 84-percent threshold that applies to urban hospitals.

Furthermore, we are aware of at least one case in which an RRC was reclassified by the MGCRB for FY 2004, but upon applying to the MGCRB for FY 2005, was found to be ineligible for reclassification because its 3-year average hourly wage was now less than 84 percent of the hospitals located in the MSA to which it applied for reclassification. In this case, the hospital's 3-year average hourly wage was still greater than 82 percent of the MSA to which it had applied for reclassification. In such a case, we believe that it would be appropriate to make an accommodation for one year, so that the hospital is not subjected to the financial strain that may be caused by receiving a lower wage index for one year until it qualifies to apply for reclassification under the revised threshold criterion that we are proposing here. Therefore, we are proposing that, in such a case, we would exercise our authority under section 1886(d)(5)(I)(i) of the Act to make an exception by assigning to the hospitals for one additional year the wage index that applied to the hospital in FY 2004 through FY 2005. We are proposing to use this authority to provide, under this unique circumstance, special protection to a small number of hospitals that would otherwise be subject to a temporary, but serious, disadvantage. Specifically, we would assign an RRC that meets the conditions described above, the wage index value of the MSA to which it was reclassified by the MGCRB in FY 2004. In order to be eligible for this exception, the hospital may not qualify for any geographic reclassification for discharges effective October 1, 2004 (under the regular rules or the special one-time appeal provision). This assignment would be valid only for FY 2005, after which the hospital would have the opportunity to apply for reclassification under the new threshold for all RRCs that we are proposing in this rule.

We are proposing to revise proposed redesignated § 412.230(d)(3) and add a new § 412.64(j) to incorporate this proposal.

4. Special Circumstances of Sole Community Hospitals (SCHs) in Low Population Density States

Medicare program policy has long provided special treatment for hospitals in rural areas. For many years, rural hospitals have experienced lower margins than other hospitals, and Congress has created several special measures to address the unique issues of hospitals in rural areas. For example, Congress created the CAH program in 1997 to ensure that beneficiaries in isolated areas had access to emergency services and certain essential inpatient services. To qualify for CAH designation, a hospital must be located more than 35 miles from the nearest similar hospital and have an average length of stay not exceeding 4 days. A CAH must provide 24-hour emergency care services and have no more than 25 acute care beds. CAHs are currently paid 101 percent of their current Medicare allowable costs for inpatient and outpatient services. Similarly, the SCH program has long served to maintain access to needed health services for beneficiaries in isolated communities. SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; or the updated hospital-specific rate based on FY 1996 costs per discharge.

Many rural hospitals have taken advantage of the opportunity to participate in the CAH program in recent years. We expect the number of hospitals to increase because of the changes made to the CAH program under recently enacted Public Law 108–173 (for example, increasing the reasonable cost payment rate from 100 percent to 101 percent and increasing the qualifying bed size limitation from 15 to 25). Because CAHs are paid on the basis of their reasonable costs, the wage index is not a factor in their payments, and geographic reclassification is thus not an issue for these hospitals. However, for many rural hospitals that cannot qualify for CAH status, the wage index remains an important factor in their payment, even in the case of SCHs paid on their hospital-specific rate, for which the only impact of the wage index may be on their inpatient capital and outpatient payments. The regulations governing reclassifications by the MGCRB provide special treatment for SCHs by exempting them from the normal rules that require hospitals to demonstrate a close

proximity (15 miles in the case of urban hospitals; 35 miles for rural hospitals), and allowing these hospitals to reclassify to the urban area or the rural area that is the closest to the hospital.

Wage index assignment is an especially pressing issue for hospitals in States with low population densities. In such States, employees are likely to commute greater distances to work. More distant areas are thus likely to compete for labor than is the case in more densely populated States. Because of this concern, and the program's longstanding recognition of these hospitals, we exercised our discretion in implementing the special one-time wage index reclassification appeal provision of section 508 of Pub. L. 108–173 to provide special consideration for SCHs in States with fewer than 10 people per square mile, based on 2000 census data (Alaska, Montana, North Dakota, South Dakota, and Wyoming). Specifically, we provided that SCHs in such a State could reclassify to an MSA within its State. More than 20 SCHs in those States were able to reclassify under this provision.

However, a number of SCHs from those States were precluded from reclassifying under the terms of section 508. We are concerned that these hospitals could now be placed at a serious disadvantage in comparison to other SCHs in their States and regions. Under the authority of section 1886(d)(5)(I)(i) of the Act, we are proposing to provide, under these unique and temporary circumstances, special protection to a small number of hospitals that would otherwise be subject to a temporary, but serious, disadvantage. Specifically, we are proposing to allow an SCH in one of the States with fewer than 10 people per square mile (Alaska, Montana, North Dakota, South Dakota, and Wyoming) to adopt the wage index of another geographic area within its State for 3 years.

Such wage index assignments would become effective for FY 2005 through FY 2007. Because the wage index assignments would be made in order to remedy a temporary disadvantage, the assignments would be for the 3-year period only and would not be available thereafter. In order to receive the wage index of another area under this proposal, a SCH may not qualify for reclassification (under the regular rules or the special one-time appeal provision) effective for discharges on or after October 1, 2004. SCHs in the identified States will not be required to meet proximity or access requirements similar to those required for reclassification in order to qualify for change in wage index under this provision. SCHs that wish to receive the wage index of another area within their State under this provision need only notify CMS in writing, at the address in the ''Addresses'' section provided for comments on this proposed rule, before the close of the comment period. The notification should contain:

- The hospital's name and street address.
- The hospital's provider number.
- The name, title, and telephone number of a contact person for communications.
- A statement certifying the SCH status.
- The name of the area within the State whose wage index the hospital wishes to adopt.

5. Possible Reclassifications for Dominant Hospitals and Hospitals in Single-Hospital MSAs

Representatives of individual hospitals have expressed concern about the special circumstances of dominant hospitals and hospitals in single-hospital MSAs in relation to the wage index and the rules governing geographic reclassification. The term ''dominant hospital'' generally refers to a hospital that pays a substantial proportion of all the wages paid by hospitals geographically located in the hospital's area. A dominant hospital necessarily has a preponderate influence on the wage index calculation for the area in which it is located. As a result, dominant hospitals find it difficult to meet the threshold requirements for wage index reclassification; for example, the requirement that an urban hospital's average hourly wage is at least 108 percent of the average hourly wage of hospitals in the area in which the hospital is located (§ 412.230(e)(1)(iii)(B)). Indeed, a dominant hospital would find it difficult to meet any threshold based on the ratio of the hospital's average hourly wage to the average hourly wage of hospitals in the area, unless the dominant hospital's wage data were removed from the denominator for purposes of the comparison. Dominant hospitals have argued that this places them in an unfair situation. While the lower wages of other, smaller hospitals in the area can still have the effect of holding down their wage index, their dominant position makes it difficult, or even impossible, to reclassify to another area where the wage index may more closely reflect their costs.

Hospitals in single-hospital MSAs face a situation that is similar in certain respects, but quite different in others. By definition, the wage index for the sole hospital in an MSA is based completely on that hospital's wage data. Such a hospital receives, in effect, its own unique wage index, reflecting the hospital's exact position in relation to the national average hourly wage. As a result, these hospitals cannot qualify for reclassification, unless they are exempt from the wage threshold requirements due to rural referral center status. By definition, the ratio of such a hospital's average hourly wages to the area average hourly wage is always 100 percent, and these hospitals thus cannot meet either the 108 percent threshold for urban hospitals or the 106 percent threshold for rural hospitals (§ 412.230(e)(1)(iii)(B)). Unlike dominant hospitals, hospitals in single-hospital MSAs cannot argue that they are disadvantaged by the effect that lower wage hospitals can have on the area wage index. However, these hospitals have contended that they are sometimes in the position of competing for labor with hospitals in nearby MSAs with higher wage indexes. Under these circumstances, these hospitals cannot reclasssify to the higher wage index area even if they meet the relevant distance requirements. These hospitals also contend that they cannot afford to compete with hospitals that are paid under a higher wage index, and the 3-year lag in the data used to compute the wage index can place them in a permanent position of playing catchup. On the other hand, it is also true that such a disadvantage may be only temporary because increasing wages may eventually equalize wage index values despite the temporary financial disadvantage that would accrue to these hospitals during the 3-year lag period.

We are inviting comment on the concerns raised by hospitals in these two situations and on possible methods of addressing these concerns. A number of measures might be considered to address the concerns of these hospitals. In the case of dominant hospitals, the threshold requirements for reclassification could be revised to provide that a hospital's average hourly wage is at least 108 percent (in the case of urban hospitals) or 106 percent (in the case of rural hospitals) of the average hourly wages of *all other* hospitals in the area. Removing a dominant hospital's wages from the denominator of the ratio would remove the current disadvantage imposed by their dominant status, and make it more realistic for a dominant hospital to meet the threshold requirement. An existing provision under § 412.230(e)(4) provides this treatment for certain dominant

hospitals, specifically those that were approved for reclassification each year from 1992 through 1997. We could develop a parallel provision that applies to dominant hospitals generally. The use of this revised ratio could be restricted to the special circumstances of dominant hospitals, or extended to all hospitals. We could also adopt a revised threshold for dominant hospitals, as we did in the notice setting forth the criteria for reclassification under the one-time wage index appeal provision of section 508 of Public Law 108–173 (69 FR 7342). Consistent with the criteria from that notice, a dominant hospital might be defined for this purpose as a hospital that pays at least 40 percent of all the wages paid by hospitals geographically located in the hospital's area. We are considering adopting one of these measures in the final rule, and welcome comments on the advisability of doing so.

In the case of hospitals in single-hospital MSAs, one new provision that we are proposing to implement in this proposed rule may address some of their concerns (*see* section III.G.3.2. of this preamble). Section 505 of Public Law 108–173 provides for a new wage index adjustment for hospitals in lower wage areas in cases where significant numbers of hospital workers commute from the lower wage area to higher wage areas nearby. The statute requires that at least 10 percent of the hospital workers in a county must be commuting to a higher wage area, or areas, in order for the hospitals in the county to receive the adjustment. The adjustment formula provides for an increase to the wage index for hospitals in the county, based on the differences between the wage index that applies to the county and the higher wage indexes of nearby areas, in proportion to the percentages of hospital workers commuting to the higher wage index areas. To the degree that hospitals in single-hospital MSAs experience disadvantages in competing for hospital workers with hospitals in higher wage index areas, we expect that the counties in which these hospitals are located would qualify for this adjustment. We are actively considering whether to address the concerns of these hospitals more directly. At the same time, we intend to analyze the extent to which this provision would alleviate the concerns of these hospitals. We welcome comments on the special circumstances of hospitals in single-hospital MSAs and whether their special circumstances should be addressed by revisions to the regulations governing reclassification, or other measures.

6. Special Circumstances of Hospitals in All-Urban States

Section 4410 of Public Law 105–33 (BBA) provides that, for the purposes of section 1886(d)(3)(E) of the Act, for discharges occurring on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in the State. This provision, commonly referred to as the ''rural floor,'' currently affects the payments received by 150 hospitals in 49 MSAs. For these 150 hospitals, the applicable wage index and overall payment amounts under the IPPS are higher than they would be if their wage indexes were computed solely on the basis of the wage data from their MSAs. The wage index floor is applied in a budget neutral manner, so that aggregate IPPS payments each year are not greater or less than those that would have been made in the absence of this provision.

The ''rural floor'' under section 4410 of Public Law 105–33 does not apply in the two States that have no rural areas under the labor market definitions that apply within the IPPS. Hospitals in these two States have commented that the absence of a rural floor disadvantages them for wage index purposes compared to hospitals in States where the ''rural floor'' provision can apply. Specifically, some hospitals contend that they would have higher wage indexes, and higher payments overall, if there were a rural area in their State to set a floor under the wage indexes within the State.

We are considering whether it would be appropriate to adopt some measure to address the concerns of these hospitals. For example, we are examining the ratios between the lowest and highest wage index values in States where the ''rural floor'' affects the wage indexes of some hospitals. We might consider employing the average ratio of highest-to-lowest wage indexes in those States to set an imputed ''rural floor'' for all-urban States. For example, assume the average ''lowest-to-highest'' ratio of States with rural floors is 0.9500. Assume further that the lowest wage index in an all-urban State is 1.0000, and the highest is 1.1000. The ''lowest-to-highest'' ratio for that State is 0.9091. If we apply the average ''lowest-to-highest'' ratio to the highest wage index in the all-urban State, we would multiply 0.9500 by 1.1000, which yields 1.0450. The imputed analogue to the ''rural floor'' for the all-urban State would then be 1.0450. Any hospital with a regular wage index value less than 1.0450 would then receive the new imputed floor.

We welcome comments on the position of hospitals in all-urban States relative to hospitals that receive the ''rural floor'' in other States. We also welcome comments on whether it would be advisable to adopt an imputed floor measure or some alternative measure to address the concerns of hospitals in these States. We note that, in order to be consistent with the statutory provision establishing the rural floor, we would apply any such measure in budget neutral manner, that is, we would adjust the standardized amount so that aggregate IPPS payments each year are not greater or less than those that would have been made in the absence of this provision.

O. Payment for Direct Graduate Medical Education (Existing § 413.86)

[If you choose to comment on issues in this section, please include the caption ''Graduate Medical Education'' at the beginning of your comment.]

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and implemented in regulations at existing § 413.86, establishes a methodology for determining payments to hospitals for the costs of approved GME programs. Section 1886(h)(2) of the Act, as added by COBRA, sets forth a payment methodology for the determination of a hospital-specific, base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable costs of GME for a base period by its number of residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, the period of October 1, 1983 through September 30, 1984). The PRA is multiplied by the weighted number of full-time equivalent (FTE) residents working in all areas of the hospital (and nonhospital sites, when applicable), and the hospital's Medicare share of total inpatient days to determine Medicare's direct GME payments. In addition, as specified in section 1886(h)(2)(D)(ii) of the Act, for cost reporting periods beginning on or after October 1, 1993, through September 30, 1995, each hospital-specific PRA for the previous cost reporting period is not updated for inflation for any FTE residents who are not either a primary care or an obstetrics and gynecology resident. As a result, hospitals that train primary care and obstetrics and gynecology residents, as well as nonprimary care residents in FY

1994 or FY 1995, have two separate PRAs: one for primary care and obstetrics and gynecology and one for nonprimary care.

The BBRA (Pub. L. 106–113) amended section 1886(h)(2) of the Act to establish a methodology for the use of a national average PRA in computing direct GME payments for cost reporting periods beginning on or after October 1, 2000, and on or before September 30, 2005. The BBRA established a ''floor'' for hospital-specific PRAs equal to 70 percent of the locality-adjusted national average PRA. In addition, the BBRA established a ''ceiling'' that limited the annual adjustment to a hospital-specific PRA if the PRA exceeded 140 percent of the locality-adjusted national average PRA. Section 511 of the BIPA (Pub. L. 106–554) increased the floor established by the BBRA to equal 85 percent of the locality-adjusted national average PRA. Existing regulations at § 413.86(e)(4) specify that, for purposes of calculating direct GME payments, each hospital-specific PRA is compared to the floor and the ceiling to determine whether a hospital-specific PRA should be revised.

Section 1886(h)(4)(F) of the Act established caps on the number of allopathic and osteopathic residents that hospitals may count for purposes of calculating direct GME payments. For most hospitals, the caps were the number of allopathic and osteopathic FTE residents training in the most recent cost reporting period ending on or before December 31, 1996.

Note to Readers: This proposed rule includes a major redesignation of the contents of § 413.86. As a result of the numerous amendments we have made over the years, the size of § 413.86 has become voluminous and difficult to follow because of the multiple levels of coding. We are taking a first step to split the one section (§ 413.86) into nine individual sections (§§ 413.75 through 413.83). We are proposing to designate each first level paragraph under existing § 413.86 as a separate new section and vacate § 413.86. At this time, we are not proposing to make any changes in the language of these new redesignated sections, except for the changes that are discussed in section IV.O. of this preamble (which would conform to the existing language of § 413.86) and any appropriate cross-reference and conforming changes. We are providing a detailed crosswalk of the existing paragraphs of § 413.86 to the proposed new §§ 413.75 through 413.83. In addition, in any discussion of changes we are proposing to make, we are providing both the existing citation under § 413.86 and the proposed redesignated section and paragraph. At a later date, we may further refine the contents of the redesignated sections to improve readability.

2. Reductions of and Increases in Hospitals' FTE Resident Caps for GME Payment Purposes Under Section 422 of Public Law 108–173 (Proposed Redesignated § 413.79 (a Proposed Redesignation of § 413.86(g))

a. General Background on Methodology for Determining the FTE Resident Count

As we explain earlier in this preamble, Medicare makes both direct and indirect GME payments to hospitals that train residents in approved medical residency training programs. Direct GME payments are made in accordance with section 1886(h) of the Act, based generally on hospital-specific PRAs, the number of FTE residents a hospital trains, and the hospital's Medicare patient share. IME payments are made in accordance with section 1886(d)(5)(B) of the Act, based generally on the ratio of the hospital's FTE residents to the number of hospital beds. Accordingly, the calculation of both direct GME and IME payments is affected by the number of FTE residents that a hospital is allowed to count; generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress instituted a cap on the number of allopathic and osteopathic residents a hospital is allowed to count for direct GME and IME purposes under the provisions of section 1886(h)(4)(F) of the Act for direct GME and section 1886(d)(5)(B)(v) of the Act for IME. Dental and podiatric residents were not included in this statutorily mandated cap.

b. Reduction of Hospitals' FTE Resident Caps Under the Provisions of Section 422 of Public Law 108–173

Medicare makes direct GME and IME payments based only on the number of FTE residents that is within a hospital's FTE resident cap. Some hospitals have trained a number of allopathic and osteopathic residents in excess of their FTE resident caps. Other hospitals have reduced their resident counts to some level below their FTE resident caps. Section 422 of Public Law 108–173 added a new section 1886(h)(7) to the Act to provide for reductions in the statutory resident caps under Medicare for certain hospitals and authorize a ''redistribution'' of the FTE resident slots resulting from the reduction in the FTE resident caps to other hospitals.

The new section 1886(h)(7)(A) of the Act provides that a hospital's FTE resident cap will be reduced if its reference resident level, as described below, is less than its otherwise applicable FTE resident cap. Rural hospitals with less than 250 acute care inpatient beds are exempt from these reductions. For other hospitals, the reduction will be equal to 75 percent of the difference between the hospital's otherwise applicable FTE resident cap and its reference resident level.

(We note that the remainder of this section IV.O. of this preamble addresses the provisions of section 1886(h)(7) of the Act, as added by section 422 of Public Law 108–173, as it relates to hospitals' FTE resident caps for direct GME and IME payment purposes. We address the provisions of section 1886(h)(7) of the Act as it relates specifically to the IME adjustment under section IV.K.2. of this preamble.)

Under the new section 1886(h)(7)(B) of the Act, the Secretary is authorized to increase the otherwise applicable FTE resident caps for certain categories of hospitals for portions of cost reporting periods occurring on or after July 1, 2005, by an aggregate number that does not exceed the estimated overall reduction in FTE resident caps for all hospitals under section 1886(h)(7)(A). A single hospital may receive an increase in its FTE resident cap of no more than 25 additional FTEs. In determining which hospitals would receive an increase in their FTE resident caps, section 1886(h)(7)(B) of the Act directs us to—

- Take into account the demonstrated likelihood of the hospital filling the additional positions within the first three cost reporting periods beginning on or after July 1, 2005.
- Establish a priority order to distribute resident slots first to programs in hospitals located in rural areas; second, to urban hospitals that are not in large urban areas; and third, to other hospitals operating a training program in a State where there is no other training program for a particular specialty in the State.

In summary, section 422 of Public Law 108–173 added a new section 1886(h)(7) of the Act that prescribes a methodology for determining reductions to certain hospitals' FTE resident caps based on unused FTE resident slots, provides for certain exceptions to the FTE resident cap reductions, and includes general criteria that CMS must consider in the redistribution, to other hospitals, of the estimated number of FTE resident slots resulting from the reductions in the FTE resident caps. In this proposed rule, we are proposing procedures for determining whether, and by what amount, a hospital's FTE resident cap is subject to a reduction under section 1886(h)(7) of the Act. We

also are proposing an application process for hospitals that seek to receive increases in their FTE resident caps and the specific criteria that we would use to determine which hospitals will receive the increases in their FTE resident caps under section 1886(h)(7)(B) of the Act.

c. Hospitals Subject to the FTE Resident Cap Reduction

As indicated earlier, section 1886(h)(7)(A) of the Act, as added by section 422 of Public Law 108–173, provides that if a hospital's ''reference resident level'' is less than its ''otherwise applicable resident limit,'' its ''otherwise applicable resident limit'' will be reduced by 75 percent of the difference between its ''otherwise applicable resident limit'' and its ''reference resident level.'' Under the amendments made by section 422, the ''reference resident level'' generally refers to the number of unweighted allopathic and osteopathic FTE residents who are training at a hospital in a given cost reporting period. The ''otherwise applicable resident limit'' refers to a hospital's FTE resident cap established under sections 1886(h)(4)(F)(i) and (h)(4)(H) of the Act. A hospital's permanent FTE cap under section 1886(h)(4)(F)(i) of the Act is based on (1) for an urban hospital, the number of unweighted allopathic or osteopathic FTE residents in the hospital's most recent cost reporting period ending on or before December 31, 1996 (the ''1996 cap''), as specified under existing regulations at § 413.86(g)(4) (proposed redesignated § 413.79(c)(2)), and, if applicable, the 1996 cap adjusted for new programs as specified under existing § 413.86(g)(6) (proposed redesignated § 413.79(e)); or (2) for a rural hospital, 130 percent of the 1996 cap increased, as specified under existing § 413.86(g)(4) and, if applicable, the 1996 cap adjusted for new programs as specified under § 413.86(g)(6), or the 1996 cap with both adjustments. We also note that a hospital's 1996 cap may be adjusted in other instances (such as temporary adjustments for program or hospital closure) if the hospital is a member of a Medicare GME affiliated group under existing § 413.86(b) (proposed redesignated § 413.75(b)), but we will discuss the applicability of affiliations under section 1886(h)(7)(A) of the Act in more detail at section IV.O.2.f.(5) of this preamble.

In our discussion of the provisions of section 422 of Public Law 108–173 under this section of this proposed rule, we will generally refer to a hospital's number of unweighted allopathic and osteopathic FTE residents in a particular period as a hospital's ''resident level.'' We will also refer to a hospital's resident level in the applicable ''reference period,'' as explained further below, as the hospital's ''reference resident level.'' In addition, we will refer to the ''otherwise applicable resident cap'' as the hospital's FTE resident cap that is applicable during a particular cost reporting period. Thus, we are proposing that if a hospital's resident level is less than the hospital's otherwise applicable resident cap in the ''reference period'' (as explained below), effective for portions of cost reporting periods occurring on or after July 1, 2005, we would permanently reduce the hospital's FTE resident cap by 75 percent of the difference between a reference resident level and the otherwise applicable FTE resident cap. For example, if a hospital's otherwise applicable FTE resident cap for the reference period is 100, and its resident level for that period is 80 FTEs, we would reduce the hospital's FTE resident cap by 15 FTEs [0.75 (100 − 80)] = 15). (Proposed redesignated § 413.79(c)(3)).

d. Exemption From FTE Resident Cap Reduction for Certain Rural Hospitals

Section 1886(h)(7)(A)(i)(II) of the Act, as added by section 422 of Public Law 108–173, specifically exempts rural hospitals (as defined in section 1886(d)(2)(D)(ii) of the Act) with less than 250 acute care inpatient beds from the possible 75 percent reduction to their FTE resident caps. Section 1886(d)(2)(D)(ii) of the Act defines a rural area as any area outside a Metropolitan Statistical Area (MSA). Under the existing regulations at § 413.62(f)(ii), an ''urban area'' means (1) a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA); or (2) the following New England counties: Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island. Under existing § 413.62(f)(iii), a ''rural area'' means any area outside an urban area. In addition, we note that under section III. of this preamble, which discusses wage areas, we are proposing to no longer recognize NECMAs as a distinct category of wage areas. Thus, for purposes of the amendments made by section 422, we are proposing that any hospital located in an area that is not in a MSA is a rural hospital, regardless of any reclassification under § 412.102 or § 412.103. We note that this definition of ''rural'' is consistent with our proposal under section III. of this preamble concerning designation of wage index areas.

A hospital's bed size is based on its number of available beds, as determined for IME payment purposes under § 412.105 of the regulations. For purposes of determining whether a rural hospital has less than 250 beds, we are proposing to use data from the rural hospital's most recent cost reporting period ending on or before September 30, 2002. (This information may be found on Worksheet S–3, Part I of the Medicare cost report, CMS–2552–96, column 2, the sum of lines 1 and 6 through 10, divided by the number of days in the cost reporting period.) This is the cost reporting period under section 1886(h)(7)(A)(ii)(I) of the Act that is to be used in determining a hospital's reference resident level (the unweighted allopathic and osteopathic FTE resident count) (unless a hospital makes and CMS grants a timely request under section 1886(h)(7)(A)(ii)(II) of the Act). We are proposing that if a rural hospital has less than 250 beds in its most recent cost reporting period ending on or before September 30, 2002, it would not be subject to a possible reduction to its FTE resident cap under section 1886(h)(7)(A) of the Act. However, if a rural hospital has at least 250 beds in its most recent cost reporting period ending on or before September 30, 2002, we are proposing that the rural hospital would be subject to a possible reduction to its FTE resident cap. (Proposed redesignated § 413.79(c)(3)(i)).

e. Determining the Estimated Number of FTE Resident Slots Available for Redistribution

Under section 1886(h)(7)(A) of the Act, we will determine the number of resident positions available for redistribution by estimating possible reductions to hospitals' FTE resident caps. We believe that section 422 allows us to distinguish between the FTE counts that are used to determine the number of FTE resident slots that are available for redistribution (that is, the ''resident pool''), and the actual number of FTE residents by which hospitals' FTE resident caps are ultimately reduced. We are proposing to estimate the reduction to a hospital's FTE resident cap under section 1886(h)(7)(A) of the Act for purposes of determining the number of FTEs that a hospital might contribute to the resident pool. This proposed interpretation is based on the language at section 1886(h)(7)(B)(i) of the Act, as added by section 422(a)(3), which states that the ''aggregate number of increases in the otherwise applicable

resident limits under this subparagraph may not exceed the Secretary's *estimate* of the aggregate reduction in such limits * * *'' (emphasis added). We are proposing to interpret this language to mean that we would have complied with the statute as long as the aggregate number of FTE residents by which we *increase* the FTE resident caps of qualifying hospitals under section 1886(h)(7)(B) of the Act is not more than the estimate of the aggregate number of FTE residents by which we would reduce the FTE resident caps of hospitals whose reference resident levels are less than their otherwise applicable FTE resident caps. However, we could subsequently perform an audit, as described further in section IV.O.2.f.(3) of this preamble, in order to make a final determination regarding any reductions to a hospital's FTE resident cap.

To ensure that we will begin making payments for most hospitals based on the revised FTE resident caps by July 1, 2005, we are proposing to set a date by which we will have estimated a hospital's resident level and compared it to the hospital's otherwise applicable resident cap to estimate whether, and by how much, the hospital's FTE resident cap would be reduced. We are not proposing to commit to make a final determination as to whether, and by how much, a particular hospital's FTE resident cap should be reduced as of this date, nor are we proposing to commit to inform any hospital that it will receive an increase to its FTE resident cap by this date. Rather, we are only proposing to use this date as an internal ''deadline'' to ensure that we will have sufficient time to distribute the resident pool and begin making payments for most hospitals based on the revised FTE resident caps by July 1, 2005. We are proposing that this date be May 1, 2005, and that date would apply for all hospitals for purposes of determining an estimate of whether and by how much their FTE resident caps should be reduced.

Accordingly, in the event that the fiscal intermediaries have not completed an audit (explained further under section IV.O.2.f.(3) of this preamble) by May 1, 2005, we are proposing that CMS may estimate the number of FTE residents by which a hospital's FTE resident cap should be reduced by May 1, 2005. For example, a fiscal intermediary may estimate by May 1, 2005, that Hospital A's FTE resident cap should be reduced by 10 FTEs. Thus, we would place 10 FTEs into the resident pool. It is possible that even after May 1, 2005, the fiscal intermediary may continue to audit Hospital A's relevant cost report(s) to determine if, in fact, 10 FTEs is the appropriate amount by which to reduce Hospital A's FTE resident cap, and could ultimately conclude that Hospital A's FTE resident cap should only be reduced by 8 FTEs. If the fiscal intermediary makes this final determination by May 1, 2005, we would change the number of FTE residents in the resident pool attributable to Hospital A from 10 FTEs to 8 FTEs. If the fiscal intermediary does not make this determination by May 1, 2005, based on the audit, we would only reduce Hospital A's FTE resident cap by 8 FTEs effective July 1, 2005, but the number of FTE residents in the resident pool attributable to Hospital A would remain at 10 FTEs (the estimated number as of May 1, 2005). Similarly, if the fiscal intermediary ultimately concluded that Hospital A's FTE resident cap should be reduced by 12 FTEs, but this final determination is not made by May 1, 2005, Hospital A's FTE resident cap would be reduced by 12 FTEs effective July 1, 2005, but the number of FTE residents in the resident pool attributable to Hospital A would remain at 10 FTEs.

As we stated above, because we believe that section 422 allows us to distinguish between the FTE counts that are used to determine the size of the resident pool, and the actual number of FTE residents by which hospitals' FTE resident caps are ultimately reduced, we are proposing, in certain instances, to use estimated information to determine possible reductions to hospitals' FTE resident caps. As described further below, sections 1886(h)(7)(A)(ii) and (h)(7)(A)(iii) of the Act direct CMS to adjust a hospital's reference resident level in certain instances, due to an expansion of an existing program that is not reflected on the most recent settled cost report, or to include the number of residents for which a new program was accredited, or for hospitals that are members of a Medicare GME affiliated group as of July 1, 2003. We note that, in adjusting the reference resident level in these instances, the number of FTE residents by which we adjust the reference resident level for purposes of determining possible reductions to a hospital's FTE resident cap may not be the actual or audited number of FTE residents that we would otherwise use for direct GME or IME payment purposes. For example, for expansions under newly approved programs (as explained in more detail in section IV.O.2.f.(3) of this preamble), we are proposing to adjust the reference resident level to include the number of residents for which a new program was accredited at a hospital, even though at the time the fiscal intermediary is determining possible reductions to a hospital's FTE resident cap, the hospital may not be training the full complement of residents for which the program was accredited. Thus, the number of FTE residents (including those training in the newly accredited program) for purposes of IME and direct GME payment would be dependent upon the actual number of FTEs the hospital is permitted to count in a particular cost reporting period, as determined in accordance with the regulations at § 412.105 for IME and § 413.86 for direct GME.

In addition, we realize that there may be instances where a hospital's FTE resident cap or a hospital's FTE resident count for the reference cost reporting period might be under appeal. We believe that appeals related to these issues should be resolved through the normal course of business. In the event that an appeal that may affect determinations made under section 1886(h)(7)(A) of the Act is not resolved by May 1, 2005, we are proposing that we would estimate the number of FTE residents by which a hospital's FTE resident cap should be reduced (or not reduced, as applicable) by May 1, 2005.

f. Determining the Possible Reduction to a Hospital's FTE Resident Cap

(1) Reference Resident Level—General

In order to determine if a hospital's resident level is less than the hospital's otherwise applicable FTE resident cap, section 1886(h)(7)(A)(ii) of the Act, as added by section 422 of Public Law 108–173, directs the Secretary to use one of two reference cost reporting periods. Section 1886(h)(7)(A)(ii)(I) of the Act directs CMS to use a hospital's most recent cost reporting period ending on or before September 30, 2002, ''for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary,'' as the reference period, unless we grant the hospital's timely request to use a later cost report under section 1886(h)(7)(A)(ii)(II) of the Act, as described under section IV.O.2.f.(2) of this preamble. Generally, if the hospital's resident level for either direct GME or IME is less than the hospital's otherwise applicable resident cap for direct GME or IME, respectively, for the most recent cost reporting period ending on or before September 30, 2002, the hospital's FTE resident cap for direct GME or IME will be reduced by 75 percent of the difference between the resident level and the otherwise

applicable FTE resident cap. On April 30, 2004, we issued a One-Time Notification (OTN) (Transmittal 77, CR 3247), ''Redistribution of Unused Resident Positions, Section 422 of the Medicare Modernization Act of 2003 (MMA), Public Law 108–173, for Purposes of Graduate Medical Education (GME) Payments'' that prescribed certain requirements related to the implementation of section 422 and established a deadline by which a hospital must exercise its option to request that we use of later cost report as the reference cost report. If the hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002, is settled by April 30, 2004, the date on which the OTN was issued, we are proposing to use that cost report to determine if, and by how much, a hospital's FTE resident cap should be reduced. We note that the ''settled'' cost report does not necessarily mean the initial cost report settlement. The fiscal intermediary may have previously settled the cost report, reopened it to audit it, and then settled the cost report again, issuing a revised Notice of Program Reimbursement (NPR). Thus, we would refer to the more recently issued NPR. When a hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002, has been settled by April 30, 2004, we are proposing to use the most recently settled cost report as of April 30, 2004, to determine any reduction to the hospital's FTE resident cap under section 1886(h)(7)(A)(ii)(I) of the Act (unless we grant the hospital's timely request under section 1886(h)(7)(A)(ii)(II) of the Act to use a later cost report, as described in section IV.O.2.f.(2) of this preamble). If the hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002 has not yet been settled as of April 30, 2004, the as-submitted cost report would be used to determine any reduction in the FTE resident cap, subject to audit by the fiscal intermediary. If the cost report was initially settled, but then reopened, and the fiscal intermediary has not issued a revised NPR prior to April 30, 2004, the data from the initially settled cost report will be used to determine the possible reductions to the FTE resident caps.

(2) Expansion of an Existing Program

Section 1886(h)(7)(A)(ii)(II) of the Act, as added by section 422(a) of Public Law 108–173, provides that if a hospital's resident level increased due to an expansion of an existing program, and that expansion is not reflected on the hospital's most recent settled cost report, a hospital may make a timely request to CMS that, rather than using its most recent cost reporting period ending on or before September 30, 2002, to determine if its FTE resident cap should be reduced, CMS should use the cost report for the hospital's cost reporting period that includes July 1, 2003. For example, assume a hospital's most recent settled cost report is September 30, 2000 (that is, no NPRs were issued for subsequent year cost reports). The hospital increased its resident level due to an expansion of an existing program in its fiscal year ending September 30, 2001. The hospital may submit a timely request that CMS use its cost report that includes July 1, 2003 (which would be its cost report for the fiscal year ending September 30, 2003), to determine if and by how much the hospital's FTE resident cap should be reduced. (Proposed redesignated § 413.79(c)(3)(ii)(A)(*2*)). As explained on page 3 of the OTN, to be considered a timely and proper request, a hospital's request to use its cost reporting period that includes July 1, 2003, must be signed and dated by the hospital's chief financial officer (or equivalent) and submitted to its fiscal intermediary on or before June 4, 2004. In its timely request, the hospital must include the following:

(1) The FTE resident caps for direct GME and IME and the number of unweighted allopathic and osteopathic FTE residents for direct GME and IME in its most recently settled cost report (that is, its cost report that is more recently settled as of April 30, 2004).

(2) The FTE resident caps for direct GME and IME and the unweighted allopathic and osteopathic FTE residents for direct GME and IME for each cost report after its most recently settled cost report, up to and including its cost reporting period that includes July 1, 2003. If the cost reporting period that includes July 1, 2003, has not ended as of June 4, 2004, the hospital must report the estimated number of unweighted allopathic and osteopathic residents for that cost reporting period.

(3) If not already reported in accordance with steps 1 and 2 above, the FTE resident caps for direct GME and IME and the number of unweighted allopathic and osteopathic FTE residents for direct GME and IME in its most recent cost reporting period ending on or before September 30, 2002.

In addition, as we stated in the One-Time Notification (OTN), (Transmittal 77, CR 3247), ''Redistribution of Unused Resident Positions, Section 422 of the Medicare Modernization Act of 2003 (MMA), Public Law 108–173, for Purposes of Graduate Medical Education a hospital should refer to its most recently settled cost report as of the issuance of the OTN (that is, April 30, 2004) to determine whether the hospital believes it has expanded an existing program in a cost reporting period subsequent to the one for the most recently settled cost report.

We also are proposing that, for purposes of this provision, an ''expansion of an existing program'' means that, except for expansions due to newly approved programs, as described below in section IV.O.2.f.(4) of this preamble, the hospital's total number of unweighted allopathic and osteopathic FTE residents training in existing programs in a cost reporting period up to and including the hospital's cost report that includes July 1, 2003, is greater than the resident level in the hospital's most recent settled cost report. (Proposed redesignated § 413.79(c)(3)(ii)(A)(*3*)). In other words, generally, as long as a hospital trained more unweighted allopathic and osteopathic FTE residents in a cost reporting period after its most recent settled cost report in programs that were existing during the cost reporting period for the most recently settled cost report, it may submit a timely request that its cost report that includes July 1, 2003, be used for purposes of determining any FTE resident cap reduction under section 1886(h)(7)(A)(i) of the Act. We note that if a hospital expanded an existing program after its most recent settled cost report, and then subsequently reduced its FTE resident count to the extent that it actually trained fewer unweighted allopathic and osteopathic FTE residents in its cost report that includes July 1, 2003, than in its most recent cost reporting period ending on or before September 30, 2002, the hospital would not benefit from, and would likely not make, a timely request that its cost report that includes July 1, 2003, be used for purposes of determining a possible reduction to its FTE resident cap.

(3) Audits of the Reference Cost Reporting Periods

As mentioned under section IV.O.2.f.(1) of this preamble, to determine a possible reduction to a hospital's FTE resident cap, section 1886(h)(7)(A)(ii)(I) of the Act, as added by section 422(a) of Public Law 108–173, directs CMS to use a hospital's most recent cost reporting period ending on or before September 30, 2002, ''for which a cost report has been *settled* (or, *if not, submitted (subject to audit*), as determined by the Secretary'' (emphasis added). We are proposing to interpret