DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS-1428-F]

RIN 0938-AM80

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates

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

ACTION: Final rule.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems; and to implement a number of changes made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) that was enacted on December 8, 2003. In addition, in the Addendum to this final rule, we describe the changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes are applicable to discharges occurring on or after October 1, 2004. We also are setting forth rate-of-increase limits as well as policy changes for hospitals and hospital units excluded from the IPPS that are paid in full or in part on a reasonable cost basis subject to these limits.

Among the policy changes that we are making are: changes to the classification of cases to the diagnosis-related groups (DRGs); changes to the long-term care (LTC)-DRGs and relative weights; changes in the wage data, labor-related share of the

wage index, and the geographic area designations used to compute the wage index; changes in the qualifying threshold criteria for and the approval of new technologies and medical services for add-on payments; changes to the policies governing postacute care transfers; changes to payments to hospitals for the direct and indirect costs of graduate medical education; changes to the payment adjustment for disproportionate share rural hospitals; changes in requirements and payments to critical access hospitals (CAHs); changes to the disclosure of information requirements for Quality Improvement Organization (QIOs); and changes in the hospital conditions of participation for discharge planning and fire safety requirements for certain health care facilities.

EFFECTIVE DATES: The provisions of this final rule are effective on October 1, 2004. This rule is a major rule as defined in 5 U.S.C. 804(2). Pursuant to 5 U.S.C. 801(a)(1)(A), we are submitting a report to Congress on July 30, 2004.

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Acronyms

ACGME	Accreditation Council on Graduate Medical Education
AHIMA	American Health Information Management Association
AHA	American Hospital Association
AOA	American Osteopathic Association
ASC	Ambulatory Surgical Center
BBA	Balanced Budget Act of 1997, Pub. L. 105-33
BIPA	Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Pub. L. 106-554
BLS	Bureau of Labor Statistics

CAH	Critical access hospital
CART	CMS Abstraction & Reporting Tool
CBSAs	Core-Based Statistical Areas
CC	Complication or comorbidity
CMS	Centers for Medicare & Medicaid Services
CMSA	Consolidated Metropolitan Statistical Area
COBRA	Consolidated Omnibus Reconciliation Act of 1985, Pub. L. 99-272
CoP	Condition of Participation
CPI	Consumer Price Index
CRNA	Certified registered nurse anesthetist
DRG	Diagnosis-related group
DSH	Disproportionate share hospital
ESRD	End-stage renal disease
FDA	Food and Drug Administration
FQHC	Federally qualified health center
FSES	Fire Safety Evaluation System
FTE	Full-time equivalent
FY	Federal fiscal year
GME	Graduate medical education
HCRIS	Hospital Cost Report Information System
HIPC	Health Information Policy Council
HIPAA	Health Insurance Portability and Accountability Act of 1996,

	Pub. L. 104-191
HHA	Home health agency
HPSA	Health Professions Shortage Area
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICD-10-PCS	International Classification of Diseases, Tenth Edition, Procedure Coding System
ICF/MRs	Intermediate care facilities for the mentally retarded
IME	Indirect medical education
IPPS	Acute care hospital inpatient prospective payment system
IPF	Inpatient psychiatric facility
IRF	Inpatient rehabilitation facility
JCAHO	Joint Commission on the Accreditation of Healthcare Organizations
LAMA	Left Against Medical Advice
LTC-DRG	Long-term care diagnosis-related group
LTCH	Long-term care hospital
LSC	Life Safety Code
MCE	Medicare Code Editor
MCO	Managed care organization
MDC	Major diagnostic category
MDH	Medicare-dependent small rural hospital
MedPAC	Medicare Payment Advisory Commission

MedPAR	Medicare Provider Analysis and Review File
MEI	Medicare Economic Index
MGCRB	Medicare Geographic Classification Review Board
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173
MPFS	Medicare Physician Fee Schedule
MSA	Metropolitan Statistical Area
NECMA	New England County Metropolitan Areas
NCHS	National Center for Health Statistics
NCVHS	National Committee on Vital and Health Statistics
NFPA	National Fire Protection Association
NPR	Notice of Program Reimbursement
NQF	National Quality Forum
NVHRI	National Voluntary Hospital Reporting Initiative
OES	Occupational Employment Statistics
OIG	Office of the Inspector General
OMB	Executive Office of Management and Budget
O.R.	Operating room
OSCAR	Online Survey Certification and Reporting (System)
OSHA	Occupational Safety and Health Act
PACE	Programs of All-Inclusive Care for the Elderly
PIP	Periodic interim payment

PMS	Performance Measurement System
PMSAs	Primary Metropolitan Statistical Areas
PPS	Prospective payment system
PRA	Per resident amount
ProPAC	Prospective Payment Assessment Commission
PRRB	Provider Reimbursement Review Board
PS&R	Provider Statistical and Reimbursement System
QIO	Utilization and Quality Control Quality Improvement Organization
RHC	Rural health clinic
RHQDAPU	Reporting Hospital Quality Data for Annual Payment Update
RRC	Rural referral center
SCH	Sole community hospital
SNF	Skilled nursing facility
SOCs	Standard occupational classifications
SOM	State Operations Manual
SSA	Social Security Administration
SSI	Supplemental Security Income
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248
UHDDS	Uniform Hospital Discharge Data Set

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I. Background

A. Summary

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

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare

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

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

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

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

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

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

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

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services “in accordance with a prospective payment system

established by the Secretary." The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital PPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Similar adjustments are also made for IME and DSH as under the operating IPPS. In addition, hospitals may receive an outlier payment for those cases that have unusually high costs.

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

2. Hospitals and Hospital Units Excluded From the IPPS

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

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

a. IRFs

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

b. LTCHs

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

during the 5-year transition period. The existing regulations governing payment under the LTCH PPS are located in 42 CFR Part 412, Subpart O.

c. IPFs

Sections 124(a) and (c) of Pub. L. 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), Pub. L. 108-173, was enacted. Pub. L. 108-173 made a number of changes to the Act relating to prospective payments to hospitals for inpatient services, payments to excluded hospitals and units, and payments to CAHs. This final rule implements amendments made by the following sections of Pub. L. 108-173:

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

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

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

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

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

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

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

in the case of a CAH that made an election of the optional payment method before November 1, 2003, the provision applies to cost reporting periods beginning on or after July 1, 2001.

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

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

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

- Section 406, which provides for a graduated adjustment to the inpatient prospective payment rates to account for the higher costs associated with hospitals described under section 1886(d) of the Act that are located more than 25 road miles from another subsection (d) hospital and that have less than 800 discharges during a fiscal

year, effective for discharges occurring on or after October 1, 2004. The increase in these payments must be based on the empirical relationship between the standardized cost per case for such hospitals and the total number of discharges of these hospitals and the amount of the additional incremental costs (if any) associated with that number of discharges, may not be greater than 25 percent, and the determination of the percentage payment increase is not subject to administrative or judicial review.

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

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

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

- Section 501, which provides the update factor for payments for hospital inpatient operating costs for FY 2005 and subsequent fiscal years is the market basket

percentage increase. For FYs 2005 through 2007, the update factor will be the market basket percentage increase minus 0.4 percentage points for any "subsection (d) hospital" that does not submit hospital quality data on 10 measures as specified by the Secretary.

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

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

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

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

Puerto Rico will be based on 62.5 percent Federal rate and 37.5 percent of the Puerto Rico rate.

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

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

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

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

- Section 713, which, during a 1-year moratorium period of January 1, 2004 through December 31, 2004, allows hospitals to count allopathic or osteopathic family practice residents training in nonhospital settings for IME and direct GME purposes,

without regard to the financial arrangement between the hospital and the teaching physician practicing in the nonhospital setting to which the resident is assigned.

- Section 733, which provides for Medicare payment of routine costs, as well as costs relating to the transplantation and appropriate related items and services, for Medicare beneficiaries participating in a clinical trial involving pancreatic islet cell transplantation, beginning no earlier than October 1, 2004.

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

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

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

On May 18, 2004, we published a proposed rule in the **Federal Register** (69 FR 28196) that set forth proposed changes to the Medicare IPPS for operating costs and for capital-related costs in FY 2005 and to implement the provisions of Pub. L. 108-173 specified in section I.B. of this preamble. We also set forth proposed changes relating to payments for GME costs, payments to certain hospitals and units that

continue to be excluded from the IPPS and paid on a reasonable cost basis, payments for DSH, requirements and payments for CAHs, conditions of participation for hospitals relating to discharge planning and fire safety requirements, requirements for Medicare provider agreements relating to bloodborne pathogen standards, and QIO disclosure of information requirements. These changes were proposed to be effective for discharges occurring on or after October 1, 2004, unless otherwise noted.

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

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

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

Among the proposed changes discussed were:

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

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

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

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

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

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

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

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

2. Changes to the Hospital Wage Index

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

- The FY 2005 wage index update, using wage data from cost reporting periods that began during FY 2001.
- Revision of the labor market areas as a result of OMB revised definitions of geographical statistical areas.
- A discussion of the collection of occupational mix data and the occupational mix adjustment to the wage index that we proposed to apply beginning October 1, 2004.
- Revisions to the wage index based on hospital redesignations and reclassifications, including changes that reflect the new OMB standards for assignment of hospitals to geographic areas.
- The adjustment to the wage index based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index, to implement section 505 of Pub. L. 108-173.

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

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

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

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

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

- Expansion of the current postacute care transfer policy.

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

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

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

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

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

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

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

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

- Payment adjustments for low-volume hospitals.

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

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

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

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

4. Changes to the PPS for Capital-Related Costs

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

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

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

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

and rehabilitation distinct part units in CAHs; and termination of the location requirement for a CAH by designating the CAH as a necessary provider.

6. Changes to QIO Disclosure of Information Requirements

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

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

We proposed to--

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

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

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

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

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

9. Impact Analysis

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

10. Recommendation of Update Factor for Hospital Inpatient Operating Costs

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

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

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

11. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, the Medicare Payment Advisory Commission (MedPAC) is required to submit a report to Congress, no later than March 1 of each year, that reviews and makes recommendations on Medicare payment policies. MedPAC's March 2004 recommendation concerning hospital inpatient payment policies addressed only the update factor for inpatient hospital operating costs and capital-related costs under the IPPS and for hospitals and distinct part hospital units excluded from the IPPS. This recommendation was addressed in Appendix B of the May 18, 2004 proposed rule. For further information relating specifically to the MedPAC March 1 report or to obtain a copy of the report, contact MedPAC at (202) 220-3700 or visit MedPAC's website at: **www.medpac.gov**.

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

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

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

Response: We believe publication of the proposed rule is fully consistent with the law. The APA does not prescribe any specific length for the comment period. In addition, the proposed rule was placed on display at the Office of the Federal Register and a copy of the rule also appeared on our website. The substance of the rule was fully

available on the website, as well as on display at the Office of the Federal Register. Finally, we note that, in accordance with section 1886(d) of the Act, the Secretary is required to ensure that the updated IPPS rates are in place at the beginning of the Federal fiscal year, or by October 1, 2004. Our priority is to ensure that hospitals receive their final updated rates for the new fiscal year.

II. Changes to DRG Classifications and Relative Weights

A. Background

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

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The changes to the DRG classification system and

the recalibration of the DRG weights for discharges occurring on or after October 1, 2004, are discussed below.

B. DRG Reclassifications

1. General

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

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

	Major Diagnostic Categories (MDCs)
1	Diseases and Disorders of the Nervous System
2	Diseases and Disorders of the Eye
3	Diseases and Disorders of the Ear, Nose, Mouth, and Throat
4	Diseases and Disorders of the Respiratory System
5	Diseases and Disorders of the Circulatory System
6	Diseases and Disorders of the Digestive System
7	Diseases and Disorders of the Hepatobiliary System and Pancreas
8	Diseases and Disorders of the Musculoskeletal System and Connective Tissue
9	Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast
10	Endocrine, Nutritional and Metabolic Diseases and Disorders
11	Diseases and Disorders of the Kidney and Urinary Tract
12	Diseases and Disorders of the Male Reproductive System
13	Diseases and Disorders of the Female Reproductive System

	Major Diagnostic Categories (MDCs)
14	Pregnancy, Childbirth, and the Puerperium
15	Newborns and Other Neonates with Conditions Originating in the Perinatal Period
16	Diseases and Disorders of the Blood and Blood Forming Organs and Immunological Disorders
17	Myeloproliferative Diseases and Disorders and Poorly Differentiated Neoplasms
18	Infectious and Parasitic Diseases (Systemic or Unspecified Sites)
19	Mental Diseases and Disorders
20	Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders
21	Injuries, Poisonings, and Toxic Effects of Drugs
22	Burns
23	Factors Influencing Health Status and Other Contacts with Health Services
24	Multiple Significant Trauma
25	Human Immunodeficiency Virus Infections

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

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

Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are based on a hierarchy that orders operating room (O.R.)

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

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

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

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

After cases are screened through the MCE and assigned to a DRG by the GROUPER, the PRICER software calculates a base DRG payment. The PRICER calculates the payments for each case covered by the IPPS based on the DRG relative

weight and additional factors associated with each hospital, such as IME and DSH adjustments. These additional factors increase the payment amount to hospitals above the base DRG payment.

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

Many of the changes to the DRG classifications are the result of specific issues brought to our attention by interested parties. We encourage individuals with concerns about DRG classifications to bring those concerns to our attention in a timely manner so they can be carefully considered for possible inclusion in the next proposed rule and so any proposed changes may be subjected to public review and comment. Therefore, similar to the timetable for interested parties to submit non-MedPAR data for

consideration in the DRG recalibration process, concerns about DRG classification issues should be brought to our attention no later than early December in order to be considered and possibly included in the next annual proposed rule updating the IPPS.

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

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

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

In the May 18, 2004 proposed rule, we noted that it had come to our attention that the title of DRG 14 (Intracranial Hemorrhage and Stroke With Infarction) may be misleading because it implies that a combination of conditions exists when the DRG is assigned. When we developed this title, we did not intend to imply that a combination of conditions exists. Therefore, we proposed to change the title of DRG 14 to read "Intracranial Hemorrhage or Cerebral Infarction".

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

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

a. Heart Assist System Implant

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

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

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

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

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

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

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

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

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

In the May 18, 2004 proposed rule, we again reviewed the FY 2003 MedPAR data for all cases in which a VAD had been implanted, using the criterion of any case containing a procedure code of 37.66. We found a total of 65 cases in 3 DRGs: DRG

103 (Heart Transplant); DRG 483 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses); and DRG 525 (Heart Assist System Implant). The following table displays our findings:

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

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

Commenters on the FY 2004 final rule suggested adding code 37.66 to DRG 103. We were concerned with the timing of that comment, as it was received after publication of the proposed rule. We noted that the commenters' suggestions on the structure of the DRGs involved were significant, and that change of that magnitude should be subject to public review and comment. We also noted that we would evaluate the suggestion further (68 FR 45370). However, as one of the indications for this device has become destination therapy, and as this new indication is more clinically aligned with DRG 103, in the May 18, 2004 proposed rule, we proposed to remove procedure code 37.66 from

DRG 525 and assign it to DRG 103. We also proposed to change the title of DRG 103 to "Heart Transplant or Implant of Heart Assist System". The proposed restructured DRG 103 included any principal diagnosis in MDC 5, plus one of the following surgical procedure codes:

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

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

Comment: A number of commenters recommended that we continue to examine the MedPAR data for code 37.66 and heart transplants to confirm that the weight is accurate. Some of these commenters noted that the weight might need to be increased in either the short term or next year. One commenter who, we believe, did not have access to the proposed rule, suggested the same proposed changes that were included in the proposed rule.

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

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

and subsequently return for a heart transplant. The commenters wanted to know if DRG 103 would be assigned in both cases.

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

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

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

Comment: One commenter urged CMS to retain a common DRG assignment for procedure codes 37.65 and 37.66. The commenter believed that assigning these two procedure codes to different DRGs would not ensure that payment is adequate to allow hospitals to provide mechanical circulatory support therapies, as clinically indicated, and in a cost-efficient manner. The commenter further believed that payment for implantable VADs (code 37.66) at a higher level than external VADs (code 37.65) would create financial incentives unrelated to, and potentially at odds with, clinical considerations, which would skew device choice and increase Medicare program costs. The commenter stated that the initial use of the least expensive device that can provide the necessary therapeutic benefit leads to the best clinical outcomes and the lowest total system costs. The commenter encouraged CMS to adopt a prudent payment policy and an adequate test of whether a patient's heart will recover before an implantable VAD procedure is undertaken.

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

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

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

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

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

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

The following table represents FY 2002 data in DRG 525.

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

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

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

Comment: One commenter stated that DRG 525, as amended on October 1, 2003 to include every type of mechanical circulatory support device requiring a sternotomy

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

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

Comment: One commenter noted that coverage of VAD procedures should be limited to Medicare-certified transplant centers. The commenter also noted that VAD implants assigned to DRG 103 are limited to those [hospitals] using devices that are approved by the FDA for use outside the inpatient hospital setting.

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

- The VAD must be used in accordance with the FDA approved labeling instructions;

- The patient is approved and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center; and

- The implanting site, if different than the Medicare-approved transplant center, must receive the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD.

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

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

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

- 37.52, Implantation of total replacement heart system*

- 37.53, Replacement or repair of thoracic unit of total replacement heart system*

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

*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.

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

b. Cardiac Resynchronization Therapy and Heart Failure

In the May 18, 2004 proposed rule, we addressed a request we had received from a manufacturer of a Cardiac Resynchronization Therapy Defibrillator (CRT-D) device for a modification to DRG 535 (Cardiac Defibrillator Implant With Cardiac Catheterization With Acute Myocardial Infarction/Heart Failure/Shock) and DRG 536 (Cardiac Defibrillator Implant With Cardiac Catheterization Without Acute Myocardial Infarction/Heart Failure/Shock). The commenter pointed out that defibrillator device implantations, including the CRT-D type of defibrillator, are assigned to DRG 535 when the patient also has a cardiac catheterization and has either an acute myocardial infarction, heart failure, or shock as a principal diagnosis. If the patient receiving the defibrillator implant and cardiac catheterization does not have a principal diagnosis of acute myocardial infarction, heart failure, or shock, the cases are assigned to DRG 536.

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

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

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

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

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

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

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

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

The data show that cases with a secondary diagnosis of acute myocardial infarction or heart failure have average charges ($94,832.14) closer to the overall average charges for DRG 536 ($89,493.85) where they are currently assigned. Overall charges for DRG 535 were $110,663.57. We do not believe these data support modifying DRG 535 and DRG 536 as requested. Many of the CRT-D patients who are admitted for

heart failure would be assigned into DRG 535. Furthermore, modifying the DRG logic for one specific type of defibrillator (CRT-D) is not consistent with our overall policy of grouping similar types of patients together in the same DRG. In addition, to modify the DRG logic for the small percentage of cases where there might be confusion concerning the selection of the principal diagnosis does not seem prudent. Therefore, we did not propose a modification to DRG 535 or 536 for CRT-Ds.

Comment: Several commenters supported our proposal not to change the current DRG structure of DRG 535 and DRG 536 for CRT-D devices. Our proposal was in response to a manufacturer that had requested that CRT-D cases be assigned to DRG 535 when the patient has heart failure as either a principal diagnosis or a secondary diagnosis.

Response: After publication of the May 18, 2004 proposed rule, we discussed the issue of coding cases implanted with a CRT-D at the June 2004 meeting of the American Hospital Association's Editorial Advisory Board for Coding Clinical for ICD-9-CM. Discussions between coding representatives from the American Hospital Association, the American Health Information Management Association, the National Centers for Health Statistics, and CMS did not identify diagnosis sequencing problems for patients receiving a CRT-D, as was suggested by the manufacturer. A number of problems in coding the implantation of these devices using the procedure codes were discussed. In addition, we learned that physicians are not clearly and consistently documenting the types of devices being implanted. This is leading to a number of questions from hospitals on how to assign the correct codes for an implantable cardiac defibrillator (ICD) versus the newer CRT-D. As a result of these further discussions, the Editorial Advisory Board for Coding

Clinical for ICD-9-CM is developing a series of questions and answers to clearly illustrate to hospitals how the various devices, leads, and generators are to be correctly coded.

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

Comment: One commenter, a national hospital organization, opposed our recommendation not to alter the logic of DRG 535. The commenter believed that resynchronization is not performed during an acute exacerbation of congestive heart failure. Rather, the commenter indicated, the patient returns at a later date once the congestive heart failure becomes more stabilized. The commenter added that, at that time, the patient often manifests associated arrhythmias that require the resynchronization. The commenter believed that, as a result, under the current proposal, this case would possibly not group to DRG 535 if the congestive heart failure were not sequenced as the principal diagnosis.

Response: The commenter stated that the hospital might not list congestive heart failure as the principal diagnosis in the case described. However, if this were a planned second admission for the implantation of a CRT-D for congestive heart failure, the hospital would assign congestive heart failure as the principal diagnosis. The associated arrhythmias would be listed as a secondary diagnosis. This case would be assigned to DRG 535. If the admission were equally due to both the congestive heart failure and the arrhythmias, the hospital could choose either one as the principal diagnosis. Once again,

the hospital could select congestive heart failure as the principal diagnosis and DRG 535 would be assigned. It would not be appropriate to change the DRG logic for DRG 535 to capture congestive heart failure as either the principal diagnosis or secondary diagnosis for CRT-D patients when appropriate coding would lead to the correct DRG assignment. Therefore, it would not be appropriate to modify the logic for DRGs 535 and 536 for congestive heart failure at this time.

Comment: Commenters who supported our proposal of maintaining the current DRG structure for DRGs 535 and 536 suggested that coders should follow the ICD-9-CM Official guidelines for Coding and Reporting (available on the following website: www.cdc.gov/nchs/icd9.htm) when sequencing the principal diagnosis for admissions involving cardiac resynchronization. The commenters indicated that, if the reason for the admission is heart failure, that condition would be sequenced as the principal diagnosis. The commenter added that when two conditions are equally responsible for the admission, the ICD-9-CM Official Guidelines for Coding and Reporting allow either condition to be sequenced as the principal diagnosis. The commenters further stated that, in that case, the condition resulting in the higher-weighted DRG adjustment would likely be sequenced as the principal diagnosis. The commenter recommended that CMS continue to analyze the data in DRGS 535 and 536 and seek additional clinical input regarding the typical principal diagnosis for patients being admitted to evaluate the need for a CRT-D device. The commenters added that further revisions to these DRGs may be warranted in the future.

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

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

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

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

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

Response: We are addressing the issue of the surgical hierarchy surfaced by the commenter in section II.B.11. of this final rule. We have carefully evaluated the other issues raised by the commenter, and we concur that assigning procedures such as the revision or relocation of defibrillator pockets to a vague code such as code 37.99 does not allow these procedures to be clearly identified. We believe that grouping disparate procedures such as repositioning of leads, removal without replacement of pulse generator, and revision or relocation of pockets within one code makes the DRG refinements difficult. We will discuss this topic at the October 7-8, 2004 meeting of the ICD-9-CM Coordination and Maintenance Committee. We will give consideration to creating one or more new codes to more clearly identify these procedures. With these more precise codes, we should be able to modify the DRG logic to resolve this issue.

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

The commenter stated that there was significant difference in hospital charges associated with cases in DRG 515 with and without these principal diagnoses. The

commenter stated that it was important to ensure more appropriate payment for all defibrillator cases and better align the DRG payment logic across all pacemaker and defibrillator cases based on important differences in hospital resource requirements.

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

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

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

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

As a result of this analysis, we find that the requested split of DRG 515 would not result in cases with as significantly different lengths of stay or charges as compared to the difference between DRGs 535 and 536. In addition, our current data show only 4,191 cases that would be assigned to a new DRG for Cardiac Defibrillator Implant without Cardiac Catheterization with a principal diagnosis of acute myocardial infarction, heart failure, or shock. Given the limited number of cases in DRG 515 and the relatively small differences between average charges and length of stay for the two DRGs suggested by the commenter, we have decided that a modification of DRG 515 is not warranted at this time. However, we will examine the data in the future to determine if changes are warranted.

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

c. Combination Cardiac Pacemaker Devices and Lead Codes

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

DRG assignment are listed under DRGs 115 and 116. The commenter recommended that the following pacemaker device and lead procedure code combinations be added to these two DRGs:

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

These codes are defined as follows:

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

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

recommended procedure code combinations to the list of procedure code combinations under DRGs 115 and 116.

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

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

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

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

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

Comment: A number of comments from physicians applauded our decision to create new procedure code 00.16. The commenters stated that, upon approval by the Food and Drug Administration (FDA) of this procedure, the code will be used to recognize the E2F Decoy (edifoligide) procedure. This procedure will be performed on patients undergoing bypass vein graft procedures if the FDA finds the procedure to be

safe and effective. The commenters stated that they are currently performing this procedure on a number of their patients, and asked that Medicare payments that are in addition to that for the cardiac bypass procedure be made to offset resource utilization and costs incurred by hospitals.

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

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

In the FY 2003 IPPS final rule (67 FR 50242), we created two new codes for procedures involving an artificial anal sphincter, effective for discharges occurring on or after October 1, 2002: code 49.75 (Implantation or revision of artificial anal sphincter) that is used to identify cases involving implantation or revision of an artificial anal sphincter and code 49.76 (Removal of artificial anal sphincter) that is used to identify cases involving the removal of the device. In Table 6B of that final rule, we assigned

both codes to one of four MDCs, based on principal diagnosis, and one of six DRGs within those MDCs. In the August 1, 2003 IPPS final rule (68 FR 45372), we discussed the assignment of these codes in response to a request we had received to consider reassignment of these two codes to different MDCs and DRGs. The requester believed that the average charges ($44,000) for these codes warranted reassignment. In the August 1, 2003 IPPS final rule, we stated that we did not have sufficient MedPAR data available on the reporting of codes 49.75 and 49.76 to make a determination on DRG reassignment of these codes. We agreed that, if warranted, we would give further consideration to the DRG assignments of these codes because it is our customary practice to review DRG assignment(s) for newly created codes to determine clinical coherence and similar resource consumption after we have had the opportunity to collect MedPAR data on utilization, average length of stay charges, and distribution throughout the system.

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

$20,831 for the cases without CC. Average charges for DRG 157 were $18,196, while average charges for DRG 158 were $9,348.

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

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

Comment: Two commenters agreed with our proposal and suggested that the recommendation be adopted as a final change. One commenter recommended that CMS continue to monitor the cost of these cases for future consideration of the creation of a

new DRG. This commenter stated that CMS has limited reassignment of codes 49.75 and 49.76 to only one pair of DRGs. Specifically, these procedures were assigned to DRGs 157 and 158 and will be reassigned to DRGs 146 and 147. The commenter took issue with this limited correction and urged CMS to create a new DRG for "Complex Anal/Rectal Procedure with Implant".

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

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

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

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

a. 360 Degree Spinal Fusions

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

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

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

We also examined cases in related DRG 497 (Spinal Fusion Except Cervical With CC) and DRG 498 (Spinal Fusion Except Cervical Without CC) in which code 81.61 was not reported. The results of our examination are summarized in the following table.

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

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

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

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

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

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

First, the commenters believed that CMS did not fully address the clinical coherence of the cases, electing instead to make its proposal largely on the basis of charge coherence, alone. The commenters further believed that the combination of anterior and posterior fusions in a single surgery is the most appropriate for defining clinical characteristic of all cases currently included in DRG 496. The commenters stated that except for the number of incisions, a 360-degree (anterior and posterior) fusion is clinically comparable to all other anterior and posterior fusions because of the patient and the surgical characteristics.

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

One commenter stated that a high rate of coding errors is not surprising in the first year of use, given that code 81.61 just became effective for FY 2003, that 360-degree spinal fusion is a complex topic, and that misinformation may have been given. The commenter recommended that consideration of a reclassification be held for at least another year or two to ensure that a sufficient volume of more accurate data can be collected and analyzed.

Third, with regard to the issue of DRGs serving as an incentive for more efficient care, the commenters believed that CMS proposed the reassignment of code 81.61 to avoid lowering the relative weight for DRG 496 in the future. They stated that, by contrast, CMS has often maintained in the past that the DRG weighting process allows changes in the resource intensity of specific types of cases (whether upward or

downward) to be reflected over time, as technology evolves. The commenters indicated that the single-incision method may be less time-consuming, use fewer hospital resources, and allow patients to enjoy a shorter recovery period. The commenters stated that collection and analysis of additional and more accurate data may well show this. However, the commenters recommended that we leave code 81.61 in DRG 496 as a financial incentive for providers to perform the lower-resource procedure. The commenters believed this would lead to the reduction of the relative weight for DRG 496 as more providers performed the less expensive procedure (single-incision anterior/posterior fusion). The commenters stated that the weighting process in DRG 496 is ideally designed to accomplish the goal of having hospitals perform a procedure that requires less resources.

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

We acknowledge that there have been a number of questions concerning the use of code 81.61. This code has been discussed at the Editorial Advisory Board on Coding

Clinic for ICD-9-CM. Based on some of the records sent to the Board, it would appear that some hospitals are incorrectly applying this code. The Board is attempting to develop additional educational material to include in future issues of Coding Clinic for ICD-9-CM.

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

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

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

Comment: One commenter opposed moving code 81.61 from DRG 496 and into DRGs 497 and 498. The commenter stated that the amount of time it takes to perform a single incision 360-degree spinal fusion is similar to that of performing an anterior and posterior spinal fusion with two approaches. The commenter stated that any extra time in completing the surgery involves turning the patient over so that the separate approach (incision) can be made. The commenter stated that, in his hospital, the length of stay for one incision versus two incision approaches to spinal fusion does not vary significantly.

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

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

b. Multiple Level Spinal Fusion

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

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

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

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

addition, adopting the commenter's recommendation would have necessitated adjusting the DRG relative weights using non-MedPAR data because Medicare claims data with the new ICD-9-CM codes would not have been available until the FY 2003 MedPAR file. Therefore, at that time, we did not redefine the spinal fusion DRGs to differentiate on the basis of the number of levels of vertebrae involved in a spinal fusion procedure.

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

In addition, no other surgical DRG is split based on the number of procedures performed. For instance, the same DRG is assigned whether one or more angioplasties are performed on a patient's arteries. The insertion of multiple stents within an artery

does not result in a different DRG assignment. Similarly, the excision of neoplasms from multiple sites does not lead to a different DRG assignment. To begin splitting DRGs based on the number of procedures performed or devices inserted could set a new and significant precedent for DRG policy. Therefore, in the May 18, 2004 proposed rule, we indicated that while we would continue to study this area, we did not propose to redefine the spinal fusion DRGs based on the number of levels of vertebrae fused.

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

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

Comment: One commenter who supported our recommendation expressed concern that our decision was grounded in part on the expectation that a "more conservative" surgical approach for back pain (that is spinal disc replacement) will be available soon. (In the proposed rule, we noted that new codes for spinal disc prosthesis procedures, codes 84.60 through 84.69, will go into effect on October 1, 2004). The

commenter stated that FDA has not approved some of the spinal disc prostheses. The commenter believed that this new technology may not become a medically accepted procedure in the clinical community. The commenter believed that we were implying that we would defer a decision on modification of the spinal fusion DRGs until such time as the FDA formally approves spinal disc prosthesis procedures. The commenter recommended that the spinal fusion DRGs should not be modified at this point; that CMS should wait for data using the multiple level spinal fusion codes prior to proposing modifications of the spinal fusion DRGs; and that CMS not wait to make any modifications to these DRGs based upon FDA approval of spinal disc prostheses.

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

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

c. Insertion of Spinal Disc Prostheses and Other Spinal Devices

In the May 18, 2004 proposed rule, we included in Table 6B of the Addendum new codes that were created to capture the insertion of spinal disc prostheses and other

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

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

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

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

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

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

Comment: Several commenters that are developing spinal disc prosthesis devices described these spinal disc prostheses devices as minimally invasive alternatives to spinal fusion. The commenters indicated that there is controversy among spine surgeons as to the cause, or causes, of back pain. However, they stated that many surgeons believe degeneration of the nucleus and annular destruction is a major source of pain. The commenters stated that if patients fail conservative treatment, spinal fusion is currently the primary treatment option. The commenters further stated that fusing one or more levels in the spine results in increased stress and strain and the potential breakdown at adjacent disc levels. In addition, the commenters stated that partial and total spinal disc replacement prosthesis devices were designed to replace the degenerated nucleus or disc and restore the normal disc function and anatomy. They believed these devices have the potential of decreasing stress, which is redistributed to adjacent levels of the spine when spinal fusions are performed. The commenters indicated that fusion surgery patients have poor return to work results, that recovery periods are extended, and that the spinal disc prosthesis devices reduce this recovery period.

The commenters objected to the proposed assignment of the new spinal disc prosthesis codes (84.60 through 84.69) to DRGs 499 and 500 in MDC 8. The commenters stated that since total and partial spinal disc prostheses will be used for patients who would very likely be candidates for spinal fusion, the procedures should be assigned to DRGs 497 and 498 for those in the lumbar spine and to DRGs 519 and 520 for those implanted in the cervical spine. One commenter compared the implantation of a total spinal disc prosthesis device in the lumbar spine to that of fusion of the lumbar spine

with the use of a BAK cage. The commenter stated that both use an anterior approach to the surgery, and both involve implanting devices in the anterior part of the spine. One procedure involves implanting the spinal disc prosthesis; the other involves implanting a BAK cage while fusing the spine.

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

Response: Based on advice from our medical advisors, we disagree with the suggestion that patients having partial and total spinal disc prosthesis procedures are clinically similar to patients assigned to the spinal fusion DRGs. To mix these two distinctly different approaches to the treatment of back pain would violate the principal of clinical cohesiveness of DRGs. DRGs 497, 498, 519, and 520 include only procedures that involve fusion of the spine. DRGs 499 and 500 include a number of other procedures performed on the spine and explicitly exclude spinal fusion procedures. Currently, spinal disc prosthesis procedures are assigned to code 80.51 (Excision of intervertebral disc). The new, more specific codes (84.60 through 84.69) will go into

effect on October 1, 2004. As stated earlier, code 80.51 is assigned to DRGs 499 and 500 within MDC 8. Our proposal of assigning the new spinal disc prosthesis codes to DRGs 499 and 500 would maintain current practice based on the assignment of the predecessor code 80.51. Our medical advisors also stated that it would be inappropriate to move the partial and total spinal disc procedures to the spinal fusion DRGs because the implantation of these disc devices do not involve fusion of the spine. We do not yet have any charge data on these new types of spinal procedures because the codes are being implemented on October 1, 2004. Thus, it would also be premature to assign these new procedures to the fusion DRGs.

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

d. Kyphoplasty

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

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

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

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

Therefore, we are adopting, as final, our proposed assignment of new codes 81.65 and 81.66 to DRGs 223 and 234 in MDC 8, DRGs 442 and 443 in MDC 21, and DRG 486 in MDC 24, as indicated in Table 6B of the Addendum to this final rule. We will

take the commenters' recommendation into consideration when we conduct our annual reviews of MedPAR data.

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

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

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

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

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

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

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

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

- 398.91, Rheumatic heart failure (congestive)

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

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

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

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

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

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

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

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

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

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

Comment: Several commenters supported our proposal not to modify DRGs 521 through 523 by removing code 292.82. One commenter representing hospital coders disagreed with our proposal to retain code 292.82 in DRGs 521 through 523. The commenter stated that DRGs 521 through 523 are described as alcohol/drug abuse and dependence DRGs. The commenter further indicated that drug-induced dementia could be caused by an adverse effect of a prescribed medication or a poisoning. The commenter did not believe that assignment of drug-induced dementia to DRGs 521 through 523 was appropriate if the drug-induced dementia is related to an adverse effect or poisoning due to a prescribed drug. The commenter recommended that admissions for drug-induced dementia be classified to DRGs 521 through 523 only if there is a secondary diagnosis indicating alcohol/drug abuse or dependence.

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

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

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

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

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

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

In the August 1, 2002 final rule, we modified DRGs 482 and 483 to recognize code 96.72 (Continuous mechanical ventilation for 96+ hours) for the first time in the DRG assignment (67 FR 49996). The modification was partially in response to concerns that hospitals could omit diagnosis codes indicating face, mouth, or neck diagnoses in order to have cases assigned to DRG 483 rather than the much lower paying DRG 482 (the payment for DRG 483 is more than four times greater than the DRG 482 payment weight). In addition, we noted that many patients assigned to DRG 483 did not have code 96.72 recorded. We believed this was due, in part, to the limited number of procedure codes (six) that can be submitted on the current billing form and the fact that code 96.72 did not affect the DRG assignment prior to FY 2003. The modification was the first attempt to refine DRGs 482 and 483 so that patients who receive long-term

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

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

- DRG 483 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses)
- DRG 504 (Extensive 3rd Degree Burns With Skin Graft)
- DRG 505 (Extensive 3rd Degree Burns Without Skin Graft)

- DRG 506 (Full Thickness Burn With Skin Graft or Inhalation Injury With CC or Significant Trauma)
- DRG 507 (Full Thickness Burn With Skin Graft or Inhalation Injury Without CC or Significant Trauma)
- DRG 508 (Full Thickness Burn Without Skin Graft or Inhalation Injury With CC or Significant Trauma)
- DRG 509 (Full Thickness Burn Without Skin Graft or Inhalation Injury Without CC or Significant Trauma)
- DRG 510 (Nonextensive Burns With CC or Significant Trauma)
- DRG 511 (Nonextensive Burns Without CC or Significant Trauma)

The following chart summarizes those findings:

DRG	Count	Average Length of Stay	Average Charges
483 All cases	31,754	37.68	$210,631.94
483 Cases with code 96.72 reported	19,669	36.54	$195,171.66
483 Cases without code 96.72 reported	12,085	39.52	$235,794.39
504 All cases	98	30.54	$191,645.49
504 Cases with code 97.62 reported	19	25.79	$264,095.16
504 Cases without code 96.72 reported	79	31.68	$174,220.89
505 All cases	119	2.96	$18,619.78
505 Cases with code 96.72 reported	20	7.70	$42,613.00
505 Cases without code 96.72 reported	99	2.00	$13,772.67
506 All cases	754	16.15	$61,370.63
506 Cases with code 96.72 reported	54	20.13	$138,272.46
506 Cases without code 96.72 reported	700	15.85	$55,438.20
507 All cases	236	8.78	$25,891.89
507 Cases with code 96.72 reported	1	38.00	$137,132.00
507 Cases without code 96.72 reported	235	8.66	$25,418.53
508 All cases	448	7.02	$18,332.46
508 Cases with code 96.72 reported	5	10.40	$83,171.80

DRG	Count	Average Length of Stay	Average Charges
508 Cases without code 96.72 reported	443	6.98	$17,600.64
509 All cases	117	4.32	$8,994.71
509 Cases with code 96.72 reported	0	0	0
509 Cases without code 96.72 reported	117	4.32	$8,994.71
510 All cases	1,209	6.90	$18,457.21
510 Cases with code 96.72 reported	21	20.52	$93,925.62
510 Cases without code 96.72 reported	1,188	6.66	$17,123.18
511 All cases	413	4.18	$10,046.89
511 Cases with code 96.72 reported	0	0	0
511 Cases without code 96.72 reported	413	4.18	$10,046.89

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

We noted that there were 21 cases that reported code 96.72 within DRG 510. Since the 21 patients were on continuous mechanical ventilation for 96 consecutive hours or more, it seems surprising that the principal diagnosis was listed as one of the nonextensive burn codes included in DRG 510. A closer review of these cases shows some questionable coding and reporting of information. It would appear that hospitals did not always correctly select the principal diagnosis (the reason after study that led to the hospital admission). For instance, one admission was for a second-degree burn of the ear. This patient was on a ventilator for over 96 hours. It would appear that the reason for the admission was a diagnosis other than the burn of the ear. Other cases where the patient received long-term mechanical ventilation included those with a principal

diagnosis of first degree burn of the face, second degree burn of the nose, second degree burn of the lip, and an unspecified burn of the foot. These four cases reported average charges ranging from $48,551 to $186,824 and had lengths of stay ranging from 8 to 36 days.

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

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

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

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

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

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

commenters also recommended that consideration be given to further refinements of DRGs 504 and 505. The commenters recommended that in the future CMS consider further DRG splits for cases in DRGs 504 and 505 that have extensive third degree burns with an inhalation injury and 96+ hours of mechanical ventilation or perhaps creating a new DRG specifically for these patients.

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

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

Coding Clinic for ICD-9-CM to assist hospitals in sequencing the principal diagnosis for burn cases in which the patients have an inhalation injury and a minor skin burn.

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

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

Response: We appreciate the commenter's support of the proposed DRG changes for burn patients on mechanical ventilation. As we indicated in the proposed rule, we agree with the commenters' suggestion that hospitals should review their medical records for cases assigned to DRG 510 or 511 that had a code for mechanical ventilation to

determine if there are coding errors. We agree that it is important for hospitals to have good medical record documentation in order to code accurately.

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

9. Pre-MDC: Tracheostomy

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

In the May 18, 2004 proposed rule, we indicated that we had examined cases in the MedPAR file in which code 96.72 was reported within DRGs 482 and 483. The

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

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

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

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

In the proposed rule we stated that in DRG 483, 19,669 cases were reported with code 96.72. However, we noted that the data were counter-intuitive. While one would expect to find higher average charges for cases reported with code 96.72, the opposite is

the case. Cases in DRG 483 reported with code 96.72 had average charges that were $40,623 lower than those not reported with code 96.72. Clearly, the presence or absence of code 96.72 does not explain differences in charges for patients within DRG 483.

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

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

We found that cases of patients assigned to DRG 483 who had a major procedure (in addition to the required tracheostomy) had average charges that were $87,023 higher

than the average charges for cases without a major O.R. procedure and had an average length of stay of 5 days more than those without a major O.R. procedure. We found that the performance of an additional major O.R. procedure helps to identify the more expensive patients within DRG 483.

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

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

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

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

Comment: Some commenters supported our proposed changes to DRG 483. One commenter stated that, based on the data presented by CMS, the proposal appears to be a reasonable approach to distinguish the more expensive cases in DRG 483. The commenter also stated that hospitals are not always reporting code 96.72 due to space limitations (that is, the electronic billing system limits the number of procedures that can

be reported to six procedure codes). The commenter stated that patients in this patient population (undergoing procedures with procedure code 96.72) may have several significant O.R. procedures that may be sequenced before code 96.72, resulting in code 96.72 not appearing on the claim.

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

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

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

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

Response: As we stated in the May 18, 2004 proposed rule, a major O.R. procedure is a procedure whose code is included on the list that would be assigned to DRG 468, except for tracheostomy codes 31.21 and 31.29. These are the procedure

codes listed as O.R. procedures in Appendix E of the Diagnosis Related Groups Definitions Manual. The reporting of a major procedure with a procedure code from Appendix E, along with an unrelated principal diagnosis, results in a case being assigned to DRG 468. Major O.R. procedures do not include prostatic or nonextensive procedures, or both, which are assigned to DRGs 476 and 477.

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

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

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

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

Response: Patients undergoing more than 96 hours of mechanical ventilation are captured through code 96.72. Currently, patients with a respiratory system diagnosis listed in MDC 4 who receive mechanical ventilation are assigned to DRG 475. Cases are assigned to DRG 475 if one of the following procedure codes is reported:

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

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

As stated in the May 4, 2001 proposed rule (66 FR 22646)*:* "Central to the success of the Medicare inpatient hospital prospective payment system is that DRGs have remained a clinical description of why the patient required hospitalization." Thus, the central classification criteria for DRG assignment has been the reason the patient was admitted (that is, the principal diagnosis for medical patients and the procedures performed for surgical patients). For a medical patient admitted for respiratory disease, the use of mechanical ventilation was used as a classification criteria because the mechanical ventilation was directly associated with the reason for hospital admission. The one exception to this rule is for patients who received a tracheostomy for long-term mechanical ventilation. These are catastrophic patients who, in general, have serious disease in multiple organ systems. Tracheostomies are performed on patients when it is anticipated that the patients will remain on mechanical ventilation for an extended period. The tracheostomy patients with long-term mechanical ventilation were all assigned to the same DRG regardless of their reason for admission. As we discussed previously, we are subdividing the patients assigned to DRG 483 into two new DRG 541 and 542 based on the presence of an additional major O.R. procedure.

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

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

In summary, in this final rule, we are deleting DRG 483 and establishing the following new DRGs 541 and 542 as replacements:

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

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

10. Medicare Code Editor (MCE) Changes

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

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

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

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

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

- 11.71, Keratomileusis
- 11.72, Keratophakia
- 11.75, Radial keratotomy
- 11.76, Epikeratophakia
- 36.32, Other 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

Diagnosis List 1:

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

● 250.21, Diabetes with hyperosmolarity, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled

● 250.22, Diabetes with hyperosmolarity, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled

● 250.23, Diabetes with hyperosmolarity, type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled

● 250.30, Diabetes with other coma, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled

● 250.31, Diabetes with other coma, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled

● 250.32, Diabetes with other coma, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled

● 250.33, Diabetes with other coma, type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled

● 250.40, Diabetes with renal manifestation, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled

● 250.41, Diabetes with renal manifestation, , type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled

● 250.42, Diabetes with renal manifestation, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled

● 250.43, Diabetes with renal manifestation, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled

● 250.50, Diabetes with ophthalmic manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled

● 250.51, Diabetes with ophthalmic manifestations, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled

● 250.52, Diabetes with ophthalmic manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled

● 250.53, Diabetes with ophthalmic manifestations, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled

● 250.60, Diabetes with neurological manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled

● 250.61, Diabetes with neurological manifestations, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled

● 250.62, Diabetes with neurological manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled

● 250.63, Diabetes with neurological manifestations, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled

● 250.70, Diabetes with peripheral circulatory disorders, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled

● 250.71, Diabetes with peripheral circulatory disorders type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled

● 250.72, Diabetes with peripheral circulatory disorders, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled

● 250.73, Diabetes with peripheral circulatory disorders, type I [insulin dependent type] [IDDM type] [juvenile type], uncontrolled

● 250.80, Diabetes with other specified manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled

● 250.81, Diabetes with other specified manifestations, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled

● 250.82, Diabetes with other specified manifestations, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled

● 250.83, Diabetes with other specified manifestations, type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled

● 250.90, Diabetes with unspecified complication, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, not stated as uncontrolled

● 250.91, Diabetes with unspecified complication, type I [insulin dependent type] [IDDM] [juvenile type], not stated as uncontrolled

● 250.92, Diabetes with unspecified complication, type II [non-insulin dependent type] [NIDDM type] [adult-onset type] or unspecified type, uncontrolled

● 250.93, Diabetes with unspecified complication, type I [insulin dependent type] [IDDM] [juvenile type], uncontrolled

Note: The proposed rule contained inadvertent typographical errors in the above list on four diabetes codes at 250.50 through 250.53. These errors have been corrected in this list in the final rule.

Diagnosis List 2:

● 403.01, Malignant hypertensive renal disease, with renal failure

● 403.11, Benign hypertensive renal disease, with renal failure

● 403.91, Unspecified hypertensive renal disease, with renal failure

● 404.02, Malignant hypertensive heart and renal disease, with renal failure

● 404.03, Malignant hypertensive heart and renal disease, with heart failure and renal failure

● 404.12, Benign hypertensive heart and renal disease, with renal failure

● 404.13, Benign hypertensive heart and renal disease, with heart failure and renal failure

● 404.92, Unspecified hypertensive heart and renal disease, with renal failure

● 404.93, Unspecified hypertensive heart and renal disease, with heart failure and renal failure

● 585, Chronic renal failure

● V42.0, Organ or tissue replaced by transplant, kidney

- V43.89, Organ or tissue replaced by other means, other

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

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

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

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

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

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

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

b. Edit 6 (Manifestations Not Allowed As Principal Diagnosis) in the MCE contains codes that describe the manifestation of an underlying disease, not the disease

itself, and therefore, should not be used as a principal diagnosis. The following codes describe manifestations of an underlying disease; they should not be used as a principal diagnosis according to ICD-9-CM coding convention. Therefore, in the May 18, 2004 proposed rule, we proposed to add the following diagnosis codes to Edit 6:

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

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

We received two comments in support of our proposal to add three diagnosis codes to Edit 6 of the MCE. However, both commenters pointed out a typographical error in one of the citations of the diagnosis codes. Code 571.3 should have read 517.3.

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

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

2004 IPPS proposed rule (69 FR 28197), we indicated that we will now be able to make the necessary system changes before the start of FY 2005. Therefore, we proposed to remove the following codes from Edit 9:

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

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

11. Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the DRG associated with the most resource-intensive surgical class.

Because the relative resource intensity of surgical classes can shift as a function of DRG reclassification and recalibrations, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications and recalibrations, to determine if the ordering of classes coincides with the intensity of resource utilization.

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

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

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average charge is ordered above a surgical class with a higher average charge. For example, the "other O.R. procedures" surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average charge for the DRG or DRGs in that surgical class may be higher than that for other surgical classes in the MDC. The "other O.R. procedures" class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients in the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

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

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

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

In the pre-MDC DRGs, we proposed to reorder DRG 541 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses With Major O.R. Procedure) and DRG 542 (Tracheostomy With Mechanical

Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth, and Neck Diagnoses Without Major O.R. Procedure) above DRG 480 (Liver Transplant).

In MDC 8, we proposed to--

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

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

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

- Reorder DRG 499 (Back and Neck Procedures Except Spinal Fusion With CC) and DRG 500 (Back and Neck Procedures Except Spinal Fusion Without CC) above DRG 218 (Lower Extremity and Humerus Procedures Except Hip, Foot, and Femur Age > 17 With CC), DRG 219 (Lower Extremity and Humerus Procedures Except Hip, Foot, and Femor Age > 17 Without CC), and DRG 220 (Lower Extremity and Humerus Procedures Except Hip, Foot, and Femur Age 0-17).

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

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

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

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

12. Refinement of Complications and Comorbidities (CC) List

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination

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

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

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

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

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

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

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

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

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

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

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

[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.

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

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

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

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

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

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

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

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

- 60.0, Incision of prostate

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

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

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[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 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

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, in the May 18, 2004 proposed rule, we did not propose to move any procedures from DRG 477 to one of the surgical DRGs in this final rule.

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

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

We also annually review the list of ICD-9-CM procedures that, when in combination with their principal diagnosis code, result in assignment to DRGs 468, 476, and 477, to ascertain if any of those procedures should be reassigned from one of these

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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.

three DRGs to another of the three DRGs based on average charges and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data. Based on a comment we received in response to last year's proposed rule (68 FR 45366), in the May 18, 2004 proposed rule, we proposed to move procedure code 51.23 (Laparoscopic cholecystectomy) from DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis) into DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis).

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

- 44.67, Laparoscopic procedures for creation of esophagogastric sphincteric competence
- 44.68, Laparoscopic gastroplasty
- 44.95, Laparoscopic gastric restrictive procedure

- 44.96, Laparoscopic revision of gastric restrictive procedure
- 44.97, Laparoscopic removal of gastric restrictive device(s)
- 44.98, Laparoscopic adjustment of size of adjustable gastric restrictive device

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

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

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

c. Adding Diagnosis or Procedure Codes to MDCs

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

14. Pancreatic Islet Cell Transplantation in Clinical Trials

Section 733(a) of Pub. L. 108-173 directs the Secretary, acting through the National Institute of Diabetes and Digestive and Kidney Disorders (NIDDKD) to conduct a clinical investigation of pancreatic islet cell transplantation that includes Medicare beneficiaries. Section 733(b) of Pub. L. 108-173 provides for Medicare payments, beginning no earlier than October 1, 2004, for the routine costs as well as the costs of the transplantation and appropriate related items and services for Medicare beneficiaries who are participating in a clinical trial as if such transplantation were covered under Medicare

Part A or Part B. Routine costs are defined as reasonable and necessary routine patient care costs (as defined in the CMS Coverage Issues Manual, Section 30-1) including immunosuppressive drugs and other followup care. Section 733(c)(2) of Pub. L. 108-173 defines transplantation and appropriate related items and services as items and services related to the acquisition and delivery of the pancreatic islet cell transplantation, notwithstanding any national noncoverage determination contained in the CMS Coverage Issues Manual.

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

determination of the reasonableness of these costs in each institution. We note there is precedent to exclude acquisition costs from the pass-through payment process. For example, stem cell transplants and corneal transplants do not have acquisition costs reimbursed as a cost pass-through payment.

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

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

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

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

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

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

rule we are modifying the structure of DRG 315 so that patients receiving infusions of islet cells without any other surgical intervention will be appropriately assigned to this DRG.

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

We were reluctant to propose assigning the islet cell codes to one specific DRG, as the islet cell infusion will have different indications depending on the merits of each case, as is shown from the MedPAR data mentioned above. In addition, we do not currently have accurate cost data or charges for patients in this type of clinical trial, which makes it difficult to determine an appropriate DRG weight. As a result, assignment of cases to a specific DRG might have the consequence of either overpaying or underpaying the cases. We believe that both of these consequences are unacceptable. Therefore, we did not propose that cases involved in the clinical trial be assigned to one specific DRG for payment purposes. As we believe that these cases will have been

assigned to DRGs 302, 315, and 468, we proposed to establish an add-on payment for cases in these three DRGs containing procedure codes 52.84 or 52.85. As stated earlier, we were not able to establish the amount of this add-on until we had determined procurement costs for the islet cells. We solicited information from transplant centers and organ procurement organizations on costs for these types of transplantations.

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

Response: The commenters are correct in their assessment. Therefore, we are modifying the structure of DRG 315 so that patients receiving infusions of islet cells without any other surgical intervention will appropriately be assigned to DRG 315. We are aware that patients will often require more than one admission for islet cell transplantation. We are making this modification in order to recognize the surgical aspects of islet cell transplantation in the absence of any other surgical procedure.

The logic for DRG 315 is modified as follows:

O.R. Procedures

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

or

Non-O.R. Procedures

52.84, Autotransplantation of cells of islets of Langerhans

52.85, Allotransplantation of cells of islets of Langerhans

or

Principal Diagnosis

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

and

Non-O.R. Procedure

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

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

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

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

Response: DRGs are created based on the need of the program to identify clinical coherence and resource consumption. Ideally, both components will be part of the decision making process in DRG creation. In this case, we have no substantial data upon which to determine an appropriate relative weight for the resources that will be utilized in all islet cell transplant cases. In addition, there may be different scenarios in which patients are transfused with islet cells. These cases could include patients receiving a kidney transplant during the same admission, or cases in which the islet cells comprise the only procedure during the admission. As cases will be varied in this clinical trial, we prefer to have MedPAR data and case histories prior to creating specific new DRGs for these cases.

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

Response: While the patient populations requiring intervention are similar, we do not believe that one can equate an operation of the magnitude of a pancreas transplant with a less intensive islet cell transplantation in which the portal vein is accessed and islet

cells infused through a catheter. It is only because the technical aspects of islet transplants are of a surgical nature that we have modified surgical DRG 315 to reflect the transfusion of islet cells.

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

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

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

Response: We continue to believe that reimbursing acquisition costs as an add-on to the DRG is an appropriate reimbursement mechanism. However, we have decided that

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

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

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

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

the isolation center data provided to CMS for use in developing the add-on payment and expressed concerns about the validity of these data.

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

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

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

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

Response: We recognize that normally two or more infusions are required for islet transplants. We also understand that it is extremely rare for two infusions to be performed at the same time. Accordingly, we have constructed our payment mechanism to pay one DRG for the infusion and one islet isolation add-on amount per discharge under most circumstances for allograft islet cell transplants. However, in those rare instances in which two infusions occur during the same hospital stay, two add-on payments for isolation of the islet cells can be made along with the single DRG payment. The cost associated with the procurement of two pancreata will be paid as an acquisition cost on a reasonable cost basis. We will issue billing instructions on this issue

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

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

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

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

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

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

Comment: One commenter believed that the costs associated with the isolation portion of the add-on amount should be between $30,000 and $40,000. This commenter

further explained that isolation centers incur cost and time to develop improvements to the islet isolation technology and pointed out the startup costs associated with an FDA approved isolation center.

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

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

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

DRG payment for the native pancreatectomy procedure itself. The isolation add-on amount will be $18,848 for an autograft islet cell transplant.

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

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

As described in section II.B.1. of this preamble, the ICD-9-CM is a coding system used for the reporting of diagnoses and procedures performed on a patient. In September 1985, the ICD-9-CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD-9-CM system. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD-9-CM to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The Official Version of the ICD-9-CM contains the list of valid diagnosis and procedure codes. (The Official Version of the ICD-9-CM is available from the Government Printing Office on CD-ROM for $25.00 by calling (202) 512-1800.) The

Official Version of the ICD-9-CM is no longer available in printed manual form from the Federal Government; it is only available on CD-ROM. Users who need a paper version are referred to one of the many products available from publishing houses.

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

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

The Committee presented proposals for coding changes for implementation in FY 2005 at public meetings held on April 3, 2003, December 4-5, 2003, and April 1-2, 2004, and finalized the coding changes after consideration of comments received at the meetings and in writing by January 12, 2004. Those coding changes are announced in Tables 6A through 6F of the Addendum to this rule. Copies of the minutes

of the procedure codes discussions at the Committee's 2003 meetings can be obtained from the CMS website: **http://www.cms.gov/paymentsystems/icd9/**. The minutes of the diagnoses codes discussions at the 2003 meetings are found at: **http://www.cdc.gov/nchs/icd9.htm**. Paper copies of these minutes are no longer available and the mailing list has been discontinued.

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

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

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

The ICD-9-CM code changes that have been approved will become effective October 1, 2004. The new ICD-9-CM codes are listed, along with their DRG classifications, in Tables 6A and 6B (New Diagnosis Codes and New Procedure Codes, respectively) in the Addendum to this final rule. As we stated above, the code numbers

and their titles were presented for public comment at the ICD-9-CM Coordination and Maintenance Committee meetings. Both oral and written comments were considered before the codes were approved. In the May 18, 2004 proposed rule, we only solicited comments on the proposed classification of these new codes.

For codes that have been replaced by new or expanded codes, the corresponding new or expanded diagnosis codes are included in Table 6A. New procedure codes are shown in Table 6B. Diagnosis codes that have been replaced by expanded codes or other codes or have been deleted are in Table 6C (Invalid Diagnosis Codes). These invalid diagnosis codes will not be recognized by the 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 Pub. L. 108-173 includes a requirement for updating ICD-9-CM codes twice a year instead of the current process of annual updates on October 1 of each year. This requirement is included as part of the amendments to the Act relating to

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

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

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

A discussion of this timeline and the need for changes are included in the December 4-5, 2003 ICD-9-CM Coordination and Maintenance Committee minutes. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this new update would have on providers. Therefore,

we have rescheduled the second Committee meeting for 2004 for October 7-8, 2004. Those who wish to have a coding issue discussed at the October Committee meeting will be required to submit their request by August 7, 2004. The Department will continue this process to accommodate all requesters who submit appropriate requests in a timely manner.

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

We stated that we believe that this proposal captures the intent of section 503(a). This requirement was included in the provision revising the standards and process for recognizing new technology under the IPPS. In addition, the need for approval of new codes outside the existing cycle (October 1) arises most frequently and most acutely

where the new codes will capture new technologies that are (or will be) under consideration for new technology add-on payments. Thus, we believe this provision was intended to expedite data collection through the assignment of new ICD-9-CM codes for new technologies seeking higher payments. We indicated that our proposal was designed to carry out that intention, while minimizing the additional administrative costs associated with mid-year changes to the ICD-9-CM codes.

Comment: Several comments expressed concerns about the impact the April 1 ICD-9-CM coding update will have on providers. While the commenters acknowledged the requirement was mandated by section 503(a) of Pub. L. 108-173, the commenters urged CMS to carefully consider the number of these mid-year coding updates. The commenters stated that these changes will have a significant impact on providers' systems. One commenter representing a large hospital organization recommended that codes being considered for the April 1 update be limited only to new technologies that present a strong and convincing case for new technology add-on payment. The commenter recommended that the annual April 1 update be limited to as few codes as possible for the following reasons:

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

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

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

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

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

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

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

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

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

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

Comment: Several commenters requested details on how the public will be notified of the April ICD-9-CM code updates. They requested clarification as to whether the current publication processes will be used. One commenter representing a national organization of codes and health information managers urged CMS to provide information on April 1 code updates at least 4 months prior to implementation. Other commenters representing hospital organizations urged CMS to provide updates 5 months ahead of implementation, or by November of the prior year.

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

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

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

Currently, code titles are also published in the IPPS proposed and final rules. The code titles are adopted as part of the ICD-9-CM Coordination and Maintenance Committee process. The code titles are not subject to comment in the proposed or final rules. We will continue to publish the October code updates in this manner within the IPPS proposed and final rules. However, we do not publish a mid-year IPPS rule, so the April 1 code updates will not be published in a mid-year IPPS rule. We will assign the new procedure code to the same DRG in which its predecessor code was assigned so there will be no DRG impact as far as DRG assignment. This mapping was specified by Pub. L. 108-173. Any proposed coding updates will be available through the websites indicated above and through the Coding Clinic for ICD-9-CM. Publishers and software vendors currently obtain code changes through these sources in order to update their code books and software systems. We will strive to have the April 1 updates available through these websites 5 months prior to implementation (that is, early November of the previous year), as is the case for the October 1 updates. Code book publishers are evaluating how they will provide any code updates to their subscribers. Some publishers may decide to publish mid-year book updates. Others may decide to sell an addendum that lists the

changes to the October 1 code book. Coding personnel should contact publishers to determine how they will update their books. CMS and its contractors will also consider developing provider education articles concerning this change to the effective date of certain ICD-9-CM codes.

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

Response: We agree that section 503(a) of Pub. L. 108-173 did not limit ICD-9-CM code updates to procedure codes. The legislation covered all of ICD-9-CM,

which includes both diagnoses and procedures codes. Therefore, consideration will be given to updates to both the diagnosis and procedure parts of ICD-9-CM on April 1 if a strong and convincing case can be made that either a diagnosis or procedure code is necessary to capture a new technology. We acknowledge that it may be necessary to recognize a new disease, such as SARS, on April 1 so that a new technology directed toward the disease can be more easily identified. We anticipate that most, if not all, requests for April 1 ICD-9-CM code updates will apply to procedure codes, as the commenters have stated. While it is unlikely that there will be many such disease code requests for an April 1 update, we will not restrict any such requests for consideration.

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

started by the end of 2004. Another commenter stated that ICD-9-CM is becoming increasingly difficult to update and progress should be made on implementing ICD-10.

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

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

16. Other Issues

a. Craniotomy Procedures

As discussed in the August 1, 2003 IPPS final rule (68 FR 45353), for FY 2004 we conducted an analysis of the charges for various procedures and diagnoses within DRG 1 (Craniotomy Age > 17 With CC) and DRG 2 (Craniotomy Age > 17 Without CC) to determine whether further changes to these DRGs were warranted. Based on our analysis and consideration of public comments received on our May 19, 2003 IPPS

proposed rule (68 FR 27161), in the August 1, 2003 IPPS final rule, we created three new DRGs: DRG 528 (Intracranial Vascular Procedures With a Principal Diagnosis of Hemorrhage) for patients with an intracranial vascular procedure and an intracranial hemorrhage; and DRGs 529 (Ventricular Shunt Procedures With CC) and 530 (Ventricular Shunt Procedures Without CC) for patients with only a vascular shunt procedure.

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

(1) Unruptured Cerebral Aneurysms

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

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

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

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

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

(2) GLIADEL® Chemotherapy Wafers

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

At that time, we had analyzed data in the March 2003 update of the FY 2003 MedPAR file and found a total of 61 cases in which procedure code 00.10 (Implantation of a chemotherapy agent) was reported for cases assigned to DRGs 1 and 2. There were

38 cases assigned to DRG 1 and 23 cases assigned to DRG 2. The 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.

In the May 18, 2004 proposed rule, we discussed our examination of more complete MedPAR data (December 2003 update for FY 2003) on cases reporting GLIADEL® chemotherapy wafers. We found a total of 127 cases in which procedure code 00.10 was reported for cases assigned to DRGs 1 and 2. There were 80 cases assigned to DRG 1 and 47 cases assigned to DRG 2. The average charges for these cases in DRGs 1 and 2 were approximately $61,866 and $47,189, respectively. The average charges for these cases were higher than the overall charges of DRGs 1 and 2 of approximately $51,300 and $28,416, respectively. Although the average charges for the GLIADEL® wafer cases within these DRGs are higher than the average charges of all cases in these DRGs, they remain within the range of average charges for other procedures included in these DRGs. The majority of the GLIADEL® wafer cases are

assigned to the second highest weighted DRG in MDC 1 behind DRG 528 (Intracranial Vascular Procedure With a Principal Diagnosis of Hemorrhage) in which the weights were derived from average charges of approximately $113,884. In DRG 1, there are 10 procedures that have higher average charges than the GLIADEL® wafer cases. However, in DRG 2, the charges associated with GLIADEL® wafer cases are the highest of the procedures included within the DRG.

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

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

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

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

We recognize that the implantation of chemotherapeutically active wafers for local therapy of malignant brain tumors represents a significant medical technology that currently offers clinical benefits to patients and holds out the promise of future innovation in the treatment of these brain tumors.

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

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

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

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

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

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

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

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

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

Although we did not propose this specific solution to the issue of payment for GLIADEL® in the proposed rule, we indicated that we would continue to consider appropriate changes to the DRG assignment of cases involving GLIADEL®. Furthermore, we believe that the creation of a new DRG for cases involving implantation of a chemotherapeutic agent or cases with an acute complex central nervous system diagnosis as the principal diagnosis ensures that GLIADEL® cases are assigned to a DRG that is clinically coherent and reflects the resources used to treat these cases and appropriately addresses the concerns of those commenters who raised questions regarding the DRG assignment for these cases.

The new DRG 543 (Craniotomy with Implantation of Chemotherapeutic Agent or Acute Complex Central Nervous System Principal Diagnosis) is being placed in MDC 1. It was created from existing DRGs 1 and 2 (Craniotomy Age >17 With and Without CC, respectively) by removing three types of patients based on their principal diagnosis. Therefore, new DRG 543

will contain patients who undergo a craniotomy procedure with a principal diagnosis belonging to one of the following three categories:

1. Patients with a major central nervous system infection, such as bacterial meningitis, encephalitis, or an intracranial abscess.

2. Patients with a subarachnoid hemorrhage, intracranial hemorrhage, or an acute stroke.

3. Patients with central nervous system trauma resulting in brain laceration or brain injury associated with an open head wound.

In addition, new DRG 543 will include cases involving treatment using chemotherapeutic agents and devices implanted in the brain, such as implantable chemotherapeutic wafers.

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

1. Patients with chronic central nervous system conditions such as malignancies, degenerative conditions, and cerebrovascular disease without acute infarct

2. Patients with subdural hematoma not associated with an open head wound.

3. Patients with lesser degrees of central nervous system trauma, such as skull fracture or other injury but without brain laceration.

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

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

- Craniotomy procedure from DRGs 1 and 2 and procedure code 00.10, Implantation of chemotherapeutic agent; or

- Craniotomy procedure from DRGs 1 and 2 and principal diagnosis of acute complex central nervous system listed below.

Principal Diagnosis (PDX) of Acute Complex CNS Diagnosis

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We noted in the proposed rule that the primary focus of updates to the Medicare DRG classification system is on changes relating to the Medicare patient population, not

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

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

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

b. Coronary Stent Procedures

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

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

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

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

place of stenting in order to avoid significant financial losses due to what it considered the inadequate reimbursement for inserting multiple stents.

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

cannot be determined. Therefore, the capabilities of the current coding structure do not permit the distinction between single vessel stenting and multiple vessel stenting that would be required under the recommended restructuring of the stenting DRGs.

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

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

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

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

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

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

We received a number of comments concerning coronary stents, both bare and drug-eluting in response to the May 18, 2004 proposed rule. As noted above, we had discussed two external recommendations for refinement or restructuring of the current

coronary stent DRGs (69 FR 28222). At that time, we indicated that we believed that arguments for change might have merit. However, as there was not an adequate database upon which to structure a DRG revision, and because the two proposals were so dissimilar, we indicated that we would continue to monitor the coronary stent DRGs and would review the DRG structure once adequate data became available. We will continue to review the data carefully and will assess whether a revised DRG structure is appropriate when we have more than 11 months of data experience. The FDA approved the drug-eluting stent for use in April 2003. Therefore, our MedPAR payment data collection began at that time.

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

Response: We take this opportunity to clarify that we did not offer a choice between two options in the proposed rule. We discussed the two options that had been suggested to us. However, we determined that it was premature to undertake a thorough restructuring of the four current stent DRGs, both because the recommendations differed

so completely from each other and because we lacked data of adequate historical duration with which to make a comprehensive analysis.

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

Comment: One commenter recommended restructuring of the four existing stent DRGs (DRG 516, 517, 526, and 527) by complex and noncomplex components. Specifically, the commenter suggested replacing the existing DRG structure that distinguishes between "with and without AMI" and the presence of bare or drug-eluting stents with a structure distinguishing between "with and without complexity." In performing its analysis, the commenter reviewed charges within each of the four stent DRGs and then stratified the cases into groups with and without the following comorbidities or procedural characteristics: a principal diagnosis of AMI, or any secondary diagnosis of congestive heart failure, renal failure, cerebrovascular disease, or cases including code 36.05, reflecting multiple vessel procedure. The commenter classified cases with the above characteristics as "complex" and cases without these characteristics as "noncomplex."

The commenter included the following table for comparison purposes:

Group	Number	Mean Charge
Current DRG 516	10,520	$41,788
Current DRG 517	21,472	34,616

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

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

Response: We appreciate the considerable thought and study that went into the analysis that was submitted. However, in reviewing the comparison, we identified the similarities of the mean charges between the current DRGs and the proposed complex DRGs, and the fact that in every single comparison, the mean charges go down in the complex DRGs. For example, according to the table, current DRG 516 has mean charges of $41,788, while the proposed complex revision of DRG 516 has mean charges of $41,762. This is a decrease of $26. Also, current DRG 526 has mean charges of $51,746, while the proposed complex revision of DRG 526 has mean charges of $51,054. This is a decrease of $692. These results indicate to us that the current DRG structure is accurate in terms of resource consumption.

In addition, we note that under the commenter's proposal, the number of cases in the complex DRG categories, while the number of noncomplex cases decreases. There

would be a shift in the number of cases per DRG, but each case would have lower average charges per case, which would reduce the relative weight of all four DRGs. We are hesitant to adopt this approach, given the comments and concerns that reimbursement for stenting procedures is already under funded.

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

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

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

Response: We note that the relative weights listed in Table 5 of the proposed rule are based on MedPAR hospital charge data as of the December 2003 update of the files,

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

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

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

In addition, it has come to our attention that there may be some coding errors that are contributing to an erroneous data and reimbursement case-mix profile for hospitals. Specifically, it has been suggested that some hospitals may be reluctant to include a code for vessel angioplasty in conjunction with stent placement. Apparently some hospital staff have expressed concerns that a “true” angioplasty is not being performed, and that

they will therefore be censured by regulatory agencies for erroneous coding. Therefore, these hospitals have instructed their coding staff not to include a code describing angioplasty of a vessel and only to include a code for insertion of a stent or stents.

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

Comment: One commenter indicated that there is a disincentive for the insertion of multiple drug-eluting stents placed during the same inpatient admission. This

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

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

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

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

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

c. Severe Sepsis

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

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

the May 18, 2004 proposed rule, we did not propose any change to the current DRG structure for sepsis.

Comment: Several commenters agreed with our proposal not to create a new DRG for severe sepsis. Some of the commenters mentioned coding problems that exist with new codes 995.90 through 995.94 that were created to capture Systemic Inflammatory Response Syndrome (SIRS). The commenters acknowledged that the codes were specifically created to capture severe sepsis. However, they indicated that there has been much confusion among coders in their use. The commenters mentioned coding notes included in the ICD-9-CM book that appear to be contradictory. The commenters agreed that it was not appropriate to modify the DRGs at this time, given the uncertainty about the use of the SIRS codes and the accuracy of the reported data.

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

Response: We agree with the commenters that there has been confusion in the correct use of the SIRS codes based on use of the ICD-9-CM code book. The related section of the ICD-9-CM code book is being revised on October 1, 2004, to help resolve this confusion. Additional coding instructions are also being developed on the correct use of these codes. These instructions will be published in the American Hospital Association's Coding Clinic for ICD-9-CM. These actions should lead to more consistency in identifying and reporting cases of severe sepsis. Once this information is available, CMS will review the data to determine any needed modifications to the DRG

to better capture severe sepsis. We agree with the commenters that we should not create a new DRG for severe sepsis based on the currently available data, and that we should continue to monitor the population with severe sepsis in order to better characterize resource utilization in these patients.

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

Response: We agree with the commenter that severe sepsis is a common, deadly, and costly clinical entity. We also acknowledge that the current coding for all forms of sepsis is problematic. We believe that the creation of code 00.17 (Infusion of vasopressor agent), which goes into effect on October 1, 2004, in combination with code 00.11 and the SIRS codes 995.90 through 995.94, will help to better identify patients with severe sepsis. We also note, as mentioned above, that improved and modified coding instructions and guidelines will be available in October 2004. However, we continue to believe that a separate DRG for severe sepsis is not appropriate at this time based on the available data. We believe that the defining criteria for severe sepsis, using the currently available ICD-9-CM codes, are not specific, accurate, or unique enough to warrant a new

DRG classification. However, we anticipate receiving data using the new and modified codes and instructions and will consider this issue again in the future.

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

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

before, CMS will closely monitor the classification of patients with severe sepsis in the near future, particularly with regard to the use of other codes commonly reported for patients with severe sepsis such as new code 00.17 (Infusion of vasopressor agent) and code 00.11 (Infusion of diotrecogin alfa (activated)). We will also work closely with the American Hospital Association and the American Health Information Management Association on their efforts to provide education to coders in the correct use of the severe sepsis codes (SIRS codes 995.90 through 995.94).

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

This commenter mentioned the set of proposed criteria put forth by another commenter to define severe sepsis ("a systemic inflammatory response syndrome associated with organ dysfunction, hypoperfusion, or hypotension") and asserted that this definition has been widely accepted within the international clinical community, that it is

encompassed by code 995.92 (Systemic inflammatory response syndrome due to infectious process with organ dysfunction), and that it should be used to identify patients for classification to a new DRG.

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

d. Implantable Cardiac Defibrillators

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

As indicated in the May 18, 2004 proposed rule, we received a coverage request to expand the indications for implantable defibrillators to include the population studied in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) sponsored by the National Institutes of Health. SCD-HeFT treated heart failure patients with conventional therapy and randomized them to one of three additional treatment strategies: (1) placebo;

(2) amiodarone (drug therapy); or (3) single lead implantable defibrillator. The SCD-HeFT investigators presented results at the American College of Cardiology annual meeting that the basic single-lead implantable defibrillator is effective for saving lives in a population at low-moderate risk for sudden cardiac death. As part of CMS' coverage decisions, we are considering whether to restrict the use of complex defibrillators to patients for whom they are medically necessary, that is, the population at low-moderate risk for sudden cardiac death.

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

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

underpaying for the more complex, expensive devices as the lower charges for simpler, less expensive devices begin to affect (lower) the DRG weights.

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

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

e. Intestinal Transplantation

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

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

Due to the small patient population associated with these transplantations, the commenter suggested that CMS lower the number of cases required to create a new DRG. In addition, the commenter suggested that CMS utilize data on non-Medicare patients and the pediatric population to supplement current MedPAR data.

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

If an intestinal transplantation alone is performed on a patient with a principal diagnosis in MDC 6 (Diseases and Disorders of the Digestive System), the case would be assigned to either DRG 148 (Major Small & Large Bowel Procedures With CC) or DRG 149 (Major Small & Large Bowel Procedures Without CC). If an intestinal

transplantation was performed and the patient required a tracheostomy, the case would be assigned to DRG 483 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth & Neck Diagnosis). In cases where multiple surgical procedures are performed, the case is assigned to the DRG associated with the most resource-intensive surgical class. If an intestinal and liver transplantation were performed simultaneously, the case would be assigned to DRG 480 (Liver Transplant). It is not uncommon that a liver transplant would be performed with an intestinal transplant. If a multivisceral transplantation is performed, the case is also assigned to DRG 480.

Based on our review of the FY 2003 MedPAR data, we identified six cases with procedure code 46.97 all performed at one facility. We are concerned that only one facility's data is contained in the MedPAR file when there are five Medicare-approved intestinal transplant centers. Of the six cases, three cases were assigned to DRG 148, with total charges ranging from $839,802 to $903,518 and an average length of stay of 36 days. Two cases were assigned to DRG 483. One case was assigned to DRG 154 (Stomach, Esophageal, & Duodenal Procedures Age >17 With CC) because, in addition to the intestinal transplantation, there was another operation on the stomach. The total charge for the one case in DRG 154 was $1,105,627, with a length of stay of 32 days.

We are open to receiving non-MedPAR data but would limit the data to Medicare patients, rather than using non-Medicare data as suggested by the commenter. We believe that, if we received data from the five approved intestinal transplant centers regarding all Medicare patients receiving intestinal transplantations during the fiscal year, the

minimum requirement of cases may be met. When we receive sufficient data, we will again consider a separate intestinal transplant DRG.

We agree that payment for isolated intestinal transplant is too low in DRGs 148 and 149. The average payments for DRGs 148 and 49 are approximately $15,314 and $6,567, respectively. As mentioned earlier, it is not uncommon for an intestinal transplant to be performed in conjunction with transplants of other organs, such as the liver. As a matter of fact, intestinal transplants are assigned to DRG 480 now since these patients frequently have both an intestinal transplant and a liver transplant. Therefore, DRG 480 already contains cases with intestinal transplants. Therefore, we would not be disrupting the clinical cohesiveness of DRG 480 by adding intestinal transplant.

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

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

change, the three main types of intestinal transplantation; isolated intestine, liver plus intestine, and multivisceral, will be assigned to DRG 480. We will continue to monitor intestinal transplantation to determine appropriate assignment of these cases.

f. Cochlear Implants

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

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

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

We have been unable to identify an alternative DRG assignment for these cases. As we discussed in the August 1, 2003 final rule (68 FR 45367), we continue to believe

that assignment of cochlear implant cases to DRG 482 (Tracheostomy for Face, Mouth and Neck Diagnoses) is inappropriate. A tracheostomy must be performed in order for the case to be assigned to this DRG. We remain reluctant to create a new DRG for specific, low-volume procedures. Doing so would create a proliferation of DRGs and a loss of some of the efficiency incentives inherent in the current system.

g. Artificial Hearts

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

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

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

The issue of the DRG assignment of new code 37.90 (Insertion of left atrial appendage device) was not presented as a topic in the May 18, 2004 proposed rule. At the April 1, 2004 ICD-9-CM Coordination and Maintenance Committee meeting, we discussed these devices. A new code was created for use in upcoming clinical trials and was fast-tracked so that the code could be used beginning October 1, 2004 for discharges for FY 2005. The new code is listed in Table 6B of the Addendum (69 FR 28672 in the proposed rule). Table 6B represents a listing of approved final new codes. The codes themselves are not subject to comment but their assignment regarding placement as an O.R. procedure and the MDC and DRG placement are open to comment. As discussed elsewhere in this preamble, the announcement of the adoption of the codes as final in the IPPS proposed rule is included in the ICD-9-CM Coordination and Maintenance Committee meeting process.

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

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

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

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

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

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

Because code 37.90 was created for use beginning on October 1, 2004, we have no data history regarding its utilization. However, given that the atrial appendage device is percutaneously inserted, and that most of the procedures in DRG 108 are open chest procedures, we do not believe that DRG 108 is the most appropriate clinical placement for new code 37.90. In addition, review of the data in the table above shows a large variance between the hospital charges and length of stay between DRG 518 and DRG 108. According to one manufacturer, the projected length of stay for insertion of an atrial appendage is overnight for observation purposes. The many open chest procedures in DRG 108, some requiring the use of cardiopulmonary bypass, would also seem to indicate that DRG 108 is not the best choice for clinical coherence. We are disinclined to assign this new code to such a resource intensive DRG without appropriate data to reinforce and justify such a decision. Therefore, we are maintaining the assignment of code 37.90 to DRG 518 in this final rule.

Review of code 35.52 (Repair of atrial septal defect with prosthesis, closed technique) in the table above shows a decided similarity to the cases found in DRG 518. We will analyze the placement of code 35.52 as part of next year's proposed rule. We will analyze these cases for both clinical coherence and charge data as part of the process of identifying the most appropriate DRG assignment for code 35.52.

i. Carotid Artery Stents

DRG Assignment for New Codes –

At the April 1, 2004 ICD-9-CM Coordination and Maintenance Committee meeting, we discussed creation of a new code or codes to identify carotid artery stenting, along with a concomitant percutaneous angioplasty or atherectomy (PTA) code for delivery of the stent(s). This subject was addressed in response to the need to identify carotid artery stenting for use in clinical trials in the upcoming fiscal year. Public comment confirmed the need for specific codes for this procedure. Implementation of the code was fast-tracked so that the code could be used beginning October 1, 2004, for discharges in FY 2005 for patients who are enrolled in an FDA-approved clinical trial and are using on-label FDA approved stents and embolic protection devices.

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

New code 00.61 was assigned to four MDCs and seven DRGs. The most likely scenario will have cases being assigned to MDC 1 (Diseases and Disorders of the Nervous System in DRGs 533 (Extracranial Procedures With CC) and 534 (Extracranial Procedures Without CC). Cases could also be assigned to MDC 5 (Diseases and Disorders of the Circulatory System), MDC 21 (Injuries, Poisoning, and Toxic Effects of

Drugs), and MDC 24 (Multiple Significant Trauma). The less likely DRG assignments can be reviewed in Table 6B in the Addendum to this final rule.

Background: Stroke is the third leading cause of death in the United States and the leading cause of serious, long-term disability. Approximately 70 percent of all strokes occur in people age 65 and older. The carotid artery is located in the neck and is the principal artery supplying the head and neck with blood. Accumulation of plaque in the carotid artery can lead to stroke either by decreasing the blood flow to the brain or by having plaque break free and lodge in the brain or in other arteries to the head. The PTA procedure involves inflating a balloon-like device in the narrowed section of the carotid artery to reopen the vessel. A carotid stent is then placed in the artery to prevent the vessel from closing and to prevent pieces of plaque from entering the bloodstream.

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

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

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

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

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

In FY 2003, any carotid stenting procedures performed would have been assigned to DRG 5. Insertion of a carotid stent or stents was a procedure for which there was no

specific coverage decision. In addition, the ICD-9-CM codes describing insertion of a stent were nonspecific, and the codes used to describe that procedure also applied to many other procedures for which there was a coverage decision. The commenter is correct that any cases in our data may have been performed within the setting of a clinical trial. In FY 2004, we restructured DRG 5, splitting all those cases into DRGs 533 and 534, and ordered the DRGs based on the presence or absence of CCs. When we reviewed the available MedPAR data, we used the following proxy: Principal diagnosis code 433.10 (Occlusion and stenosis of carotid artery, without mention of cerebral infarction), and procedure codes 39.50 (Angioplasty or atherectomy of noncoronary vessel), plus code 39.90 (Insertion of nondrug-eluting, noncoronary artery stent(s)). The following table shows the results of our review:

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

*Table 7A, MedPAR update March 2002 (67 FR 50249)
**Table 5, MedPAR update March 2003 (68 FR 45594)
***Final rule Table 5 and Table7A, MedPAR update March 2004

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

The FDA has not given final approval to the safety and efficacy of carotid PTA with stenting as clinical trials are still ongoing. CMS has not yet approved this procedure and device under Medicare, outside of the clinical trial setting. To reiterate, specific codes were recently created and have not yet been put into use in hospitals. We believe that the data that we have reviewed in DRGs 5, 533, and 534 are reasonably correct regarding hospital charges for this procedure. We believe that adjusting the IPPS system

for a specific device that has not been used outside the clinical trial setting, without substantiating data, obviates the intent of the diagnosis-related groups. Therefore, we believe the assignment of code 00.61 to DRGs 533 and 534 as proposed is appropriate at this time. We will continue to monitor DRGs 533 and 534 and procedure codes 00.61 in combination with 00.63 in upcoming annual DRG reviews.

At the April 1, 2004 ICD-9-CM Coordination and Maintenance Committee Meeting, we also created procedure codes 00.62 (Percutaneous angioplasty or atherectomy of intracranial vessel(s), 00.64 (Percutaneous insertion of other precerebral (extracranial) artery stent(s), and 00.65 (Percutaneous insertion of intracranial vascular stent(s). We assigned procedure code 00.62 to the same MDCs and DRGs as code 00.61, mimicking the DRG assignment for predecessor codes.

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

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

evidence, we are not making any changes to the MDC or DRG assignments of code 00.62.

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

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

j. Acute Intermittent Porphyria

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

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

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

C. Recalibration of DRG Weights

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

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

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

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

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

- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment

rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average charge for the DRG and before eliminating statistical outliers.

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

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

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

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

The new weights are normalized by an adjustment factor of 1.46795 so that the average case weight after recalibration is equal to the average case weight before

recalibration. This adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS.

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

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

Comment: Two commenters addressed the proposed DRG weights for three DRGs. One commenter was appreciative of the increased proposed DRG weight for

DRG 36 (Retinal Procedures). The current DRG weight is 0.6298 and the proposed weight was 0.6766. Another commenter expressed concern that the proposed weights for DRGs 535 (Cardiac Defibrillator Implant With Cardiac Catheterization With AMI, Heart Failure, or Shock) and DRG 536 (Cardiac Defibrillator Implant With Cardiac Catheterization Without AMI, Heart Failure or Shock) believes this would not cover the cost of the Cardiac Resynchronization Therapy Defibrillator (CRT-D), much less the procedure and nursing care costs associated with these procedures. The commenter believed that the DRG weight data are problematic because they are based on hospital charges. The commenter stated that hospitals do not like to mark up the cost of an item at $34,000. The commenter inquired whether CMS has evaluated the cost of the CRT-Ds from the claims which was calculated using the cost-to-charge ratio compared to outside data on the cost of the CRT-Ds.

Response: In the process of recalibration of the DRG weights, we consider the most recent charge data available. Both high and low cost technologies are absorbed gradually into the data that are used to determine the DRG weight.

D. LTC-DRG Reclassifications and Relative Weights for LTCHs for FY 2005

1. Background

In the June 6, 2003 LTCH PPS final rule (68 FR 34122), we changed the LTCH PPS annual payment rate update cycle to be effective July 1 through June 30 instead of October 1 through September 30. In addition, because the patient classification system utilized under the LTCH PPS is based directly on the DRGs used under the IPPS for acute care hospitals, in that same final rule, we explained that the annual update of the

long-term care diagnosis-related group (LTC-DRG) classifications and relative weights will continue to remain linked to the annual reclassification and recalibration of the CMS-DRGs used under the IPPS.

The annual update to the IPPS DRGs is based on the annual revisions to the ICD-9-CM codes and is effective each October 1. In the health care industry, annual changes to the ICD-9-CM codes are effective for discharges occurring on or after October 1 each year. The use of the ICD-9-CM coding system is also compliant with the requirements of the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191, under 45 CFR Parts 160 and 162. Therefore, the manual and electronic versions of the GROUPER software, which are based on the ICD-9-CM codes, are also revised annually and effective for discharges occurring on or after October 1 each year. Because the LTC-DRGs are based on the patient classification system used under the IPPS (CMS-DRGs), which is updated annually and effective for discharges occurring on or after October 1 through September 30 each year, in the May 7, 2004 LTCH PPS final rule (69 FR 25674), we specified that we will continue to update the LTC-DRG classifications and relative weights to be effective for discharges occurring on or after October 1 through September 30 each year. Furthermore, we stated that we will publish the annual update of the LTC-DRGs in the proposed and final rules for the IPPS.

In the May 18, 2004 IPPS proposed rule (69 FR 28225), we proposed revisions to the LTC-DRG classifications and relative weights. We are finalizing them in this IPPS final rule, to be effective October 1, 2004 through September 30, 2005, using the latest available data. The final LTC-DRGs and relative weights for FY 2005 in this final rule

are based on the IPPS DRGs (GROUPER Version 22.0) discussed in section II. of this final rule.

Comment: One commenter questioned whether the rate update cycle for the LTCH PPS will revert from a July 1 through June 30 cycle to the Federal fiscal year cycle (October 1 through September 30) since we proposed to update the LTC-DRGs effective for discharges on or after October 1, 2004.

Response: In the June 6, 2003 LTCH PPS final rule (68 FR 34122), we changed the LTCH PPS annual payment rate update cycle to be effective July 1 through June 30 instead of October 1 through September 30. As we discussed in that same LTCH PPS final rule and as we discussed in the May 18, 2004 IPPS proposed rule (69 FR 28225), because the patient classification system utilized under the LTCH PPS is based directly on the DRGs used under the IPPS for acute care hospitals, the annual update of the LTC-DRG classifications and relative weights will continue to remain linked to the annual reclassification and recalibration of the CMS-DRGs used under the IPPS.

The most recent annual LTCH PPS payment rate update and policy changes for the 2005 LTCH PPS rate year (July 1, 2004 through June 30, 2004) was published in the **Federal Register** on May 7, 2004 (69 FR 25674 through 25749). In that same LTCH PPS final rule, we established rate updates and policy changes that were effective for discharges occurring on or after July 1, 2004, including an update to the standard Federal LTCH PPS rate, the LTCH PPS wage index and the LTCH PPS outlier threshold. However, because the LTC-DRGS are linked to the IPPS DRGs, the LTC-DRG classifications and relative weights established in the August 1, 2003 final rule

(68 FR 45374), which were effective beginning in Federal FY 2004, remain in effect through September 30, 2004. The updated LTC-DRG classifications and relative weights established for FY 2005 shown in Table 11 of this final rule will be effective for LTCH discharges on or after October 1, 2004 and before September 30, 2005. As we stated in the June 6, 2003 LTCH PPS final rule, the rate update cycle for the LTCH PPS will continue to remain on a July 1 through June 30 cycle while the annual update to the LTC-DRG classifications and relative weights will remain on a Federal fiscal year cycle (October 1 through September 30). Accordingly, the updated LTCH PPS Federal rate ($36,833.69) and other payment factors (such as the outlier threshold and wage index values) effective July 1, 2004 (see May 7, 2004, (69 FR 25674)), are applied in conjunction with the LTC-DRGs and relative weights established in the August 1, 2003 IPPS final rule (68 FR 45374) that are in effect through September 30, 2004, for LTCH discharges occurring from July 1, 2004 through September 30, 2004. However, beginning with discharges occurring on or after October 1, 2004, the LTC-DRGs and relative weights established in this final rule will be applied in conjunction with the LTCH PPS Federal rate ($36,833.69) and other payment factors (such as the outlier threshold and wage index values) effective July 1, 2004, as established in the May 7, 2004 LTCH PPS final rule (69 FR 25674), for discharges occurring through June 30, 2005.

2. Changes in the LTC-DRG Classifications

a. Background

Section 123 of Pub. L. 106-113 specifically requires that the PPS for LTCHs be a

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

In accordance with section 307(b)(1) of Pub. L. 106-554 and §412.515 of our existing regulations, the LTCH PPS uses information from LTCH patient records to classify patient cases into distinct LTC-DRGs based on clinical characteristics and expected resource needs. The LTC-DRGs used as the patient classification component of the LTCH PPS correspond to the DRGs under the IPPS for acute care hospitals. Thus, as we proposed in the May 18, 2004 IPPS proposed rule, we will use the IPPS GROUPER Version 22.0 for FY 2005 to process LTCH PPS claims in this final rule. The changes to the IPPS DRG classification system for FY 2005 (GROUPER Version 22.0) are discussed in section II.B. of this preamble.

Under the LTCH PPS, we determine relative weights for each of the CMS DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCH patients. In a departure from the IPPS, as we discussed in the August 30, 2002 final rule (67 FR 55985), which implemented the LTCH PPS, and the August 1, 2003 IPPS final rule (68 FR 45374), we

use low-volume quintiles in determining the LTC-DRG weights for LTC-DRGs with less than 25 LTCH cases, since LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Specifically, we group those low-volume LTC-DRGs (LTC-DRGs with fewer than 25 cases) into 5 quintiles based on average charge per discharge. (A listing of the composition of low-volume quintiles for the FY 2004 LTC-DRGs (based on FY 2002 MedPAR data) appears in section II.D.3. of the August 1, 2003 IPPS final rule (68 FR 45377 through 45380).) We also adjust for cases in which the stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay; that is, short-stay outlier cases (§412.529), as discussed below in section II.D.4. of this preamble.

b. Patient Classifications into DRGs

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

As discussed in section II.B. of this preamble, the CMS DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Accordingly, the principal diagnosis determines MDC assignment. Within most

MDCs, cases are then divided into surgical DRGs and medical DRGs. Some surgical and medical DRGs are further differentiated based on the presence or absence of CCs. (See section II.B. of this preamble for further discussion of surgical DRGs and medical DRGs.)

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

The emphasis on the need for proper coding cannot be overstated. Inappropriate coding of cases can adversely affect the uniformity of cases in each LTC-DRG and produce inappropriate weighting factors at recalibration and result in inappropriate payments under the LTCH PPS. LTCHs are to follow the same coding guidelines used by the acute care hospitals to ensure accuracy and consistency in coding practices. There will be only one LTC-DRG assigned per long-term care hospitalization; it will be assigned at the discharge. Therefore, it is mandatory that the coders continue to report

the same principal diagnosis on all claims and include all diagnostic codes that coexist at the time of admission, that are subsequently developed, or that affect the treatment received. Similarly, all procedures performed during that stay are to be reported on each claim.

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

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

intermediary and to submit additional information within a specified timeframe (§412.513(c)).

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

3. Development of the FY 2005 LTC-DRG Relative Weights

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

As we stated in the August 30, 2002 LTCH PPS final rule (67 FR 55981), one of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly. To accomplish these goals, we adjust the LTCH PPS standard Federal prospective payment system rate by the applicable LTC-DRG relative weight in determining payment to LTCHs for each case.

Under the LTCH PPS, relative weights for each LTC-DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§412.515). To ensure that Medicare patients classified to each LTC-DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each LTC-DRG that represents the resources needed by an average inpatient LTCH case in that LTC-DRG. For example, cases in an LTC-DRG with a relative weight of 2 will, on average, cost twice as much as cases in an LTC-DRG with a weight of 1.

b. Data

To calculate the LTC-DRG relative weights for FY 2005 in this final rule, we obtained total Medicare allowable charges from FY 2003 Medicare hospital bill data from the March 2004 update of the MedPAR file, and we used Version 22.0 of the CMS

GROUPER for IPPS, as discussed in section II.B. of this preamble, to classify cases. Consistent with the methodology under the IPPS, we recalculated the FY 2005 LTC-DRG relative weights based on the best available data for this final rule.

As we discussed in the May 18, 2004 proposed rule (69 FR 28227), we have excluded the data from LTCHs that are all-inclusive rate providers and LTCHs that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Pub. L. 90-248 (42 U.S.C. 1395b-1) or section 222(a) of Pub. L. 92-603 (42 U.S.C. 1395b-1). Therefore, in the development of the FY 2005 LTC-DRG relative weights, we have excluded the data of the 22 all-inclusive rate providers and the 3 LTCHs that are paid in accordance with demonstration projects that had claims in the FY 2003 MedPAR file.

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

problem will be self-correcting as LTCHs submit more completely coded data in the future.

As we discussed in the May 7, 2004 LTCH PPS final rule (69 FR 25674), an analysis of LTCH claims data from the September 2003 update of the FY 2003 MedPAR file contained coding errors. Specifically, a large hospital chain of LTCHs continued to consistently code diagnoses inaccurately on the claims it submitted, and these coding errors were reflected in the September 2003 update of the FY 2003 MedPAR file. Upon discovering the coding errors, we notified the large chain of LTCHs whose claims contained the coding inaccuracies to request that they resubmit those claims with the correct diagnoses codes by December 31, 2003, so that those corrected claims would be contained in the December 2003 update of the FY 2003 MedPAR file. As we discussed in that same final rule, it appears that those claims were submitted timely with the correct diagnoses codes. Therefore, it was not necessary to correct the FY 2003 MedPAR data for the development of the rates and factors established in the May 7, 2004 LTCH PPS final rule. Accordingly, in the May 18, 2004 IPPS proposed rule, we used LTCH claims data from the December 2003 update of the FY 2003 MedPAR file for the determination of the proposed FY 2005 LTC-DRG relative weights. For this final rule, we used the latest available LTCH claims data from the March 2004 update of the FY 2003 MedPAR file.

c. Hospital-Specific Relative Value Methodology

By nature LTCHs often specialize in certain areas, such as ventilator-dependent patients and rehabilitation and wound care. Some case types (DRGs) may be treated, to a

large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonarbitrary distribution of cases with relatively high (or low) charges in specific LTC-DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, we use a hospital-specific relative value method to calculate the LTC-DRG relative weights instead of the methodology used to determine the DRG relative weights under the IPPS described above in section II.C. of this preamble. We believe this method will remove this hospital-specific source of bias in measuring LTCH average charges. Specifically, we reduce the impact of the variation in charges across providers on any particular LTC-DRG relative weight by converting each LTCH's charge for a case to a relative value based on that LTCH's average charge.

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

In accordance with the methodology established under §412.523, we standardize charges for each case by first dividing the adjusted charge for the case (adjusted for

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

Multiplying by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight in a LTCH with higher average costs than they would at a LTCH with low average costs which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. Because we standardize charges in this manner, we count charges for a Medicare patient at a LTCH with high average charges as less resource intensive than they would be at a LTCH with low average charges. For example, a $10,000 charge for a case in a LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case in a LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

Comment: MedPAC supported the use of the hospital-specific relative value methodology for determining the LTC-DRG relative weights, stating that “[t]his method

eliminates distortions in weights due to systematic differences among hospitals in the level of costs per case and in charge markups." The Commission believed that we should explore the use of this methodology for the DRG relative weights used under the IPPS.

Response: We appreciate MedPAC's support of the use of the hospital-specific relative value methodology for determining the LTC-DRG relative weights. As we discuss above, because by nature LTCHs often specialize in certain types of care, we believe it is important to remove any hospital-specific source of bias in measuring LTCHs' average charges. Therefore, we have continued to use of the hospital-specific relative value methodology for determining the final FY 2005 LTC-DRG relative weights shown in Table 11 of this final rule.

As discussed above, we believe that the LTCHs' charge data are particularly vunerable to having a hospital-specific source of bias when measuring LTCHs' average charges because of the small number of LTCHs (approximately 300 hospitals with approximately 100,00 discharges annually) and the relatively high degree of specialization of many LTCHs. There are over 4,000 short-term acute care hospitals paid under the IPPS, with approximately 11.9 million discharges annually, that generally treat a wide range of conditions, rather than specializing in one or two types of conditions. Therefore, although we agree with the Commission that the hospital-specific relative value methodology eliminates distortions in relative weights due to systematic differences among hospitals' charges, we do not believe that it is necessary to use the hospital-specific relative value methodology under the IPPS since short-term acute care

hospitals' charge data is not as susceptible to having a hospital-specific source of bias when measuring average charges.

Furthermore, as we discussed in the August 1, 2000 IPPS final rule (65 FR 47103), in 1995 the MedPAC's predecessor, the Prospective Payment Assessment Commission, made a similar recommendation to adopt the hospital-specific relative value methodology under the IPPS. In the June 2, 1995 proposed rule (60 FR 29246), we agreed with the Commission's judgment that basing the IPPS DRG weights on standardized charges results in weights that are somewhat distorted as measures of the relative costliness of treating a typical case in each DRG, and that the hospital-specific relative value method of setting weights may reduce or eliminate distortions present in the current system. However, in our discussion on DRG refinements under the IPPS in the same rule (60 FR 29209), we reiterated our position published in the final rule on September 1, 1992 (57 FR 39761) that we would not propose to make significant changes to the DRG classification system under the IPPS, unless we are able to either improve our ability to predict coding changes by validating in advance the impact that potential DRG changes may have on coding behavior, or to make methodological changes to prevent building the inflationary effects of the coding changes into future program payments. Without further evaluation, we do not believe it would be appropriate to change the methodology for determining the DRG relative weights under the IPPS at this time. The development of the FY 2005 DRG relative weights used under the IPPS for short-term acute care hospitals is discussed in section II.C. of this preamble.

d. Low-Volume LTC-DRGs

In order to account for LTC-DRGs with low-volume (that is, with fewer than 25 LTCH cases), in accordance with the methodology discussed in the August 30, 2002 LTCH PPS final rule (67 FR 55984) and in the May 18, 2004 IPPS proposed rule (69 FR 28228), we group those low-volume LTC-DRGs into one of five categories (quintiles) based on average charges, for the purposes of determining relative weights. For this final rule, using LTCH cases from the March 2004 update of the FY 2003 MedPAR file, we identified 172 LTC-DRGs that contained between 1 and 24 cases. This list of LTC-DRGs was then divided into one of the 5 low-volume quintiles, each containing a minimum of 34 LTC-DRGs (172/5 = 34 with 2 LTC-DRGs as the remainder). For FY 2005, as we described in the May 18, 2004 IPPS proposed rule, we are making an assignment to a specific low-volume quintile by sorting the low-volume LTC-DRGs in ascending order by average charge. For this final rule, this results in an assignment to a specific low volume quintile of the sorted 172 low-volume LTC-DRGs by ascending order by average charge. Since the number of LTC-DRGs with less than 25 LTCH cases is not evenly divisible by five, the average charge of the low-volume LTC-DRG was used to determine which low-volume quintile received the additional LTC-DRG. After sorting the 172 low-volume LTC-DRGs in ascending order, we grouped the first fifth (34) of low-volume LTC-DRGs with the lowest average charge would be grouped into Quintile 1. The highest average charge cases are grouped into Quintile 5. Since the average charge of the 103rd LTC-DRG in the sorted list is closer to the previous LTC-DRG's average charge (assigned to Quintile 3) than to the average charge of the 104th LTC-

DRG in the sorted list (to be assigned to Quintile 4), we placed it into Quintile 3. This process was repeated through the remaining low-volume LTC-DRGs so that 3 low-volume quintiles contain 34 LTC-DRGs and 2 low-volume quintiles contain 35 LTC-DRGs.

In order to determine the relative weights for the LTC-DRGs with low volume for FY 2005, in accordance with the methodology described in the August 30, 2002 LTCH PPS final rule (67 FR 55984) and cited in the May 18, 2004 IPPS proposed rule, we used the five low-volume quintiles described above. The composition of each of the five low-volume quintiles shown below in Table 1 is used in determining the LTC-DRG relative weights for FY 2005. We determine a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the formula that we apply to the regular LTC-DRGs (25 or more cases), as described below in section II.D.4. of this preamble. We assign the same relative weight and average length of stay to each of the LTC-DRGs that make up that low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of LTC-DRGs with a low volume of LTCH cases will vary in the future. We use the best available claims data in the MedPAR file to identify low-volume LTC-DRGs and to calculate the relative weights based on our methodology.

Table 1.--Composition of Low-Volume Quintiles

LTC-DRG	Description
QUINTILE 1	
11	NERVOUS SYSTEM NEOPLASMS W/O CC
43	HYPHEMA
45	NEUROLOGICAL EYE DISORDERS
47	OTHER DISORDERS OF THE EYE AGE >17 W/O CC

LTC-DRG	Description
84	MAJOR CHEST TRAUMA W/O CC
93	INTERSTITIAL LUNG DISEASE W/O CC
95	PNEUMOTHORAX W/O CC
110	MAJOR CARDIOVASCULAR PROCEDURES W CC
119	VEIN LIGATION & STRIPPING
143	CHEST PAIN
149	MAJOR SMALL & LARGE BOWEL PROCEDURES W/O CC
178	UNCOMPLICATED PEPTIC ULCER W/O CC
193	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W CC
208	DISORDERS OF THE BILIARY TRACT W/O CC
229	HAND OR WRIST PROC, EXCEPT MAJOR JOINT PROC, W/O CC
237	SPRAINS, STRAINS, & DISLOCATIONS OF HIP, PELVIS & THIGH
241	CONNECTIVE TISSUE DISORDERS W/O CC
260	SUBTOTAL MASTECTOMY FOR MALIGNANCY W/O CC
273	MAJOR SKIN DISORDERS W/O CC
275	MALIGNANT BREAST DISORDERS W/O CC
284	MINOR SKIN DISORDERS W/O CC
324	URINARY STONES W/O CC
326	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W/O CC
339	TESTES PROCEDURES, NON-MALIGNANCY AGE >17
347	MALIGNANCY, MALE REPRODUCTIVE SYSTEM, W/O CC
367	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM W/O CC
404	LYMPHOMA & NON-ACUTE LEUKEMIA W/O CC
427	NEUROSES EXCEPT DEPRESSIVE
433	ALCOHOL/DRUG ABUSE OR DEPENDENCE, LEFT AMA
450	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W/O CC
500	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W/O CC
509	FULL THICKNESS BURN W/O SKIN GRFT OR INH INJ W/O CC OR SIG TRAUMA
522*	ALC/DRUG ABUSE OR DEPEND W REHABILITATION THERAPY W/O CC
532	SPINAL PROCEDURES W/O CC
QUINTILE 2	
8	PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W/O CC
17	NONSPECIFIC CEREBROVASCULAR DISORDERS W/O CC
22	HYPERTENSIVE ENCEPHALOPATHY
25	SEIZURE & HEADACHE AGE >17 W/O CC
31	CONCUSSION AGE >17 W CC
46	OTHER DISORDERS OF THE EYE AGE >17 W CC
69	OTITIS MEDIA & URI AGE >17 W/O CC
83	MAJOR CHEST TRAUMA W CC
109	CORONARY BYPASS W/O PTCA OR CARDIAC CATH
117	CARDIAC PACEMAKER REVISION EXCEPT DEVICE REPLACEMENT
129	CARDIAC ARREST, UNEXPLAINED
140	ANGINA PECTORIS
142*	SYNCOPE & COLLAPSE W/O CC
181	G.I. OBSTRUCTION W/O CC
206	DISORDERS OF LIVER EXCEPT MALIG,CIRR,ALC HEPA W/O CC
227	SOFT TISSUE PROCEDURES W/O CC
250	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W CC

LTC-DRG	Description
251	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W/O CC
276	NON-MALIGANT BREAST DISORDERS
295	DIABETES AGE 0-35
305	KIDNEY,URETER & MAJOR BLADDER PROC FOR NON-NEOPL W/O CC
323	URINARY STONES W CC, &/OR ESW LITHOTRIPSY
328	URETHRAL STRICTURE AGE >17 W CC
348	BENIGN PROSTATIC HYPERTROPHY W CC
349	BENIGN PROSTATIC HYPERTROPHY W/O CC
399	RETICULOENDOTHELIAL & IMMUNITY DISORDERS W/O CC
414	OTHER MYELOPROLIF DIS OR POORLY DIFF NEOPL DIAG W/O CC
441	HAND PROCEDURES FOR INJURIES
449	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W CC
455	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W/O CC
467	OTHER FACTORS INFLUENCING HEALTH STATUS
479	OTHER VASCULAR PROCEDURES W/O CC
511	NON-EXTENSIVE BURNS W/O CC OR SIGNIFICANT TRAUMA
518	PERC CARDIO PROC W/O CORONARY ARTERY STENT OR AMI
QUINTILE 3	
29	TRAUMATIC STUPOR & COMA, COMA <1 HR AGE >17 W/O CC
44	ACUTE MAJOR EYE INFECTIONS
86*	PLEURAL EFFUSION W/O CC
122	CIRCULATORY DISORDERS W AMI W/O MAJOR COMP, DISCHARGED ALIVE
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG
128	DEEP VEIN THROMBOPHLEBITIS
136	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE >17 W/O CC
159	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W CC
175*	G.I. HEMORRHAGE W/O CC
177	UNCOMPLICATED PEPTIC ULCER W CC
200	HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR NON-MALIGNANCY
228	MAJOR THUMB OR JOINT PROC,OR OTH HAND OR WRIST PROC W CC
234	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W/O CC
262	BREAST BIOPSY & LOCAL EXCISION FOR NON-MALIGNANCY
266	SKIN GRAFT &/OR DEBRID EXCEPT FOR SKIN ULCER OR CELLULITIS W/O CC
270	OTHER SKIN, SUBCUT TISS & BREAST PROC W/O CC
288	O.R. PROCEDURES FOR OBESITY
301*	ENDOCRINE DISORDERS W/O CC
307	PROSTATECTOMY W/O CC
310	TRANSURETHRAL PROCEDURES W CC
319*	KIDNEY & URINARY TRACT NEOPLASMS W/O CC
325	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W CC
369	MENSTRUAL & OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS
447	ALLERGIC REACTIONS AGE >17
454	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W CC
476	PROSTATIC O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS
496	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION
497	SPINAL FUSION EXCEPT CERVICAL W CC
505	EXTENSIVE BURNS OF FULL THICKNESS BURNS WITH MECH VENT 96+HRS WITHOUT SKIN GRAFT

LTC-DRG	Description
517	PERC CARDIO PROC W NON-DRUG ELUTING STENT W/O AMI
519	CERVICAL SPINAL FUSION W CC
523*	ALC/DRUG ABUSE OR DEPEND W/O REHABILITATION THERAPY W/O CC
535	CARDIAC DEFIB IMPLANT W CARDIAC CATH W AMI/HF/SHOCK
538	LOCAL EXCIS & REMOV OF INT FIX DEV EXCEPT HIP & FEMUR W/O CC
539	LYMPHOMA & LEUKEMIA W MAJOR OR PROCEDURE W CC
QUINTILE 4	
1	CRANIOTOMY AGE >17 W CC
21	VIRAL MENINGITIS
63	OTHER EAR, NOSE, MOUTH & THROAT O.R. PROCEDURES
102*	OTHER RESPIRATORY SYSTEM DIAGNOSES W/O CC
108	OTHER CARDIOTHORACIC PROCEDURES
115	PRM CARD PACEM IMPL W AMI/HR/SHOCK OR AICD LEAD OR GNRTR
157	ANAL & STOMAL PROCEDURES W CC
168	MOUTH PROCEDURES W CC
173*	DIGESTIVE MALIGNANCY W/O CC
201	OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES
218	LOWER EXTREM & HUMER PROC EXCEPT HIP,FOOT,FEMUR AGE >17 W CC
292	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W CC
299	INBORN ERRORS OF METABOLISM
303	KIDNEY,URETER & MAJOR BLADDER PROCEDURES FOR NEOPLASM
304	KIDNEY,URETER & MAJOR BLADDER PROC FOR NON-NEOPL W CC
306	PROSTATECTOMY W CC
308	MINOR BLADDER PROCEDURES W CC
312	URETHRAL PROCEDURES, AGE >17 W CC
336	TRANSURETHRAL PROSTATECTOMY W CC
352	OTHER MALE REPRODUCTIVE SYSTEM DIAGNOSES
394	OTHER O.R. PROCEDURES OF THE BLOOD AND BLOOD FORMING ORGANS
401	LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W CC
408	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W OTHER O.R.PROC
410	CHEMOTHERAPY W/O ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS
419	FEVER OF UNKNOWN ORIGIN AGE >17 W CC
420	FEVER OF UNKNOWN ORIGIN AGE >17 W/O CC
485	LIMB REATTACHMENT, HIP AND FEMUR PROC FOR MULTIPLE SIGNIFICANT TRA
493	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W CC
499	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W CC
501	KNEE PROCEDURES W PDX OF INFECTION W CC
502	KNEE PROCEDURES W PDX OF INFECTION W/O CC
503	KNEE PROCEDURES W/O PDX OF INFECTION
506	FULL THICKNESS BURN W SKIN GRAFT OR INHAL INJ W CC OR SIG TRAUMA
529	VENTRICULAR SHUNT PROCEDURES W CC
531	SPINAL PROCEDURES W CC
QUINTILE 5	
55	MISCELLANEOUS EAR, NOSE, MOUTH & THROAT PROCEDURES
77	OTHER RESP SYSTEM O.R. PROCEDURES W/O CC
116	OTHER PERMANENT CARDIAC PACEMAKER IMPLANT
118	CARDIAC PACEMAKER DEVICE REPLACEMENT

LTC-DRG	Description
125	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG
150	PERITONEAL ADHESIOLYSIS W CC
152	MINOR SMALL & LARGE BOWEL PROCEDURES W CC
154	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W CC
161	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W CC
171*	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W/O CC
191	PANCREAS, LIVER & SHUNT PROCEDURES W CC
197	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W CC
209	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF LOWER EXTREMITY
210	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W CC
216	BIOPSIES OF MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE
226	SOFT TISSUE PROCEDURES W CC
230	LOCAL EXCISION & REMOVAL OF INT FIX DEVICES OF HIP & FEMUR
261	BREAST PROC FOR NON-MALIGNANCY EXCEPT BIOPSY & LOCAL EXCISION
267	PERIANAL & PILONIDAL PROCEDURES
268	SKIN, SUBCUTANEOUS TISSUE & BREAST PLASTIC PROCEDURES
338	TESTES PROCEDURES, FOR MALIGNANCY
341	PENIS PROCEDURES
344	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES FOR MALIGNANCY
345	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROC EXCEPT FOR MALIGNANCY
365	OTHER FEMALE REPRODUCTIVE SYSTEM O.R. PROCEDURES
406	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R.PROC W CC
424	O.R. PROCEDURE W PRINCIPAL DIAGNOSES OF MENTAL ILLNESS
443*	OTHER O.R. PROCEDURES FOR INJURIES W/O CC
486	OTHER O.R. PROCEDURES FOR MULTIPLE SIGNIFICANT TRAUMA
488	HIV W EXTENSIVE O.R. PROCEDURE
515	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH
533	EXTRACRANIAL PROCEDURES W CC
536	CARDIAC DEFIB IMPLANT W CARDIAC CATH W/O AMI/HF/SHOCK
543	CRANIOTOMY W IMPLANT OF CHEMO AGENT OR ACUTE COMPLEX CNS PDX

*One of the original 172 low -volume LTC-DRGs initially assigned to this low-volume quintile; removed from the low- volume quintiles in addressing nonmonotonicity (see step 5 below).

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

As we noted previously, the FY 2005 LTC-DRG relative weights are determined in accordance with the methodology described in the August 1, 2003 IPPS final rule (68 FR 45367) and cited in the May 18, 2004 IPPS proposed rule (69 FR 28231). In summary, LTCH cases must be grouped in the appropriate LTC-DRG, while taking into

account the low-volume LTC-DRGs as described above, before the FY 2005 LTC-DRG relative weights can be determined. After grouping the cases in the appropriate LTC-DRG, we calculate the relative weights for FY 2005 in this final rule by first removing statistical outliers and cases with a length of stay of 7 days or less. Next, we adjust the number of cases in each LTC-DRG for the effect of short-stay outlier cases under §412.529. The short-stay adjusted discharges and corresponding charges are used to calculate "relative adjusted weights" in each LTC-DRG using the hospital-specific relative value method described above.

Below we discuss in detail the steps for calculating the FY 2005 LTC-DRG relative weights.

Step 1--Remove statistical outliers.

The first step in the calculation of the FY 2005 LTC-DRG relative weights is to remove statistical outlier cases. We define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each LTC-DRG. These statistical outliers are removed prior to calculating the relative weights. We believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among the LTC-DRGs.

Step 2--Remove cases with a length of stay of 7 days or less.

The FY 2005 LTC-DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay 7 days or

less do not belong in a LTCH because these stays do not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH. If we were to include stays of 7 days or less in the computation of the FY 2005 LTC-DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate.

We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at a LTCH, in order to include data from these very short-stays. Thus, in determining the FY 2005 LTC-DRG relative weights, we remove LTCH cases with a length of stay of 7 days or less.

Comment: One commenter believes that it is inappropriate to exclude cases with a length of stay of 7 days or less from the calculation of the proposed LTC-DRG relative weights since it is not uncommon for very resource intensive patients to expire within the first 7 days of the stay. The commenter also suggested that we consider creating a separate LTC-DRG for LTCH patients that expire within the first 7 days of the stay.

Response: While we understand the commenters concerns, as we discussed in the August 30, 2002 final rule (67 FR 55989) which implemented the LTCH PPS, in calculating the LTC-DRG relative weights, we exclude cases with a length of stay of 7 days or less because we believe that, generally, cases with a length of stay of 7 days or less do not belong in a LTCH. In general, LTCHs are defined by statute as hospitals having an average length of stay of greater than 25 days. LTCHs typically furnish

extended medical and rehabilitative care for patients who are clinically complex and have multiple or chronic conditions. Generally, LTCH cases with very short lengths of stay (that is, 7 days or less) are discharged from the LTCH before the patient receives a full course of treatment, and therefore do not use the same amount or type of resources as typical LTCH "inlier" cases (that is, cases in which Medicare covered days exceed five-sixths of the geometric average length of stay for the LTC-DRG and the patient is discharged prior to receiving a LTCH PPS high cost outlier payment). We believe that the length of stay of an "inlier" case is indicative of a LTCH patient receiving a full course of treatment because such cases include cases with stays that received a full LTC-DRG payment, which represents the average resources used for that DRG (that is, the case does not receive an adjusted short-stay outlier payment or a high-cost outlier payment). LTCH discharges with very short lengths of stay (that is, 7 days or less) often occur when it is determined, following admission to a LTCH, that the beneficiary would receive more appropriate care at another setting. Other circumstances that result in cases with very short stays (that is, 7 days or less) would involve patients who were either discharged to their home or who expired within the first 7 days of being admitted to an LTCH. Because LTCH cases with very short lengths of stay (that is, 7 days or less) do not use the same amount or type of resources as typical LTCH inlier cases, our simulations indicate that including these cases would significantly bias payments against LTCH inlier cases to a point where LTCH inlier cases would be underpaid.

As we also discussed in the August 30, 2002 LTCH PPS final rule (65 FR 55989), the LTC-DRG relative weights reflect the average resources used on representative cases

of a specific type. Stays of 7 days or less generally do not fully receive or benefit from treatment that is typical in a LTCH stay because the patient is discharged prior to receiving a full course of treatment that a LTCH inlier patient would receive. In addition, full resources are often not used in the earlier stages of an admission to a LTCH because the patient is often medically unstable, and initial efforts are focused on stabilizing the patient before beginning treatment of the patient's additional complications and comorbidities. If we did include stays of 7 days or less in the calculation of the LTC-DRG relative weights, the value of many relative weights would decrease for cases that do, in fact, receive a full course of treatment, and, therefore, LTCH inlier payments could decrease to a level that would not be appropriate (that is, provide sufficient payment). We continue to believe that it is not appropriate to compromise the integrity of the payment amounts for LTCH inlier cases that actually benefit from and receive a full course of treatment at a LTCH in order to include data from cases with stays of 7 days or less. Therefore, we disagree with the commenter that cases with lengths of stay of 7 days or less should be included in the calculation of the LTC-DRG relative weights. Accordingly, in this final rule, in calculating the FY 2005 LTC-DRG relative weights, as we proposed, we have removed cases with a length of stay of 7 days or less.

With regard to the commenter's suggestion that we create a separate LTC-DRG for patients who expire, as we also discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56002), we do not believe that a separate LTC-DRG for patients who expire is necessary. We continue to believe that the short-stay outlier policy at §412.529 adequately addresses payments for patients who expire August 30, 2002 LTCH PPS final

rule (65 FR 56006), because a case with a length of stay up to and including five-sixths of the average length of stay of the LTC-DRG is paid under the short-stay outlier policy regardless of whether or not the patient expires. Under the short-stay outlier policy (§412.529), generally a case is paid the least of 120 percent of the estimated cost of the case, 120 percent of the LTC-DRG specific per diem amount, or the full LTC-DRG payment.

We continue to believe that adjusted payments under the short-stay outlier policy for cases that expire generally compensate for any increased costs associated with treating a severely ill patient who dies, including those who expire within 7 days of being admitted to a LTCH. We note that one of the principles underlying prospective payment is that it is a system of payments based on average costs that assumes that some patient stays will consume more resources than the typical stay, while other patients will demand fewer resources. Thus, an efficiently operated hospital should be able to deliver care to its Medicare patients for an overall cost that is at or below the amount paid under the LTCH PPS. We continue to believe the LTCH PPS payment adequately address payments for patients who expire, and therefore, we are not adopting the commenter's suggestion to create a separate LTC-DRG for LTCH patients that expire within the first 7 days of the stay. Accordingly, in establishing the final FY 2005 LTC-DRG relative weights, we continue to exclude cases with a length of stay of 7 days or less and we continue to include the total charges of cases with a length of stay of 8 days or more, including patients who expire, in the LTC-DRG to which the case is assigned based on version 22.0 of the GROUPER.

Step 3--Adjust charges for the effects of short-stay outliers.

The third step in the calculation of the FY 2005 LTC-DRG relative weights is to adjust each LTCH's charges per discharge for short-stay outlier cases (that is, a patient with a length of stay that is less than or equal to five-sixths the average length of stay of the LTC-DRG).

We make this adjustment by counting a short-stay outlier as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the LTC-DRG for nonshort-stay outlier cases. This has the effect of proportionately reducing the impact of the lower charges for the short-stay outlier cases in calculating the average charge for the LTC-DRG. This process produces the same result as if the actual charges per discharge of a short-stay outlier case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the LTC-DRG.

As we explained in the May 18, 2004 proposed rule (69 FR 28231), counting short-stay outlier cases as full discharges with no adjustment in determining the LTC-DRG relative weights would lower the LTC-DRG relative weight for affected LTC-DRGs because the relatively lower charges of the short-stay outlier cases would bring down the average charge for all cases within an LTC-DRG. This would result in an "underpayment" to nonshort-stay outlier cases and an "overpayment" to short-stay outlier cases. Therefore, in this final rule, we adjust for short-stay outlier cases under §412.529 in this manner because it results in more appropriate payments for all LTCH cases.

Step 4--Calculate the FY 2005 LTC-DRG relative weights on an iterative basis.

The process of calculating the LTC-DRG relative weights using the hospital specific relative value methodology is iterative. First, for each LTCH case, we calculate a hospital-specific relative charge value by dividing the short-stay outlier adjusted charge per discharge (see step 3) of the LTCH case (after removing the statistical outliers (see step 1)) and LTCH cases with a length of stay of 7 days or less (see step 2) by the average charge per discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. An initial case-mix index value of 1.0 is used for each LTCH.

For each LTC-DRG, the FY 2005 LTC-DRG relative weight is calculated by dividing the average of the adjusted hospital-specific relative charge values (from above) for the LTC-DRG by the overall average hospital-specific relative charge value across all cases for all LTCHs. Using these recalculated LTC-DRG relative weights, each LTCH's average relative weight for all of its cases (case-mix) is calculated by dividing the sum of all the LTCH's LTC-DRG relative weights by its total number of cases. The LTCHs' hospital-specific relative charge values above are multiplied by these hospital specific case-mix indexes. These hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of LTC-DRG relative weights across all LTCHs. In this final rule, this iterative process is continued until there is convergence between the weights produced at adjacent steps, for example, when the maximum difference is less than 0.0001.

Step 5--Adjust the FY 2005 LTC-DRG relative weights to account for nonmonotonically increasing relative weights.

As explained in section II.B. of this preamble, the FY 2005 CMS DRGs, which the FY 2005 LTC-DRGs are based, contain “pairs” that are differentiated based on the presence or absence of CCs. The LTC-DRGs with CCs are defined by certain secondary diagnoses not related to or inherently a part of the disease process identified by the principal diagnosis, but the presence of additional diagnoses does not automatically generate a CC. As we discussed in the May 18, 2004 IPPS proposed rule (69 FR 28232), the value of monotonically increasing relative weights rises as the resource use increases (for example, from uncomplicated to more complicated). The presence of CCs in an LTC-DRG means that cases classified into a "without CC" LTC-DRG are expected to have lower resource use (and lower costs). In other words, resource use (and costs) are expected to decrease across "with CC"/"without CC" pairs of LTC-DRGs.

For a case to be assigned to a LTC-DRG with CCs, more coded information is called for (that is, at least one relevant secondary diagnosis), than for a case to be assigned to an LTC-DRG "without CCs" (which is based on only one principal diagnosis and no relevant secondary diagnoses). Currently, the LTCH claims data include both accurately coded cases without complications and cases that have complications (and cost more), but were not coded completely. Both types of cases are grouped to an LTC-DRG "without CCs" because only one principal diagnosis was coded. Since the LTCH PPS was only implemented for cost reporting periods beginning on or after October 1, 2002 (FY 2003) and LTCHs were previously paid under cost-based reimbursement, which is

not based on patient diagnoses, coding by LTCHs for these cases may not have been as detailed as possible.

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

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

There are three types of "with CC" and "without CC" pairs that could be nonmonotonic, that is, where the "without CC" LTC-DRG would have a higher average charge than the "with CC" LTC-DRG. For this final rule, using the LTCH cases in the March 2004 update of the FY 2003 MedPAR file, we identified two of the three types of nonmonotonic LTC-DRG pairs.

The first category of nonmonotonically increasing relative weights for FY 2005 LTC-DRG pairs "with and without CCs" contains 2 pairs of LTC-DRGs in which both the LTC-DRG "with CCs" and the LTC-DRG "without CCs" had 25 or more LTCH cases and, therefore, did not fall into one of the 5 low-volume quintiles. For those nonmonotonic LTC-DRG pairs, as discussed in the May 18, 2004 proposed rule, we combine the LTCH cases and compute a new relative weight based on the case-weighted average of the combined LTCH cases of the LTC-DRGs. The case-weighted average charge is determined by dividing the total charges for all LTCH cases by the total number of LTCH cases for the combined LTC-DRG. This new relative weight is then assigned to both of the LTC-DRGs in the pair. In this final rule, for FY 2005, LTC-DRGs 144 and 145 and LTC-DRGs 444 and 445 are in this category.

The second category of nonmonotonically increasing relative weights for LTC-DRG pairs with and without CCs consists of zero pairs of LTC-DRGs that has fewer than 25 cases, and each LTC-DRG is grouped to different low-volume quintiles in which the "without CC" LTC-DRG is in a higher-weighted low-volume quintile than the "with CC" LTC-DRG. For those pairs, as we discussed in the May 18, 2004 proposed rule (69 FR 28232), we combine the LTCH cases and determine the case-weighted

average charge for all LTCH cases. The case-weighted average charge is determined by dividing the total charges for all LTCH cases by the total number of LTCH cases for the combined LTC-DRG. Based on the case-weighted average LTCH charge, we determine which low-volume quintile the “combined LTC-DRG” is grouped. Both LTC-DRGs in the pair are then grouped into the same low-volume quintile, and thus have the same relative weight. In this final rule, for FY 2005, there are no LTC-DRGs that fall into this category.

The third category of nonmonotonically increasing relative weights for LTC-DRG pairs with and without CCs consists of 10 pairs of LTC-DRGs where one of the LTC-DRGs has fewer than 25 LTCH cases and is grouped to a low-volume quintile and the other LTC-DRG has 25 or more LTCH cases and has its own LTC-DRG relative weight, and the LTC-DRG "without CCs" has the higher relative weight. As discussed in the May 18, 2004 proposed rule (69 FR 28232), we remove the low-volume LTC-DRG from the low-volume quintile and combine it with the other LTC-DRG for the computation of a new relative weight for each of these LTC-DRGs. This new relative weight is assigned to both LTC-DRGs, so they each have the same relative weight. In this final rule, for FY 2005, the following LTC-DRGs are in this category: LTC-DRGs 85 and 86; LTC-DRGs 101 and 102; LTC-DRGs 141 and 142; LTC-DRGs 170 and 171; LTC-DRGs 172 and 173; LTC-DRGs 175 and 175; LTC-DRGs 300 and 301; LTC-DRGs 318 and 319; LTC-DRGs 442 and 443; and LTC-DRGs 521, 522 and 523 (We note, 3 LTC-DRGs make up this non-monotonic “pair” of DRGs because the “without CCs” DRG is further divided into two DRGs based on the presence or absence

of rehabilitation therapy, so that there is one DRG in this non-monotonic “pair” with CCs and two DRGs in this non-monotonic “pair” without CCs) .

Step 6—Determine an FY 2005 LTC-DRG relative weight for LTC-DRGs with no LTCH cases.

As we stated above, we determine the relative weight for each LTC-DRG using charges reported in the March 2004 update of the FY 2003 MedPAR file. Of the 520 LTC-DRGs for FY 2005, we identified 171 LTC-DRGs for which there were no LTCH cases in the database. That is, based on data from the FY 2003 MedPAR file used in this final rule, no patients who would have been classified to those LTC-DRGs were treated in LTCHs during FY 2003 and, therefore, no charge data were reported for those LTC-DRGs. Thus, in the process of determining the LTC-DRG relative weights, we are unable to determine weights for these 171 LTC-DRGs using the methodology described in steps 1 through 5 above. However, because patients with a number of the diagnoses under these LTC-DRGs may be treated at LTCHs beginning in FY 2005, we assign relative weights to each of the 171 "no volume" LTC-DRGs based on clinical similarity and relative costliness to one of the remaining 349 (520 - 171 = 349) LTC-DRGs for which we are able to determine relative weights, based on FY 2003 claims data.

As there are currently no LTCH cases in these "no volume" LTC-DRGs, as we discussed in the May 18, 2004 proposed rule (69 FR 28233), we determine relative weights for the 171 LTC-DRGs with no LTCH cases in the FY 2003 MedPAR file used in this final rule by grouping them to the appropriate low-volume quintile. This

methodology is consistent with our methodology used in determining relative weights to account for the low-volume LTC-DRGs described above.

Our methodology for determining relative weights for the "no volume" LTC-DRGs is as follows: We crosswalk the no volume LTC-DRGs by matching them to other similar LTC-DRGs for which there were LTCH cases in the FY 2003 MedPAR file based on clinical similarity and intensity of use of resources as determined by care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, post-operative care, and length of stay. We assign the relative weight for the applicable low-volume quintile to the no volume LTC-DRG if the LTC-DRG to which it is crosswalked is grouped to one of the low-volume quintiles. If the LTC-DRG to which the no volume LTC-DRG is crosswalked is not one of the LTC-DRGs to be grouped to one of the low-volume quintiles, we compare the relative weight of the LTC-DRG to which the no volume LTC-DRG is crosswalked to the relative weights of each of the five quintiles and we assign the no volume LTC-DRG the relative weight of the low-volume quintile with the closest weight. For this final rule, a list of the no volume FY 2005 LTC-DRGs and the FY 2005 LTC-DRG to which it is crosswalked in order to determine the appropriate low-volume quintile for the assignment of a relative weight for FY 2005 is shown below in Table 2.

Table 2.--No Volume LTC-DRG Crosswalk and Quintile Assignment for FY 2005

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

LTC-DRG	Description	Cross-Walked LTC-DRG	Low-Volume Quintile Assigned
67	EPIGLOTTITIS	63	Quintile 4
70	OTITIS MEDIA & URI AGE 0-17	69	Quintile 2
71	LARYNGOTRACHEITIS	97	Quintile 1
72	NASAL TRAUMA & DEFORMITY	73	Quintile 3
74	OTHER EAR, NOSE, MOUTH & THROAT DIAGNOSES AGE 0-17	69	Quintile 2
81	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE 0-17	69	Quintile 2
91	SIMPLE PNEUMONIA & PLEURISY AGE 0-17	90	Quintile 3
98	BRONCHITIS & ASTHMA AGE 0-17	97	Quintile 1
104	CARDIAC VALVE & OTH MAJOR CARDIOTHORACIC PROC W CARD CATH	110	Quintile 1
105	CARDIAC VALVE & OTH MAJOR CARDIOTHORACIC PROC W/O CARD CATH	110	Quintile 1
106	CORONARY BYPASS W PTCA	110	Quintile 1
107	CORONARY BYPASS W CARDIAC CATH	110	Quintile 1
111	MAJOR CARDIOVASCULAR PROCEDURES W/O CC	110	Quintile 1
137	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE 0-17	136	Quintile 3
146	RECTAL RESECTION W CC	148	Quintile 5
147	RECTAL RESECTION W/O CC	148	Quintile 5
151	PERITONEAL ADHESIOLYSIS W/O CC	150	Quintile 5
153	MINOR SMALL & LARGE BOWEL PROCEDURES W/O CC	152	Quintile 5
155	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W/O CC	154	Quintile 5
156	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE 0-17	154	Quintile 5
158	ANAL & STOMAL PROCEDURES W/O CC	157	Quintile 4
160	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W/O CC	159	Quintile 3
162	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W/O CC	178	Quintile 1
163	HERNIA PROCEDURES AGE 0-17	178	Quintile 1
164	APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W CC	148	Quintile 5
165	APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W/O CC	148	Quintile 5
166	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W CC	148	Quintile 5
167	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W/O CC	148	Quintile 5
169	MOUTH PROCEDURES W/O CC	185	Quintile 3
184	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE 0-17	183	Quintile 2
186	DENTAL & ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AGE 0-17	185	Quintile 3
187	DENTAL EXTRACTIONS & RESTORATIONS	185	Quintile 3
190	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE 0-17	189	Quintile 3

LTC-DRG	Description	Cross-Walked LTC-DRG	Low-Volume Quintile Assigned
192	PANCREAS, LIVER & SHUNT PROCEDURES W/O CC	191	Quintile 5
194	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W/O CC	193	Quintile 1
195	CHOLECYSTECTOMY W C.D.E. W CC	197	Quintile 5
196	CHOLECYSTECTOMY W C.D.E. W/O CC	197	Quintile 5
198	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W/O CC	197	Quintile 5
199	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	233	Quintile 4
224	SHOULDER,ELBOW OR FOREARM PROC,EXC MAJOR JOINT PROC, W/O CC	227	Quintile 2
232	ARTHROSCOPY	234	Quintile 3
252	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE 0-17	234	Quintile 3
255	FX, SPRN, STRN & DISL OF UPARM,LOWLEG EX FOOT AGE 0-17	234	Quintile 3
257	TOTAL MASTECTOMY FOR MALIGNANCY W CC	275	Quintile 1
258	TOTAL MASTECTOMY FOR MALIGNANCY W/O CC	275	Quintile 1
259	SUBTOTAL MASTECTOMY FOR MALIGNANCY W CC	275	Quintile 1
279	CELLULITIS AGE 0-17	273	Quintile 1
282	TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE 0-17	281	Quintile 3
286	ADRENAL & PITUITARY PROCEDURES	292	Quintile 4
289	PARATHYROID PROCEDURES	63	Quintile 4
290	THYROID PROCEDURES	63	Quintile 4
291	THYROGLOSSAL PROCEDURES	63	Quintile 4
293	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W/O CC	292	Quintile 4
298	NUTRITIONAL & MISC METABOLIC DISORDERS AGE 0-17	297	Quintile 2
309	MINOR BLADDER PROCEDURES W/O CC	308	Quintile 4
311	TRANSURETHRAL PROCEDURES W/O CC	310	Quintile 3
313	URETHRAL PROCEDURES, AGE >17 W/O CC	312	Quintile 4
314	URETHRAL PROCEDURES, AGE 0-17	305	Quintile 2
322	KIDNEY & URINARY TRACT INFECTIONS AGE 0-17	326	Quintile 1
327	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE 0-17	326	Quintile 1
329	URETHRAL STRICTURE AGE >17 W/O CC	305	Quintile 2

LTC-DRG	Description	Cross-Walked LTC-DRG	Low-Volume Quintile Assigned
330	URETHRAL STRICTURE AGE 0-17	305	Quintile 2
333	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE 0-17	332	Quintile 2
334	MAJOR MALE PELVIC PROCEDURES W CC	345	Quintile 5
335	MAJOR MALE PELVIC PROCEDURES W/O CC	345	Quintile 5
337	TRANSURETHRAL PROSTATECTOMY W/O CC	306	Quintile 4
340	TESTES PROCEDURES, NON-MALIGNANCY AGE 0-17	339	Quintile 1
342	CIRCUMCISION AGE >17	339	Quintile 1
343	CIRCUMCISION AGE 0-17	339	Quintile 1
351	STERILIZATION, MALE	339	Quintile 1
353	PELVIC EVISCERATION, RADICAL HYSTERECTOMY & RADICAL VULVECTOMY	365	Quintile 5
354	UTERINE,ADNEXA PROC FOR NON-OVARIAN/ADNEXAL 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

LTC-DRG	Description	Cross-Walked LTC-DRG	Low-Volume Quintile Assigned
382	FALSE LABOR	367	Quintile 1
383	OTHER ANTEPARTUM DIAGNOSES W MEDICAL COMPLICATIONS	367	Quintile 1
384	OTHER ANTEPARTUM DIAGNOSES W/O MEDICAL COMPLICATIONS	367	Quintile 1
385	NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY	367	Quintile 1
386	EXTREME 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 3
405	ACUTE LEUKEMIA W/O MAJOR O.R. PROCEDURE AGE 0-17	404	Quintile 1
407	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R.PROC W/O CC	408	Quintile 4
411	HISTORY OF MALIGNANCY W/O ENDOSCOPY	367	Quintile 1
412	HISTORY OF MALIGNANCY W ENDOSCOPY	367	Quintile 1
417	SEPTICEMIA AGE 0-17	416	Quintile 3
422	VIRAL ILLNESS & FEVER OF UNKNOWN ORIGIN AGE 0-17	426	Quintile 2
432	OTHER MENTAL DISORDER DIAGNOSES	427	Quintile 1
446	TRAUMATIC INJURY AGE 0-17	445	Quintile 3
448	ALLERGIC REACTIONS AGE 0-17	447	Quintile 3
451	POISONING & TOXIC EFFECTS OF DRUGS AGE 0-17	455	Quintile 2
471	BILATERAL OR MULTIPLE MAJOR JOINT PROCS OF LOWER EXTREMITY	236	Quintile 3
481	BONE MARROW TRANSPLANT	394	Quintile 4
482	TRACHEOSTOMY FOR FACE,MOUTH & NECK DIAGNOSES	63	Quintile 4
484	CRANIOTOMY FOR MULTIPLE SIGNIFICANT TRAUMA	1	Quintile 4
491	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF UPPER EXTREMITY	209	Quintile 5
492	CHEMOTHERAPY W ACUTE LEUKEMIA OR W USE OF HI DOSE CHEMOAGENT	410	Quintile 4
494	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W/O CC	493	Quintile 4
498	SPINAL FUSION EXCEPT CERVICAL W/O CC	497	Quintile 3
504	EXTENSIVE BURNS OF FULL THICKNESS BURNS WITH MECH VENT 96+HRS WITH SKIN GRAFT	468	Quintile 5

LTC-DRG	Description	Cross-Walked LTC-DRG	Low-Volume Quintile Assigned
507	FULL THICKNESS BURN W SKIN GRFT OR INHAL INJ W/O CC OR SIG TRAUMA	508	Quintile 3
516	PERCUTANEOUS CARDIOVASC PROC W AMI	518	Quintile 2
520	CERVICAL SPINAL FUSION W/O CC	497	Quintile 3
525	OTHER HEART ASSIST SYSTEM IMPLANT	468	Quintile 5
526	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 relative weights for the 171 LTC-DRGs with no LTCH cases, we are providing the following examples, which refer to the no volume LTC-DRGs crosswalk information for FY 2005 provided above in Table 2:

Example 1:

There were no cases in the FY 2003 MedPAR file used for this final rule for LTC-DRG 163 (Hernia Procedures Age 0-17). Since the procedure is similar in resource use and the length and complexity of the procedures and the length of stay are similar, we determined that LTC-DRG 178 (Uncomplicated Peptic Ulcer Without CC), which is assigned to low-volume quintile 1 for the purpose of determining the FY 2005 relative weights, would display similar clinical and resource use. Therefore, we assign the same relative weight of LTC-DRG 178 of 0.4586 (Quintile 1) for FY 2005 (Table 11 in the Addendum to this final rule) to LTC-DRG 163.

Example 2:

There were no LTCH cases in the FY 2003 MedPAR file used in this final rule for LTC-DRG 91 (Simple Pneumonia and Pleurisy Age 0-17). Since the severity of illness in patients with bronchitis and asthma is similar in patients regardless of age, we determined that LTC-DRG 90 (Simple Pneumonia and Pleurisy Age >17 Without CC) would display similar clinical and resource use characteristics and have a similar length of stay to LTC-DRG 91. There were over 25 cases in LTC-DRG 90. Therefore, it would not be assigned to a low-volume quintile for the purpose of determining the LTC-DRG relative weights. However, under our established methodology, LTC-DRG 91, with no

LTCH cases, would need to be grouped to a low-volume quintile. We identified that the low-volume quintile with the closest weight to LTC-DRG 90 (0.7494; see Table 11 in the Addendum to this final rule) would be low-volume quintile 2 (0. 8508; see Table 11 in the Addendum to this final rule). Therefore, we assign LTC-DRG 91 a relative weight of 0. 8508 for FY 2005.

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

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

However, if in the future a LTCH applies for certification as a Medicare-approved transplant center, we believe that the application and approval procedure would allow sufficient time for us to determine appropriate weights for the LTC-DRGs affected. At the present time, we are only including these six transplant LTC-DRGs in the GROUPER program for administrative purposes. Because we use the same GROUPER program for

LTCHs as is used under the IPPS, removing these LTC-DRGs would be administratively burdensome.

Again, we note that as this system is dynamic, it is entirely possible that the number of LTC-DRGs with a zero volume of LTCH cases based on the system will vary in the future. We used the best most recent available claims data in the MedPAR file to identify zero volume LTC-DRGs and to determine the relative weights in this final rule.

Table 11 in the Addendum to this final rule lists the LTC-DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (to assist in the determination of short-stay outlier payments under §412.529) for FY 2005.

Comment: A few commenters believe that the budget neutrality requirement found in section 123 of the Pub. L. 106-113 requires CMS to adjust the LTC-DRG relative weights to ensure that total payments to LTCHs are budget neutral for the proposed changes to the LTC-DRG classifications and relative weights. Alternatively, the commenters suggested that we make an adjustment to the LTCH PPS Federal rate to account for the estimated $55 million reduction in LTCH PPS payments which resulted from the proposed changes in the LTC-DRG classifications and relative weights.

Response: In the May 18, 2004 proposed rule (69 FR 28806), we estimated a $55 million aggregate decrease in LTCH PPS payments as a result of the proposed changes in the LTC-DRG relative weights and proposed version 22.0 GROUPER for FY 2005. We note that we incorrectly estimated the impact of the change in the proposed LTC-DRGs for FY 2005 in the proposed rule because we failed to account for the change

in DRG classifications and the change in the geometric average length of stay for each LTC-DRG. As discussed in section VII.B. of Appendix A to this final rule, we are estimating that the impact of the change in LTC-DRGs for FY 2005 (including changes in the DRG classifications, relative weights and geometric average lent of stay) will result in approximately a $14.9 million decrease in LTCH PPS payments. In that same proposed rule, we explained that we found that based on an analysis of the LTCH claims in the FY 2003 MedPAR files, the average LTC-DRG relative weight across all LTC-DRGs has increased due to an increase in the number of cases being assigned to higher weighted LTC-DRGs. As a result, including cases with relatively lower charges into LTC-DRGs that have a relatively higher relative weight in the GROUPER version 21.0 (FY 2004) decreases the average relative weight in the proposed GROUPER version 22.0 (FY 2005).

As we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 55960), which implemented the LTCH PPS, section 123 of Pub. L. 106-113 requires that the LTCH PPS, among other things, shall include an adequate patient classification system that is based on DRGs and that reflects the differences in patient resource use and costs, and shall maintain budget neutrality. With respect to budget neutrality, we interpreted section 123(a)(1) of Pub. L. 106-113 to require that total payments under the LTCH PPS during FY 2003 will be projected to equal estimated payments that would have been made for LTCHs' operating and capital-related inpatient hospital costs had the LTCH PPS not have been implemented. Consistent with this requirement, under §412.523(d)(2) an adjustment is made in determining the standard Federal rate for FY 2003 so that

aggregate payments under the LTCH PPS are estimated to equal the amount that would have been paid to LTCHs under the reasonable cost-based (TEFRA) payment system if the LTCH PPS were not implemented. Therefore, in that same final rule (67 FR 56027 through 56037), in order to maintain budget neutrality, we adjusted the LTCH PPS Federal rate for FY 2003 so that aggregate payments under the LTCH PPS are estimated to equal the amount that would have been paid to LTCHs under the reasonable cost-based (TERFA) payment system had the LTCH PPS had not been implemented.

In addition, when we implemented the LTCH PPS in the August 30, 2002 LTCH PPS final rule, we provided subpart O of the regulations at 42 CFR, including §412.517, for an annual adjustment to the LTC-DRG classifications and weighting factors to reflect changes in treatment patterns, technology, number of discharges, and other factors affecting the relative use of hospital resources. We do not believe that section 123 of the Pub. L. 106-113 requires that the annual update to the LTC-DRG classifications and relative weights maintain budget neutrality. We believe we have satisfied the budget neutrality requirement of section 123 of the Pub. L. 106-113 by establishing the LTCH PPS Federal rate for FY 2003 under §412.523(d)(2) so that aggregate payment under the LTCH PPS are projected equal to estimated aggregate payments under the reasonable cost-based payment system if the LTCH PPS were not implemented. Therefore, we disagree with the commenters that an adjustment to the FY 2005 LTC-DRG relative weights or to the LTCH PPS Federal rate is required as a result of the annual update to the LTC-DRGs under §412.517 for FY 2005. Accordingly, we have updated the LTC-DRG classifications and relative weights for FY 2005 (as shown in Table 11 of

Addendum to this final rule) without an adjustment for budget neutrality. We note that this is our policy regardless of whether the annual update to the LTC-DRG classifications and relative weights results in higher or lower estimated aggregate payments. For instance we estimate that the annual update to the LTC-DRG classifications and relative weights from FY 2003 to FY 2004 resulted in an estimated increase in LTCH PPS payments yet the update to the LTC-DRGs in the August 1, 2003 final rule for FY 2004 were not adjusted to maintain budget neutrality. In either case, at this time we do not make an adjustment to maintain budget neutrality for the effects of changes in the LTC-DRG classifications and relative weights. Accordingly, in developing the FY 2005 LTC-DRGs and relative weights shown in Table 11 of this final rule, we have not applied an adjustment for budget neutrality nor are we adjusting the 2005 LTCH PPS rate year Federal rate established in the May 7, 2004 LTCH PPS final rule (69 FR 25674) to account for the estimated change in LTCH PPS payments which result from the annual update to the LTC-DRG classifications and relative weights for FY 2005.

The commenter raises the issue that it may be appropriate for certain aspects of the LTCH PPS to maintain budget neutrality when they are updated annually as they are in other PPSs, such as the annual update to the DRGs and wage index. Under section 123 of Pub. L. 106-113 and section 307 of Pub. L. 106-554, the Secretary generally has broad authority in developing the LTCH PPS, including whether and how to make adjustments to LTCH PPS payments. Specifically, section 307(b)(1) of Pub. L. 106-554 provides that "the Secretary shall examine and may provide for appropriate adjustments to the long-term hospital payment system, including adjustments to DRG weights, area wage

adjustments, geographic classification, outliers, updates, and a disproportionate share adjustment […]." We will consider whether it is appropriate for use to propose a] future revision to the LTCH PPS regulations at subpart O of 42 CFR to maintain budget neutrality in the annual update of some aspects of the LTCH PPS under our broad discretionary authority under the statute to provide "appropriate adjustments to the long-term hospital payment system." Any changes to the LTCH PPS regulations would be made in accordance with Administrative Procedures Act guidelines.

5. Out of Scope Comments Relating to the LTCH PPS Payment Rates

Comment: A few commenters submitted comments that addressed aspects of the existing LTCH PPS, including the standard Federal rate and outlier methodology, which are not relevant to the LTCH policy proposals set forth in the May 18, 2004 IPPS proposed rule.

Response: Because those comments pertain to specific aspects of the existing LTCH PPS rather than to any specific proposed changes to the LTCH PPS presented in the May 18, 2004 IPPS proposed rule, we are unable to respond to those comments at this time. Rather, we believe it is more appropriate to address those issues in the annual LTCH PPS proposed and final rules, and we will consider the issues raised in those comments in the context of future rulemaking for the LTCH PPS.

E. Add-On Payments for New Services and Technologies

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will

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

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

otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion for this section."

In the May 18, 2004 proposed rule (69 FR 28237), we stated that the 2-year to 3-year period of newness for a technology or medical service would ordinarily begin with FDA approval, unless there was some documented delay in bringing the product onto the market after that approval (for instance, component production or drug production had been postponed until FDA approval due to shelf life concerns or manufacturing issues). After the DRGs have been recalibrated to reflect the costs of an otherwise new medical service or technology, the special add-on payment for new medical services or technology ceases (§412.87(b)(2)). For example, an approved new technology that received FDA approval in October 2003 and entered the market at that time may be eligible to receive add-on payments as a new technology until FY 2006 (discharges occurring before October 1, 2005), when data reflecting the costs of the technology would be used to recalibrate the DRG weights. Because the FY 2006 DRG weights will be calculated using FY 2004 MedPAR data, the costs of such a new technology would likely be reflected in the FY 2006 DRG weights.

Section 412.87(b)(3) further provides that, to receive special payment treatment, new medical services or technologies must be inadequately paid otherwise under the DRG system. To assess whether technologies would be inadequately paid under the DRGs, we establish thresholds to evaluate applicants for new technology add-on payments. In the August 1, 2003 final rule (68 FR 45385), we established the threshold at the geometric mean standardized charge for all cases in the DRG plus 75 percent of

1 standard deviation above the geometric mean standardized charge (based on the logarithmic values of the charges and transformed back to charges) for all cases in the DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant DRGs, if the new medical service or technology occurs in many different DRGs). Table 10 in the Addendum to the August 1, 2003 final rule (68 FR 45648) listed the qualifying threshold by DRG, based on the discharge data that we used to calculate the FY 2004 DRG weights.

However, section 503(b)(1) of Pub. L. 108-173 amended section 1886(d)(5)(K)(ii)(I) of the Act to provide for "applying a threshold…that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved." The provisions of section 503(b)(1) apply to classification for fiscal years beginning with FY 2005. We updated Table 10 from the October 6, 2003 **Federal Register** correction document, which contains the thresholds that we used to evaluate applications for new service or technology add-on payments for FY 2005, using the section 503(b)(1) measures stated above, and posted these new thresholds on our website at: **www.cms.hhs.gov/providers/hipps/newtech.asp**. In the May 18, 2004 proposed rule, we included preliminary thresholds for evaluating applicants for new technology add-on payments for FY 2006. Table 10 of this final rule contains the final thresholds that will be used to evaluate applicants for new technology add-on payments for FY 2006. (Refer to section IV.D. of this preamble for a discussion of a revision of the regulations to incorporate the change made by section 503(b)(1) of Pub. L. 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 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.

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

Applicants for add-on payments for new medical services or technologies for FY 2006 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate the medical service or technology meets the high-cost threshold, no later than early October 2004. Applicants must submit a complete database no later than mid-December 2004. Complete application information, along with final deadlines for submitting a full application, will be available at our website after publication of this 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 website will also list the tracking forms completed by each applicant.

2. Other Provisions of Section 503 of Pub. L. 108-173

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

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries.

- Make public and periodically update a list of the services and technologies for which an application for add-on payments is pending.

- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial improvement.

- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new

service or technology represents a substantial clinical improvement to the clinical staff of CMS.

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

Approximately 70 participants registered and attended in person, while additional participants listened over an open telephone line. The participants focused on presenting data on the substantial clinical improvement aspect of their products, as well as the need for additional payments to ensure access to Medicare beneficiaries. In addition, we also received many written comments regarding the substantial clinical improvement criterion for the applicants. As indicated in the May 18, 2004 proposed rule, we considered these comments in our evaluation of each new application for FY 2005 in the proposed rule. In the proposed rule, we summarized these comments or, if applicable, indicated that no comments were received, at the end of the discussion of the individual applications.

Section 503(c) of Pub. L. 108-173 amended section 1886(d)(5)(K) of the Act by adding a new clause (ix) requiring that before establishing any add-on payment for a new medical service or technology, that the Secretary shall seek to identify one or more DRGs

associated with the new technology, based on similar clinical or anatomical characteristics and the costs of the technology and assign the new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology. No add-on payment shall be made with respect to such a new technology.

At the time an application is submitted, the DRGs associated with the new technology are identified. We only determine that a new technology add-on payment is appropriate when the reimbursement under these DRGs is not adequate for this new technology. The criterion for this determination is the cost threshold, which we discuss below. We discuss the assignments of several new technologies within the DRG payment system in section II.B. of this final rule. The comment regarding the DRG assignment of the treatment for AIP is addressed in section II.B.16.i. of this final rule.

Comment: We received several letters from commenters stating that we should address the inequities in the DRG system with respect to several drugs and technologies that appeared to go unnoticed by us, according to the commenters. Specifically, payments for the treatment of acute intermittent porphyria (AIP) were brought to our attention. We received additional comments from physicians and a company concerning new procedure code 00.16 (Pressurized treatment of venous bypass graft (conduit) with pharmaceutical substance). The commenters requested that we evaluate potential reimbursement scenarios for these new procedures.

Response: We discuss the method for applying for consideration for the new technology add-on payment in section II.E.1. of this preamble. The Medicare program pays for thousands of medical services, drugs and technologies and may not necessarily

be aware of all new technologies that come to the market. We have implemented the new technology add-on payment provision by providing a process by which applicants can present these technologies to us for add-on payment consideration. Commenters should also consider the application process for obtaining new ICD-9-CM codes to further aid in obtaining specifically identifying procedure codes in an effort to seek new technology add-on payments. We discuss the DRG assignment of procedure code 00.16 in section II.B.16.c. of this final rule. The comment regarding the DRG assignment of the treatment for AIP is addressed in section II.B.16.i. of this final rule.

Comment: Some commenters objected to the application of the newness criterion in the proposed rule. These commenters asserted that CMS's description of the criterion requiring a technology to be new was inconsistent with the statute and the September 7, 2001 final rule. Specifically, the commenters maintained that defining the period of new as during the 2-year to 3-year period after FDA market approval would "represent a significant shift, retroactively changing the conditions under which companies have been developing innovative technologies and filing new technology applications." These commenters further stated that this makes the regulatory process unpredictable, "potentially having an adverse effect on patient access to breakthrough medical technologies." The commenters urged us to "reaffirm" our September 7, 2001, policy and reevaluate the applications that CMS proposed to deny on the newness issue.

Response: The intent of section 1886(d)(5)(K) of the Act and regulations under §412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new

technology are not yet fully reflected in the DRG weights. Generally, we use the FDA approval as the indicator of the time when a technology begins to become available on the market and data reflecting the costs of the technology begin to become available for recalibration of the DRGs. In some specific circumstances, we have recognized a date later than the FDA approval as the appropriate starting point for the 2-year to 3-year period. For example, we have recognized a later date where an applicant could prove a delay in actual availability of a product after FDA approval. The costs of the new medical service or technology, once paid for by Medicare for this 2-year to 3-year period, are accounted for in the MedPAR data that are used to recalibrate the DRG weights on an annual basis. Therefore, it is appropriate to limit the add-on payment window for those technologies that have passed this 2- to 3-year timeframe.

We disagree that our statement of the policy in the proposed rule is inconsistent with policy that was implemented in previous rules. In the first year that new technology applications were considered in the IPPS (that is, during calendar year 2002), we discussed several applications and determined whether they could be considered new on the basis of when FDA approval was granted to the technologies. Again in our August 1, 2003 final rule for FY 2004, we denied applicants on the basis that the technologies had gained FDA approval prior to FY 2001; and thus, were not eligible for new technology add-on payments. In these instances, we employed the actual date of FDA market approval, not the date a separate ICD-9-CM code became available, since data reflecting the costs associated with those technologies had already been included in the DRG weights prior to the adoption of a separate ICD-9-CM code.

Using the ICD-9-CM code alone is not an appropriate test of newness because technologies that are new to the market are automatically placed into the closest ICD-9-CM category when they first come on the market, unless the manufacturer requests the assignment of a new ICD-9-CM code because existing codes do not adequately reflect or describe the medical service or device. The services and technologies that have been placed into existing ICD-9-CM codes have been paid for using those descriptors. Therefore, while it may be impossible to actually identify when a particular product was used because there is no unique code to identify it amongst other products in the category, the product is nonetheless used and paid for. In addition, hospital charges reflect the services provided to patients receiving the new service or device whether or not a specific code is assigned. Therefore, data containing payments for these new technologies are already in our MedPAR database and when DRG recalibration occurs these costs are accounted for. Furthermore, assignment of new codes can occur for many reasons other than the introduction of new procedures and technologies. For example, new codes can simply reflect more refined and discriminating descriptions of existing procedures and technologies.

If we were strictly to use the ICD-9-CM coding system for the purposes of identifying what technologies are new, there would be an incentive for nearly every product, service and surgical technique to apply for a new, unique ICD-9-CM code. The ICD-9-CM system could not absorb all these potential new codes. It would also be inappropriate to pay more, in the form of new technology add-on payments, for most of the codes, as the technology may have been in use prior to the assignment of the new

code for several years, or several decades in some cases. For example, there is currently no procedural distinction between a patient receiving a kidney transplant from a living or cadaver donor. It is conceivable that this kidney transplant could be broken out into several procedures, identifying the source of the kidney (from living/deceased, relative/stranger, etc.), and each would be a "new" procedure if we were to adopt the commenters' approach. These procedures have been in use for up to half a century; and therefore, clearly should not qualify as a new medical service or technology simply because a new ICD-9-CM code has been assigned. Another example that further exemplifies the limitations of this ICD-9-CM-based approach is the esophageal permanent tube, which is a stent implanted in a patient who cannot be medically treated and is unable to swallow. If we create a new code, and use it to determine if the esophageal permanent tube should qualify for new technology payment under the commenters' approach, the technology could qualify as new, although the procedure has been used for the last 20 years.

We also note that our existing interpretation does not hamper the ability of patients to receive technologies that do not qualify for new technology add-on payments. The IPPS will continue to pay for existing and new medical services and technologies through the regular payment mechanism established by the DRG payment methodology. Therefore, patient access to these technologies is not adversely affected by this interpretation, and this interpretation is not inconsistent with the framework used to review new technology applications in previous years.

Comment: One commenter stated, "we believe that the 2- to 3-year clock should not start until a technology receives final approval by the Food and Drug Administration." The commenter also submitted an additional comment that stated that the "date of ICD-9 code assignment should start the add-on payment eligibility time clock, not the date of FDA approval."

Response: We note that the commenter's comments were somewhat contradictory on the issue of newness. The timeframe that a new technology can be eligible to receive new technology add-on payments begins when data become available. Section 412.87(b)(2) clearly states that "a medical service or technology may be considered new within the 2 to 3 year after the point at which data begins to become available reflecting the ICD-9-CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration)." Section 412.87(b)(2) also states "…[a]fter CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion of this section." Therefore, regardless of whether a technology can be individually identified by a separate ICD-9-CM code, if the costs of the technology are included in the charge data, and the DRGs have been recalibrated using that data, then the device can no longer be considered new for the purposes of this provision.

Comment: A commenter suggested that CMS adopt a different strategy for defining the newness criterion. The commenter believes that the decision of whether a

technology is new should involve consideration of both the FDA approval date and the date of issuance of an ICD-9-CM code. The commenter explained that if an ICD-9-CM code is issued within 12 months of FDA approval, the 2- to 3-year period of a technology being considered new should begin from the date of issuance of the ICD-9-CM code. If a code is issued more than 12 months after FDA approval, the 2-to 3-year period should begin from the FDA approval date. The commenter noted that adoption of this interpretation would strike a balance between the FDA approval date and the procedure code effective date and is consistent with the preamble of the September 7, 2001 Federal Register (66 FR 46914) and the text of the regulation (42 CFR 412.87(b)(2)).

Response: We note that the time period does not necessarily start with the approval date for the medical service or technology and does not necessarily start with the issuance of a distinct code. Instead, it begins with availability of the product on the market, which is when data become available. We have consistently applied this standard, and believe that it is most consistent with the purpose of new technology add-on payments.

Comment: MedPAC recommended that we use a different approach to DRG recalibration. In these instances, MedPAC recommends that we exclude those cases involving a new technology from our DRG recalibration method. Doing so "would avoid overpaying for the technology by including its costs in the base payment while also providing an add-on payment" during the overlapping 2- to 3-year period in question. MedPAC further stipulates that this approach "should be used for all cases where the new technology can be tracked" with an ICD-9-CM code or where cases can be identified by

other characteristics in our MedPAR data. They also stressed the importance of maintaining a conservative approach when CMS evaluates technologies for add-on payments. In addition, they noted that paying indiscriminately for too many technologies "can be seen as unbundling of the DRG system" which would threaten the "incentives for hospitals to be efficient and weigh the benefits of new technologies against their costs." Moreover, they noted that section 503(b)(1) of Pub. L. 108-173 changed the cost criteria by lowering the threshold to qualify for add-on payments. As such, MedPAC believes that the number of technologies that could potentially be eligible to qualify will likely increase expenditures to the program since these payments are no longer budget neutral.

Response: We appreciate MedPAC's recommendations and will consider its suggestion regarding excluding the costs of cases involving new technologies from DRG recalibration calculations in the future. We also believe that we have consistently applied an appropriately high standard of clinical improvement to restrict these types of payments to relatively few technologies that are truly new. We will continue to apply this high standard in our review of applications for new technology add-on payments in the future.

Comment: A commenter noted that if "CMS believes that it erred in developing the payment period policy published in the September 7, 2001 final rule, then it should propose a policy change applying to all applications for new technology add-on payments." The commenter also stated, that "the implementation of such a policy change should affect only the applications received thereafter, and should not apply to any applications currently under consideration."

Response: We believe that the commenter, the manufacturer of InFUSE™ Bone Graft, wanted to ensure that if we made a change in the policy, that change would be done through notice and comment rulemaking and that the change would not be applied retroactively to applicants that are currently under consideration. However, we note that we have not made any changes to the policies implemented in the September 7, 2001 final rule.

Comment: Several commenters urged us to be as clear as possible in implementing section 503 of Pub. L.108-173. The commenters stated that transparency is necessary, particularly for "small companies doing a disproportionate amount of the medical device research and development." Many commenters urged us to clearly state and adopt an approach to the provision so there is "a clear path to follow and a reliable set of requirements to meet." Several commenters also noted that, despite how we have been applying the definition of new, many of the companies that have applied or could apply for new technology add-on payments do not neatly fall into a standard definition because different manufacturers follow different pathways. These commenters stated, "many device manufacturers, especially small device entrepreneurs, lack the nationwide marketing, distribution, and reputation of the larger companies in the industry. These small companies are most affected by the so-called 'payment lag' during which new products are under-reimbursed…." In addition, commenters stated, despite or because of these problems of distribution, the rates of adoption and utilization of new products should be accounted for before we decide technologies are no longer new. In addition, commenters call for CMS to "clarify what the bar is for a device to represent a substantial

[clinical] improvement." Commenters stated that determinations of what represents a substantial clinical improvement have been largely subjective, but that, "for future generations of add-on applicants, an elaborated definition would be helpful."

Response: As stated previously, we have used as our uniform standard, the date of FDA approval in combination with market availability to evaluate new technology applications. We also note that in our evaluation of previous new technology applications, we have stated whether or not the applicants have met the substantial clinical improvement criterion as part of the basis for our approval or disapproval of the application. We follow the guidelines, as listed in the September 7, 2001 final rule, to make these determinations as they apply to improving the quality of care for the elderly Medicare population. However, as discussed in response to several of the other comments, we may need to consider revising our policies in the future to make the process more streamlined as more technologies apply for the new technology add-on payments. We will also consider the commenter's views concerning the payment lag for new products as we continue to develop policy in this area. However, at this time we believe that the 2-to 3-years timeframe remains an appropriate standard for determining when the costs of new technologies have been incorporated into the DRG weights.

Comment: Several commenters urged CMS to adopt a uniform standard for reviewing new technology add-on payment applications that is consistent between both the IPPS and the OPPS. Additionally, one commenter believes that CMS is inconsistent in its use of external data for verifying or amending payment rates. The commenter recommended that CMS should acknowledge that different types of data are appropriate

for different uses such as revisions to APCs in the outpatient setting and adjustment of DRG relative weights in the inpatient setting. The commenter added that data requirements for determining eligibility for a new technology add-on payment should not be the same as for adjusting DRG relative weights. The commenter also recommended that external data provided for DRG assignments or payments for new technologies may be appropriately proprietary in these cases and the commenter believes CMS should release such data in a summary format agreed to by the companies and should not make the data available for public inspection without the companies' consent. The commenter also suggested that CMS should not require identification of a hospital by its Medicare provider number in cases where there may be a confidentiality agreement between the manufacturer or data vendor and the hospital submitting the data. The commenter recommended that CMS use pseudo-identifiers as an alternative to actual provider numbers. The commenter also proposed that CMS allow the use of external data from recent timeframes without corresponding MedPAR data, particularly for procedures involving new technologies and codes. The commenter explained that external data from private vendors has only a 60-90 day time lag compared to MedPAR, which has a lengthier time lag. The commenter further recommended that when determining the price of a drug or device CMS should accept the disclosure of discounts and rebates at the estimated aggregate level since the company may not know the final price paid by the hospital for a given product. Finally, the commenter recommended that CMS should request that medical technology companies offer the HCPCS codes and ICD-9-CM codes that seem most clinically appropriate to the procedure since this information would be

most helpful to CMS and allow companies to target their resources in providing external data. Another commenter expressed that companies will not make the best data available "unless CMS agrees to hold it confidential."

Another commenter encouraged CMS to expand its acceptance of external data in order to ease the process of establishing adequate initial inpatient payment for new technology procedures at or as close as possible to the time of FDA approval. The commenter also urged CMS to accept external data as part of the recalibration of the DRG weights. The commenter also recommended that CMS apply reasonable standards that take into account the limited amount of data that may be available for new technologies and the difficulties involved in collecting such data in determining whether external data provides an acceptable basis for making a new DRG assignment or adjustment of the DRG weights.

One commenter, a company that gathers data on hospital services, noted that its data could be used to project national trends and establish Medicare policies. The commenter also noted that there are instances where its data are more detailed than MedPAR. The commenter believes CMS should work with the industry to develop criteria for making use of external data. The commenter was also concerned about the difficulty of obtaining MedPAR data. The commenter explained that CMS no longer makes available quarterly updates to the MedPAR and that the MedPAR data used to develop the FY 2005 proposed rule were not made available in a timely manner.

Response: We note that we have followed many of these examples when reviewing previous technologies. In the case of Xigris®, we worked very closely with the

applicant to review the applicant's data in order to identify a cohort of cases that would be appropriate candidates to receive the new drug. For FY 2005, we have also worked very closely with the applicants to help them identify what data requirements needed to be met and to help them to determine the best strategies to meet these requirements. We note, however, that applicants should weigh the advantages of submitting additional data in support of an application for new technology add-on payments with the need to preserve the confidentiality of certain proprietary data. We thank the commenters for their other comments and recommendations regarding accepting non-MedPAR data. We intend to take these comments into consideration and review the feasibility of adopting one or more of these approaches at some time in the future. Because we did not make any proposals regarding the use of external data in the May 18, 2004 proposed rule, we are not making any changes at this time. However, we will consider the comments in developing future proposals.

We also note that we offer two annual updates of the MedPAR data used for determining the rates in FY 2005. One update is based on the data used for the proposed rule. This update is usually issued in May. The second update is based on the data used in the final rule and is usually issued in September. Information on purchasing the MedPAR data used in determining the rates for FY 2005 can be found on our website at http://www.cms.hhs.gov/data/order/default.asp. Finally, we note, that in the interests of providing the most accurate and complete data files and due to time and work constraints, we are no longer able to issue quarterly updates of the MedPAR to the public.

Comment: Commenters in general contended that they "cannot meet the public's demands to adopt new technologies… because their ability to access capital is deteriorating". Commenters stated that since very few new technologies have qualified for this add-on payment, hospitals continue to underutilize and potentially limit use of clinically important new technologies in the absence of these higher payments. Commenters again urged CMS to increase the payment for new technology add-on payments from 50 percent of the cost of the device to 80 percent of the costs. They stated that to do so would be in line with the Conference Committee Agreement accompanying Public Law 108-173 which states, "the Secretary should consider increasing the percent of payment associated with the add-on payments up to the marginal rate used for the inpatient outlier." (108 Cong., 2d Sess., 212(2003)). Commenters further stated that CMS "apparently believes that this outlier payment level strikes the appropriate balance between ensuring that providers are not unduly at financial risk for expensive cases…", yet has offered no explanation for why this payment level would not be appropriate for the new technology add-on payment as well.

Response: We note that we have made substantial changes to the application threshold in the last year, reducing the cost threshold to qualify for new technology add-on payments twice. In addition, we have eliminated the budget neutrality provision, thus increasing the total moneys spent to pay for deserving, new technologies. While the conference report to the MMA recommended that the Secretary should consider changing the payment factor, we will not make such a change this year. Rather, we will analyze the impacts of the other MMA changes, especially the reduction in the cost threshold and

the elimination of the budget neutrality of the add-on payments, before we consider making changes in the payment percentage. We will continue to consider the conference report's recommendation and will determine whether to proceed with a change in the light of our continuing analysis.

Comment: Commenters urged CMS to adopt an approach to the public meetings required by the MMA in a manner that is similar to the ICD-9 Coordination and Maintenance Committee meetings. Commenters noted that a specific agenda and preliminary opinions are released to the public prior these meetings and urged CMS to present preliminary opinions on substantial clinical improvement prior to the public meeting on this topic.

Response: We have traditionally not provided our opinion on substantial clinical improvement of applicants for new technology add-on payments until the final rule. We note that if all the criteria are met prior to the publication of the proposed rule, we would prefer to make our preliminary determinations available at that time. However, to date we have not been able to make a sound determination regarding substantial clinical improvement until after the publication of the proposed rule.

Section 503(b)(2) of Pub. L. 108-173 requires CMS to consider public comments regarding whether an applicant for new technology payments meets the substantial clinical improvement criterion. Comments must be received and considered prior to the publication of the proposed rule for the annual IPPS update. This requirement, which was implemented for the first time through the new technology town hall meeting held in March of this year, and the subsequent comment period is further evidence that we do

take the issue of substantial clinical improvement into account prior to the publication of the proposed rule. However, the MMA provision does not require the type of procedure recommended by the commenter, but merely the opportunity for presentation of comments, recommendations, and data to CMS.

We designed the town hall-styled meeting this spring to provide a forum for public comment on the applicants. This format appeared to be received well by most of the attendees. We accepted comments and topics from attendees and presenters at the meeting, as well as accepting comments on substantial clinical improvement of the applicants after the meeting. If presenters would like a more detailed agenda to be published prior to the rule, we welcome them to register to attend the annual meeting and provide the information requested in the Federal Register notice announcing the meeting (this includes personal information for registration purposes as well as topics to be presented at the meeting). If we have this information well in advance of the meeting, the agenda will reflect all issues that have been raised regarding the assessment of the substantial clinical improvement criterion for each applicant. We welcome further input on how to better incorporate input prior to the announcement of the next town hall meeting on this topic.

In the May 18, 2004 proposed rule (69 FR 28236), we also evaluated whether new technology add-on payments will continue in FY 2005 for the two technologies that currently receive such payments. In accordance with section 503(e)(2) of Pub. L. 108-173, we also reconsidered one application for new technology add-on

payments that was denied last year. Finally, we presented our evaluations of 10 new applications for add-on payments in FY 2005.

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

a. Drotrecogin Alfa (Activated)--Xigris®

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

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

Xigris® became available on the market at the time of its FDA licensure on November 21, 2001. Early in FY 2005, Xigris® will be beyond the 2-year to 3-year period during which a technology can be considered new. Therefore, in the May 18, 2004 proposed rule, we proposed that Xigris® would not continue to receive new technology add-on payments in FY 2005. During the period of 2 years and 8 months since it came onto the market, Xigris® has been used frequently in the appropriate DRGs. For FY 2005, we analyzed the number of cases involving this technology in the FY 2003

MedPAR file. We found 4,243 cases that received Xigris®, the majority of which fell appropriately into DRGs 415, 416, 475, and 483, with by far the most cases in DRG 416 (Septicemia Age >17). Accordingly, the costs of Xigris® are now well represented in those DRGs. Therefore, we proposed that FY 2004 would be the final year for Xigris® to receive add-on payments.

Prior to the publication of the May 18, 2004 proposed rule, we received no public comments regarding the continuation of add-on payments for Xigris®. During the 60-day comment period for the proposed rule, we received 3 comments on this application.

Comment: The manufacturer submitted comments that were highly critical of CMS' proposal to discontinue add-on payments for Xigris®. The commenter brought up several points, which it believes, show that CMS is in violation of the statutory provisions. First, the manufacturer expressed opposition to the proposal to terminate the new technology add-on payments. It agreed that it was important to consider when a product comes on the market, but stated, "[w]hether a technology is 'new' is not salient in determining whether a third year of add-on payments should continue." It stated that the costs of the drug had not been adequately accounted for as required by statute and that the period during which it was eligible to receive add-on payments should continue another year, until 3 full years of add-on payments had been made. It stated, that "the fact that costs of a new technology or service may be included in the Medicare hospital discharge database (MedPAR) starting at the time an item or service is introduced into the marketplace is irrelevant. What matters is the ability to examine 2 years of cost data for cases coded as having used the new technology or service." Further, it argued, "these

cost data cannot be identified and collected until the ICD code is assigned and used in the coding of cases." It also stated that, since this 3-year maximum period had not yet ended, the costs of the cases could not have adequately been accounted for in our DRG recalibration using only data from FY 2003. It further stated that we should wait to remove them from add-on payment status until data from the FY 2004 MedPAR are available to recalibrate the DRGs. The manufacturer also stated that "the point of the legislative changes was to improve the old way of doing business…. It is unfortunate that CMS proposes to take the path of least resistance because it is the Medicare beneficiaries who will ultimately suffer."

Another commenter stated that our proposal to deny additional add-on payments in FY 2005 will deny Medicare beneficiaries the access to Xigris®. An additional commenter noted that, particularly because CMS was unable to implement the systems changes necessary to pay the new technology add-on payment for Xigris® until 8 months after the new code and higher payment were allowed, many hospitals were unclear as to the significance of correctly coding the new ICD-9-CM code identifying Xigris®, and therefore, the data for the first year of add-on payments do not adequately reflect the actual use of the drug.

Response: As stated previously, when we determine the newness criterion for new technology add-on applications, we use the date of FDA approval to determine that data including the technology are being incorporated into DRG recalibration, except in those rare cases where evidence can be presented that demonstrates that the product could not be marketed immediately after FDA approval. We have used this method of

determining newness since we began reviewing new technology applications. While there was no clearly distinguishable code assigned to Xigris® prior to the implementation of the new ICD-9-CM code 00.11 on October 1, 2002, treatment with Xigris® was identified prior to that time by procedure code 99.19. While this may not suit the applicant in terms of the ability to track specific cases that involved the use of Xigris®, the drug was being used for more than 10 months prior to the assignment of code 00.11 and the costs associated with the drug were, therefore, clearly included in the FY 2003 MedPAR update. Additionally, we note that the manufacturer itself was able to identify patients that would or could use Xigris®, as discussed in the May 9, 2002 proposed rule. There we stated, "Lilly also submitted detailed ICD-9-CM diagnosis and procedure codes for a subset of … patients with billing data…." (67 FR 31428). Because the manufacturer was able to identify a subset of patients without billing data at that time, we have met the criteria set forth by the manufacturer itself in being able to identify "2 years of cost data for cases coded as having used the new technology…. "The data we have captured since including the data used for the FY 2003 proposed rule analysis, have adequately accounted for costs associated with these cases. Including the 2 subsequent years during which Xigris® was eligible to receive new technology add-on payments, this makes a total of 3 years of data that CMS has used to incorporate the costs associated with the drug into the weights of the DRGs into which these cases fall.

In the FY 2004 annual update, we estimated that there would be 3,000 cases involving Xigris® in the relevant DRGs and we note that there are now 4,313 cases involving the drug in the March update of the FY 2003 MedPAR. We have conducted an

analysis of the FY 2002 MedPAR to determine the frequency of these cases in the DRGs in which Xigris® has been used. We have identified 593 cases using procedure code 99.19 in these 5 DRGs, which is significantly lower than the most recent 2 years of data. Additionally, we recognize that this code included other drugs and that not all 593 cases reporting this code in these 5 DRGs necessarily involved Xigris®. However, this low number of cases is consistent with what we would expect, given that the initial ICD-9-CM code did not drive DRG placement or payments. It is also consistent with the reasoning behind our of approval Xigris® for new technology add-on payments, since it was clearly a new technology that provided great potential benefit to Medicare beneficiaries and met the other criteria as defined by the statute. It is also reasonable to expect that, once the new ICD-9-CM code went into effect, with a payment incentive to encourage its rapid adoption and use, the number of cases including this code rose dramatically. While the figure of 593 cases using procedure code 99.19 in the relevant cases in FY 2002 is not very high, we note that in the August 1, 2002 final rule we stated that, based on the sales figures from the company at that time, there was already "$35 million in sales reported by Lilly through February 2002 (since the drug was approved in November 2001). (At $6,800 per patient, $35 million in sales equates to just over 5,000 cases for the first 4 months since FDA approval.)" (67 FR 50015). Therefore, we are confident that we have adequate data reflecting the use of Xigris® over the past 3 years. If we were to continue add-on payments beyond FY 2004, the technology would be beyond its 2-3 year maximum as allowed by the statute. We have used these data to recalibrate the DRGs into which these cases most frequently fall, so the costs of the

technology have already been accounted for in those DRG weights. Similarly, although we regret that systems changes delayed the processing of add-on payments for Xigris® in FY 2003, hospitals received add-on payments for all cases reporting the ICD-9-CM code for Xigris®. Furthermore, the costs of the new technology are nonetheless represented in the 2003 MedPAR data, whether hospitals used the new ICD-9-CM code for Xigris® (00.11) or the earlier procedure code (99.19). We do not agree with the assertion that Medicare beneficiaries will no longer have access to this important drug once the new technology add-on payments associated with it are terminated. To the contrary, we will continue to pay for the drug through DRG payment, and as noted above, the costs associated with the drug have been included in the weights of the relevant DRGs through the DRG recalibration.

Comment: The manufacturer also noted that section 1886(d)(5)(K)(ii)(IV) of the Act requires, "that discharges involving such a service or technology that occur after the close of the period [of add-on payments] will be classified within a new or existing diagnosis-related group with a weighting factor … that is derived from the cost data collected with respect to discharges occurring during such period." The commenter argues that there is no room for interpretation of the statute and that, since the average costs of cases involving the technology are very high, they should be assigned either to a new DRG or remapped to higher-weighted DRGs to reflect the cost of the cases. Another commenter asked that, if CMS refused to continue add-on payments for the entirety of FY 2005, such payments should be "maintained at least until the agency has analyzed the

available data and has classified cases in which Xigris® is administered into an appropriate DRG."

Response: We do not agree with the implications the commenter draws from the statutory language. We have assigned cases involving the use of Xigris® to clinically coherent DRGs, and the weights of these DRGs have been recalibrated to reflect the costs of these technology. We have also analyzed the costs of these cases and determined that, although the average standardized charge for these cases is higher than the average charges for the DRGs into which the cases involving Xigris® fall, there appears to be no justification to warrant creation of a new DRG or re-assignment of cases involving Xigris® into higher-weighted DRGs. We do not believe that it is necessary to assign cases involving Xigris® to a separate unique DRG, as requested by the manufacturer, in order to satisfy the statutory requirement. Indeed, we note that the commenter's own comment stated, "Xigris® is administered to only a small proportion of the severe sepsis population and is not representative of the comprehensive incidence of the disease." Therefore, by the manufacturer's own statements, we cannot use cases involving the code for Xigris® as the standard by which to assign severe sepsis cases. We discuss the DRG assignment of Xigris® in section II B.16.c. of this final rule.

Comment: One national hospital association agreed with our proposal to discontinue add-on payments for this technology. The commenter noted that the termination of the add-on payments falls outside the timeframe in which a technology is new for add-on payment purposes. The association strongly encouraged CMS to continue monitoring the use of Xigris® and associated conditions of severe sepsis to

determine if future revisions to the current DRGs will be necessary. Another commenter urged us to continue to monitor the use and diffusion of all new technologies that qualify or have previously qualified for this provision. Commenters urged CMS to require that all hospitals continue to code for the use of the new technologies, even after the period of add-on payment for the technologies has ended, thus ensuring adequate tracking of diffusion of the new technologies as they continue to be used.

Response: We appreciate the commenter's support for our decision to remove this technology from add-on payment status. We note that we review new technology add-on payment recipients annually to determine whether they continue to meet the criteria to receive add-on payments. In the case of Xigris®, this review led us to find that it no longer meets the newness criterion. While we encourage hospitals to continue to code for the drug, even though there is no longer a payment incentive to do so, we cannot require hospitals to code for the use of the drug.

We are finalizing our proposal to remove Xigris® from new technology status and will no longer pay new technology add-on payments for this technology, starting October 1, 2004. The manufacturer also asked us to consider creating a DRG specifically for severe sepsis. We discuss this request in section II.B.16.c. of the preamble to this final rule.

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

InFUSE™ was approved by FDA for use on July 2, 2002, and became available on the market immediately thereafter. In the August 1, 2003 IPPS final rule (68 FR 45388), we approved InFUSE™ for add-on payments under §412.88, effective for FY 2004. This

approval was on the basis of using InFUSE™ for single-level, lumbar spinal fusion, consistent with the FDA's approval and the data presented to us by the applicant. Therefore, we limited the add-on payment to cases using this technology for anterior lumbar fusions in DRGs 497 (Spinal Fusion Except Cervical With CC) and 498 (Spinal Fusion Except Cervical Without CC). Cases involving InFUSE™ that are eligible for the new technology add-on payment are identified by assignment to DRGs 497 and 498 as a lumbar spinal fusion, with the combination of ICD-9-CM procedure codes 84.51 (Insertion of interbody spinal fusion device) and 84.52 (Insertion of recombinant bone morphogenetic protein).

Because InFUSE™ was approved by the FDA for use on July 2, 2003, it is still within the 2-year to 3-year period during which a technology can be considered new under the regulations. Therefore, in the May 18, 2004 proposed rule, we proposed to continue add-on payments for FY 2005 for cases receiving InFUSE™ for spinal fusions in DRGs 497 (Spinal Fusion Except Cervical With CC) and 498 (Spinal Fusion Except Cervical Without CC). We also proposed to continue limiting the add-on payment for cases receiving InFUSE™, to those cases identified by the presence of procedure codes 84.51 and 84.52. However, we proposed to eliminate add-on payment for the interbody fusion device that is used in combination with this recombinant human bone morphogenetic protein (rhBMP) product (procedure code 84.52). We note that currently add-on payments for InFUSE™ include costs for the interbody fusion device (the LT cage, identified by procedure code 84.51), used in the spinal fusion procedure with the InFUSE™ product. Because this device is not a new technology, but in fact has been in

use for 9 years for spinal fusions, we believe that it is inappropriate to pay for this device in conjunction with the genuinely new rhBMP technology. Therefore, we proposed no longer to pay for the interbody fusion device as bundled in the current maximum add-on payment amount of $4,450 for cases that qualify for additional payment. The proposal would reduce the add-on payment to account for no longer including the costs of the LT cage in computing the add-on payment amount. This would reduce the cost of this new technology by $4,990, which results in a total cost of $3,910 for InFUSE™. Therefore, we proposed a maximum add-on amount of $1,955 for cases that qualify for additional payment. Although we proposed to eliminate payment for the LT cage, we would still require the presence of procedure code 84.51 (in combination with procedure code 84.52) when making new technology add-on payments for InFUSE™. This is due to the fact that the LT cage is still required by the FDA when InFUSE™ is used for single level spinal fusions.

Prior to the publication of the May 18, 2004 proposed rule, we received public comments in accordance with section 503(b)(2) of Pub. L. 108-173 regarding the continuation of add-on payments for this technology. Commenters expressed support for the continuation of new technology add-on payments for this technology in FY 2005.

We are finalizing that proposal in this final rule.

We received the following comments in response to the May 18, 2004 proposed rule.

Comment: Several commenters supported our proposal to no longer pay for the LT cage as a bundled add-on payment with InFUSE™. They noted that it was not

appropriate to pay for the LT Cage as part of the InFUSE™ add-on since the technology has been available for several years.

Response: When we initially reviewed the application, the applicant indicated to us that the FDA approval was for a pre-packaged product that included the LT Cage, the InFUSE™ biotechnology product, and an absorbable collagen sponge to carry the rhBMP. While the FDA label required the product to be used with the LT Cage, we were initially under the impression that these devices were provided to hospitals in the same package. It later was brought to our attention that the product was not marketed this way and that in fact the rhBMP product is supplied to hospitals in several different sized "kits" that have differing amounts of InFUSE™ in them, and that the LT Cage is purchased separately. As such, it is not only easy to see why the add-on payment should be unbundled, but also easy to do so.

Comment: Some commenters, including the manufacturer, were opposed to our proposal to discontinue bundled payment for InFUSE™ in combination with the LT Cage. They argue that to remove the payment for the LT Cage would result in even further restricting the use of this much needed technology that eliminates a painful second surgery and extensive blood loss for the patients who must otherwise undergo spinal fusions via conventional, autogeneous bone-harvesting methods. Other commenters were very concerned that the lower add-on payment amount would result in hospitals using cages other than the FDA-approved LT-Cage with this technology. These commenters stated that to encourage this off-label use by not continuing the higher payments is

contrary to our statement in last year's final rule requiring that a product qualify for add-on payments based upon usage consistent with its FDA labeling.

Response: In this clear case where a new technology is being used in conjunction with an old technology, we do not believe it is appropriate to continue to pay an add-on payment for the old device, as this device has already been in use for 9 years and has been accounted for in DRG payments. We are finalizing our proposal to approve InFUSE™ for spinal fusion for an additional year of new technology add-on payments, through the end of FY 2005. We note that in order to receive new technology add-on payment for InFUSE™, we are continuing to require both the procedure code for InFUSE™ (84.52) and the code for the LT Cage (84.51) due to the FDA label that requires the LT Cage to be used in conjunction with the InFUSE™ product. While the procedure code for the LT Cage (84.51) does include other brands and types of cages for spinal fusion, we expect that doctors will maintain the best clinical standard for their patients and will continue to use the LT-Cage with the InFUSE™ product. We are therefore finalizing our proposal to unbundle the new technology add-on payments for this device for FY 2005 by removing payment for the LT Cage from the add-on payment for cases involving InFUSE™. We are also finalizing the maximum add-on payment amount of $1955 for cases that are eligible to receive the add-on payment.

Comment: Other commenters were pleased about our proposal to discontinue bundled payments that include the LT Cage for spinal fusions because this bundled payment precluded payment for similar technologies that are used in spinal fusion surgery but that do not require use of the LT Cage. One commenter noted that another

BMP product was just awarded FDA approval for spinal fusion involving posterolateral approach. This commenter requested that the other devices of this nature be included in any approval of rhBMPs for new technology add-on payments or an unfair economic advantage would be created.

Response: As we discussed in the September 7, 2001 final rule (66 FR 46915), an approval of a new technology for special payment should extend to all technologies that are substantially similar. Otherwise, our payment policy would bestow an advantage to the first applicant to receive approval for a particular new technology. The new product, called OP-1 Putty, manufactured by Stryker Biotech, utilizes a similar mechanism to promote natural bone growth by using a closely related bone morphogenetic protein called rhBMP-7 (InFUSE™ is rhBMP-2). Because the OP-1 Putty is now available on the market (it received FDA approval for spinal fusions in May of this year) for similar spinal fusion procedures and also eliminates the need for the autograft bone surgery, we are extending new technology add-on payments to this technology as well, for FY 2005. Because the new product does not require the LT-Cage to be used simultaneously, we are requiring that providers use different codes when the different products are used.

Cases using InFUSE™ should be identified by the combination of procedure codes 84.51 and 84.52, as described above and as required in the previous year of new technology add-on payments for this technology. For cases using the OP-1 Putty, the procedure code 84.52 (Insertion of recombinant bone morphogenetic protein) must be coded in combination with procedure codes identifying posterolateral spinal fusions, as is consistent with the FDA approval for this device. Therefore, procedure code 84.52 must

be coded with any of the following procedure codes: 81.08 (Lumbar/lumbosac fusion posterior technique), 81.38 (refusion of lumbar posterior approach), 81.05 (Dorsal and dorsolumbar fusion, posterior technique), or 81.35 (Refusion of dorsal and dorsolumbar spine, posterior technique) in order to receive add-on payments under this provision. Both of these devices have FDA approval that is consistent with cases that would be assigned to DRGs 497 or 498. Because Stryker Biotech did not submit a new technology add-on payment application, we were unable to do a complete analysis of the cost of the device. However, we have been able to determine that the costs associated with the OP-1 Implant are similar to those associated with InFUSE™. Therefore, we believe that the same payment amount for new technology add-on payments is appropriate for both devices. Accordingly, cases containing one of the above combinations of procedure codes and that fall into DRGs 497 or 498 will be eligible to receive the add-on payment, with a maximum of $1,955 for FY 2005.

4. Reevaluation of FY 2004 Applications That Were Not Approved

Section 503(e)(2) of Pub. L. 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 stated that the technology was still new because it had not been possible to specifically identify cases involving use of the GLIADEL® wafer in the MedPAR data prior to the adoption of a new ICD-9-CM code 00.10 (Implantation of a chemotherapeutic agent) on October 1, 2002. However, as discussed in the September 7, 2001 final rule (66 FR 46914), the determination concerning whether a technology meets this criterion depends on the date of its availability for use in the Medicare population rather than the date a specific code may be assigned. A technology can be considered new for 2 or 3 years after data reflecting the costs of the technology begin to become available. Data on the costs of this technology began to become available in September 1996. As a result, the costs of this technology

are currently reflected in the DRG weights. As discussed in the final rule for FY 2004 (68 FR 45391), on February 26, 2003, the FDA approved the GLIADEL® wafer for use in newly diagnosed patients with high-grade malignant glioma as an adjunct to surgery and radiation. However, our understanding is that many newly diagnosed patients were already receiving this therapy. To the extent that this is true, the charges associated with this use of the GLIADEL® wafer were also reflected in the DRG relative weights. Therefore, the GLIADEL® wafer did not meet this criterion for FY 2004.

Section 503(e)(2) of Pub. L. 108-173 required us to reconsider this application, but did not revise the criterion for determining whether a medical service or technology is new. As stated above, the FDA originally approved the GLIADEL® wafer on September 23, 1996. Therefore, this technology is beyond the period in which it can be considered new. Accordingly, in the May 18, 2004 proposed rule, we proposed to deny this application for new technology add-on payments for FY 2005.

Prior to the publication of the May 18, 2004 proposed rule, we received no public comments regarding our reconsideration of this application for add-on payments. During the 60-day comment period for the May 18, 2004 proposed rule, we received the following public comments regarding our reconsideration of the application.

Comment: One commenter stated, "[a]s a country that prides itself on being a leader in cancer research, it is disheartening that patients must battle to gain access to the benefits that this research has provided."

Response: We continue to pay for technologies that do not meet the criteria to receive new technology add-on payments through the regular payment mechanism

established by the DRG payment methodology. Therefore, patient access to these technologies should not be adversely affected by a determination that a technology does not qualify to receive add-on payments.

Comment: One commenter believes that the GLIADEL® chemotherapy wafer merits a separate DRG, which the applicant contends would be similar to our treatment of the establishment of new DRGs for drug-eluting stents. The commenter acknowledges that DRGs are "not normally created to recognize the presence or absence of new technology." Nevertheless, the commenter argues that CMS' recognition of the "unique circumstances surrounding the potential breakthrough nature" of drug-eluting stents should also be applied to GLIADEL® wafer.

Response: Guilford asked us to consider reclassifying this device into another DRG. We discuss issues relating to the DRG assignment of the GLIADEL® wafer in section II.B.16.c. of this final rule. In that discussion, we announce our decision to create a new DRG 543 (Craniotomy with implantation of chemotherapeutic agent or acute complex central nervous system principle diagnosis) to which Gliadel cases will be assigned. The cases assigned to this new DRG have similar resource utilization and comparable charges to cases involving the GLIADEL® wafer. As a result, we believe this DRG assignment will result in appropriate payments for these cases. In this rule we are finalizing our denial of new technology add-on payments for this technology.

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

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

Bone Morphogenetic Proteins (BMPs) have been shown to have the capacity to induce new bone formation and, therefore, to enhance healing. Using recombinant techniques, some BMPs (referred to as rhBMPs) can be produced in large quantities. This has cleared the way for their potential use in a variety of clinical applications such as in delayed unions and nonunions of fractured bones and spinal fusions. One such product, rhBMP-2, is developed for use instead of a bone graft with spinal fusions.

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

In cases of open tibia fractures, InFUSE™ is applied using an absorbable collagen sponge, which is then applied to the fractured bone in order to promote new bone formation. The manufacturer contends that this use is severely limited due to the greatly increased costs for treating these cases with InFUSE™ at the time of wound debridement and closure. The manufacturer has conducted a clinical trial and FDA approval for the use of InFUSE™ for open tibia fractures was awarded on April 30, 2004. The application for add-on payments for the use of InFUSE™ for open tibia fractures proposes that such payment would encourage the use of InFUSE™ for treatment of these fractures of grade II or higher (up to and including grade III, which often must be amputated due to the

severity of injury). The additional payment, according to the applicant, would encourage more hospitals to use the technology at the time of initial wound closure and would result in reduced rates of infection and nonunion currently associated with the treatment of these injuries.

The manufacturer submitted data on 315 cases using InFUSE™ for open tibia fractures in the FY 2002 MedPAR file, as identified by procedure code 79.36 (Reduction, fracture, open, internal fixation, tibia and fibula) and diagnosis codes of either 823.30 (Fracture of tibia alone, shaft, open) or 823.32 (Fracture of fibula and tibia, shaft, open). The applicant also noted that the patients in their clinical trials as well as patients that would be likely candidates to receive InFUSE™ for tibia fractures would include those cases that had malunion of their fractures (diagnosis code 733.81) or nonunion of fractures (diagnosis code 733.82). The applicant also submitted data for a hospital sample that included 63 cases using the same identifying codes. Based on the data submitted by the applicant, InFUSE™ would be used in four different DRGs: 217 (Wound Debridement and Skin Graft Except Hand, for Musculoskeletal and Connective Tissue Disorders), 218 and 219 (Lower Extremity and Humerus Procedures Except Hip, Foot, Femur Age > 17, With and Without CCs, respectively) and 486 (Other O.R. Procedures for Multiple Significant Trauma). The analysis performed by the applicant resulted in a case-weighted cost threshold of $27,111 for these four DRGs. The average case-weighted standardized charge for cases using InFUSE™ in these four DRGs would be $46,468. Therefore, the applicant maintains that InFUSE™ for open tibia fractures meets the cost criterion.

Further discussions with the applicant revealed that the more appropriate DRGs to which this device should be limited are DRGs 218 and 219 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur Age > 17, With and Without CC). The manufacturer projects that there would be approximately 550 cases (based on the number of open tibia fractures that would have qualified for InFUSE™ in the FY 2002 MedPAR) in FY 2005. Since FDA approval for use of InFUSE™ for open tibia fractures, we have performed an analysis to determine the number of cases that may have already received InFUSE™ for treatment of open tibia fractures. We identified 3,788 cases in DRGs 218 and 219 (Lower Extremity & Humerus Procedures except hip, foot, femur, age >17, with and without CCs) that also had procedure code 79.36 (Reduction, fracture, open, internal fixation, tibia and fibula) and any of the following diagnosis codes: 823.30 (Fracture of tibia alone, shaft, open), 823.32 (Fracture of fibula with tibia, shaft, open), 733.81 (Malunion of fracture), or 733.82 (Nonunion of fracture). We identified 38 cases in DRGs 218 and 219 that contained a code identifying a BMP product (identified by the presence of procedure code 84.52) in the FY 2003 MedPAR.

In the May 18, 2004 proposed rule, we noted that as part of its application, the applicant submitted evidence on the substantial clinical improvement criterion. The applicant cited data from a prospective, controlled study published on December 12, 2002 in The Journal of Bone and Joint Surgery (Govender , S., 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 of an absorbable collagen sponge soaked with .75 mg/ml of rhBmP-2, or the standard of care plus implantation of an absorbable collagen sponge soaked with 1.50 mg/ml of rhBMP-2. The study followed up with 421 (94 percent) of all patients. The applicant stated that the study found that patients who received the standard of care plus an absorbable collagen sponge soaked with 1.50 mg/ml of rhBMP-2 achieved the following results compared to the standard of care without the rhBMP: a 44-percent reduction in the rate of secondary surgery, an average of 39 days reduction in time of clinical healing and lower infection rates. As a result, the applicant maintains that InFUSE™ in tibia fractures represents a substantial clinical improvement over previously available technologies.

In the May 18, 2004 proposed rule, we did not present a full analysis of this application under the substantial clinical improvement criterion because the technology had not yet received FDA approval for this use in time for consideration in the proposed rule. However, we noted that, although the cited study provides some evidence of clinical efficacy, we had some concerns about whether the study conclusively demonstrates substantial clinical improvement over previously available technologies because of its design. (It is important to note, as we stated in the August 1, 2002 **Federal Register** (67 FR 50015), that we do not employ FDA guidelines to determine what drugs, devices, or technologies qualify for new technology add-on payments under Medicare.

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

Since the publication of the proposed rule, the manufacturer has provided additional information regarding substantial clinical improvement. The applicant provided research indicating both the efficacy of the rhBMP product in the elderly, Medicare population as well as satisfactorily answering any remaining questions our physicians had regarding the clinical trials for this use of InFUSE™.

In the proposed rule, we indicated that we determined that this technology still qualifies as new in the context of extending new technology add-on payments for InFUSE™ for single-level spinal fusions (refer to InFUSE™ for spinal fusion in section 3(b) above). We noted that, in the September 7, 2001 final rule (66 FR 46915), we stated that if an existing technology was assigned to different DRGs than those in which the technology was initially used, the new use may be considered for new technology add-on payments if it also meets the substantial clinical improvement and inadequacy of payment criteria. Under the policy suggested in that rule, approval of InFUSE™ for tibia fractures would start a new period of add-on payments for the new use of this technology. However, we stated that we had some reservations about whether this result would be appropriate. We stated that it might be possible, under the policy described in the September 7, 2001 final rule, for a technology to receive new technology add-on payments for many years after it is introduced, provided that use of the technology is

continually expanded to treatment of new conditions (in this case, every time the product is used to treat a new bone injury). We invited comment on whether it would be more appropriate merely to extend the existing approval of InFUSE™ for spinal fusions to cases where InFUSE™ is used for open tibia fractures, without extending the time period during which the technology will qualify for add-on payments. We also invited comments on whether use of InFUSE™ for open tibia fractures should qualify for add-on payments under the cost and substantial clinical improvement criteria.

Comment: One commenter wrote "to bring to Medicare's immediate attention that there is more that one BMP manufacturer with approved indications for long bone fractures…". The commenter went on to note that "Stryker[Biotech]'s …OP-1 Implant for recalcitrant long bone non-unions received FDA clearance in October, 2001." The commenter urged Medicare that "the decision for add-on payment should be for the BMP, not the manufacturer."

Response: We agree with the commenter that determinations concerning new technology add-on payments should not make distinctions between different manufacturers of the same technology. As we stated in the proposed rule on May 18, 2004: "an approval of a new technology for special payment should extend to all technologies that are substantially similar. Otherwise, our payment policy would bestow an advantage to the first applicant to receive approval for a particular new technology." (69 FR 28242). In this case, we had received no information concerning the existence of the OP-1 Implant for long bone fusion, created by Stryker Biotech, prior to this comment. Since the OP-1 Implant received FDA clearance in October, 2001, it has been necessary

to reevaluate whether InFUSE™ for open tibia fractures can still be considered new in the light of this new information. This determination turns on two considerations: whether these products are substantially similar, and whether the indications for the two products lead to the assignment of cases involving the use of the two products to the same DRGs. The crucial consideration in determining whether a technology is new from a payment policy perspective is whether data reflecting the costs of the technology have been incorporated into setting the DRG weights. A technology can be considered new for 2 to 3 years after the point at which charge data begin to become available.

We have been able to determine that the OP-1 Implant created by Stryker Biotech in fact was approved by the FDA under Humanitarian Device Exemption (HDE) on October 17, 2001, for the indication of "use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed." It came onto the market shortly after approval. The trials where the OP-1 Implant was used demonstrated the safety and efficacy of OP-1 Implant for patients with complicated fractures of the tibia[3]. These cases and the study protocol are similar to those described in the clinical trials involving InFUSE™ for open tibia fractures. In fact, many of the cases that were brought for review during the application process for Infuse™ were patients that had already experienced non-union, were not candidates for autograft (due to already having autograft surgery and there not being enough material left in the hip to acquire more, or poor quality of the bone, etc.), or had fractures in long bones other than the tibia (many cases were femur fractures). Therefore, we believe the technology

[3] Friedlaender, GE, at al. "Osteogenic Protein-1 (Bone Morphogenetic Protein-7) in the Treatment of Tibial Nonunions: A Prospective, Randomize Clinical Trial Comparing rhOP-1 with Fresh Bone Autograft." *Journal of Bone & Joint Surgery*. 2001;83A(S1): 151-158.

involving use of rhBMP to treat severe long bone fractures, including open tibial fractures, and recalcitrant long bone fractures has been in use for more than 3 years. In addition, cases involving use of the OP-1 Implant for long bone nonunions and open tibia fractures are assigned to the same DRGs (218 and 219, (Lower extremity procedures with and without complication or comorbidity, respectively). Therefore, data reflecting the costs associated with this technology began to become available in the relevant DRGs in 2001, and are now reflected in the DRG weights. We therefore find that the use of rhBMPs for these indications is not a new technology for the purposes of the new technology add-on payment. In addition, if we were to approve InFUSE™ for open tibia fractures for the new technology add-on payment there would be no way to distinguish the claims getting InFUSE™ BMP and those cases receiving the OP-1 Implant BMP, because they are indistinguishable by patient characteristics or ICD-9 code.

Accordingly, we are denying the application for add-on payments for InFUSE™ for open tibia fractures because this device is not a substantial clinical improvement over existing technologies, and therefore is not a new technology for purposes of new technology add-on payments. We acknowledge, however, that products may evolve that are very closely related but that have very different clinical efficacies, and we are committed to continuing to refine and share our methodology for deciding what should or should not be considered a new and innovative technology. In this context, we would note that MedPAC has encouraged us "to be conservative in [evaluating]… technologies for add-on payments, ensuring that technologies are substantially different from predecessor technologies, costly, and with clinical benefit."

Comment: Several commenters stated their concerns regarding a number of issues raised in our discussion in the proposed rule. They do not think that it would be appropriate to deny add-on payments for InFUSE™ for tibia fractures regardless of the existing status of the device for use in other surgeries. They stated that CMS should not indiscriminately impose our policy criteria without considering the clinical opinions of experts involved in these cases and as a result deny patients access to the latest breakthrough medical technologies. Several other commenters wrote to encourage CMS to make add-on payments for the InFUSE™ bone graft for treatment of "compound fractures of the tibia." The manufacturer commented that it would go against CMS precedent not to consider the new indication for InFUSE™ as qualifying for its own determination of substantial clinical improvement since we had made a similar analysis in FY 2004 for GLIADEL® wafer. One commenter also supported the review and approval of new technology add-on payments where the new technology is being used for a different medical procedure than the original use and will group to separate DRGs.

Response: As stated previously, we do not believe that patient access to breakthrough technologies is being denied. Because another device using rhBMPs for these indications has been in use for 3 years and the costs for this technology have been included in the weights for the DRGs where cases involving InFUSE™ for open tibia fractures have been assigned, this technology is not a substantial clinical improvement over exisitng technologies and can no longer be considered "new". We further note that because we determined that the GLIADEL® wafer did not meet the newness criterion, we did not conduct an analysis on the substantial clinical improvement criterion in FY 2004.

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

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

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

Despite the time that has elapsed since FDA approval, the manufacturer contends that Norian SRS® Cement should still be considered new for several reasons. First, until April 2002, Norian SRS® Cement was hand mixed using a mortar and pestle. Once Norian SRS® Cement was approved by the FDA in December 2001 (for the indication of

use in bony voids or defects that are not intrinsic to the stability of the bony structure), the manufacturer issued a new pneumatic mixer. According to the manufacturer, this new pneumatic mixer allows for better preparation, reliability, and ease of use. In addition, a new injection syringe mechanism was developed and made available in May 2002 and replaced the "Norian Delivery Device". The manufacturer believes these new procedures for mixing and delivery of the product to the patient should be considered new services as stated in section 1886(d)(5)(k)(ii) of the Act and §412.87(b)(1) of the regulations. Second, the manufacturer contends that the cement should still be considered new because there is no ICD-9-CM code to uniquely identify Norian SRS® Cement within the DRGs.

In the May 18, 2004 proposed rule, we indicated that, although there have been changes in the way Norian SRS® Cement is mixed and delivered to the patient, we do not believe these changes are significant enough to regard the technology as new. While these changes may enhance the ease with which the technology is used, the product remains substantially the same as when it was initially developed. As we have indicated previously, technology can be considered new only for 2 to 3 years after data reflecting the costs of the technology begin to become available. Data on the costs of this technology began to become available after FDA approval in 1998, and these costs are currently reflected in the DRG weights. As we discussed in the September 7, 2001 final rule (66 FR 46914), the determination concerning whether a technology meets this criterion depends on the date of its availability for use in the Medicare population rather

than the date a specific code may be assigned. Therefore, we proposed that Norian SRS® Cement does not meet the newness criterion.

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

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

In the May 18, 2004 proposed rule, we did not present a full evaluation of the application for add-on payments for Norian SRS® Cement under these criteria because

the technology did not meet the newness criterion. Therefore, we proposed to deny add-on payments for this technology.

In the proposed rule we indicated that prior to publication of the proposed rule, we had received no public comments on this application for add-on payments. During the 60-day comment period for the proposed rule, we received the following public comments on this application.

Comment: One commenter, the manufacturer, noted that Norian SRS® Cement should still be considered "new" since there is sufficient information on the record, including sales data, to prove that Norian SRS®Cement could not have been included in the DRGs until the middle of 2002. The commenter also noted that public comments were indeed submitted prior to the proposed rule supporting a new technology add-on payment for Norian SRS® Cement. Another commenter also explained that Norian SRS® Cement should be considered new since it was not generally distributed to the public for use because of technical difficulties in mixing the product even though the product had been produced and released for quite some time.

Response: As stated previously and as we discussed in the September 7, 2001 final rule (66 FR 46914), the determination concerning whether a technology is new depends on the date of its availability for use in the Medicare population, rather than the date a specific code may be assigned. Data on the costs of this technology began to become available after FDA approval in 1998, and these costs are currently reflected in the DRG weights. Therefore we do not consider Norian SRS® cement to meet the

newness criterion. As a result we are denying add-on payments for this technology in FY 2005.

As a final note, the February 27, 2004 **Federal Register** notice specified the method of submitting comments on the town hall meeting. Our statement in the proposed rule that we did not receive comments regarding this application referred to not having received any comments using that method. We are glad to receive the information now. We did, however, consider this comment as part of our discussion to deny add-on payments for this technology in FY 2005.

Comment: One commenter noted that the Norian SRS® Cement is an outstanding product that allows the stabilization of fractures that would normally develop postoperative deformity and problems after surgery. The commenter added that allograft or autogenic bone graft that uses a bone void filler would often deform and cause settling of the joint while the Norian SRS® cement seems to glue all of the small fracture fragments together and can hold together very tenuous reductions extremely well. The commenter also noted that it only began to use the Norian SRS® Cement once the new mixer system became available. Another commenter also noted that the clinical benefits of Norian SRS® cement allow for earlier removal of external fixators and pins without risk of collapse of the fracture site and allow permanent internal fixation to load share with the Norian SRS® cement. This results in earlier range of motion in a safe manner, which ultimately results in earlier return to a functional and productive lifestyle for patients.

Response: We thank the commenters for providing information on the clinical benefits of Norian SRS® cement. However, as stated above, we do not consider Norian SRS® cement to meet the newness criterion and are denying add-on payments for this technology in FY 2005.

Comment: Some commenters supported the creation of procedure code 84.55 (insertion of bone filler) but requested the title of the code be revised to injection of bone void filler cement from insertion of bone filler in order to capture cases of bone void filler cements that require mixing and are applied via injection. One commenter requested we review the data upon implementation of this code to see how these devices affect the DRG weights.

Response: A new code was created for bone void filler which will be implemented on October 1, 2004. The code is as follows: 84.55 Insertion of bone void filler. Various options for this new code were discussed at the April 1-2, 2004 ICD-9-CM Coordination and Maintenance Committee. A summary of this meeting can be found at: **www.cms.hhs.gov/paymentsystems/icd9**.

Public comments received at the meeting and later submitted in writing were mixed. The manufacturer and some physicians supported new codes that differentiated between bone void fillers that were pre-mixed and required little or no mixing prior to insertion versus those that required more extensive pre-mixing. The manufacturer suggested a new code for the injection of bone void filler and another new code for insertion of bone void filler. Representatives of hospital and coder organizations were opposed to such a differentiation and recommended the creation of a single new code to

capture this technology: 84.55, Insertion of bone void filler. The hospital and coding organizations stated that hospital coders would have difficulty differentiating between the insertion versus the injection of bone void filler. They stated that this would be especially true in cases where it would be necessary to determine the amount of mixing of the product that was necessary. These organizations did not believe that the medical records would provide this type of documentation.

The American Hospital Association will be providing education to hospital coders on the use of this and other new codes. We will review data on claims submitted using this new code to determine if DRG modifications are necessary.

We are finalizing our proposal not to approve this technology for new technology add-on payments.

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

Cardiac Resynchronization Therapy (CRT), also known as bi-ventricular pacing, is a therapy for chronic heart failure. A CRT implantable system provides electrical stimulation to the right atrium, right ventricle, and left ventricle to 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-D devices have a dual therapeutic nature intended to treat two aspects of a patient's heart disease concurrently: (1) the symptoms of moderate to severe heart failure (that is, the ventricular dysynchrony); and (2) high risk of ventricular arrhythmias, as documented by a electrophysiologic testing or clinical history or both, which would cause sudden cardiac death.

InSync® Defibrillation System received FDA approval on June 26, 2002. However, another manufacturer, Guidant, received FDA approval for its CRT-D device on May 2, 2002. Guidant, and another competitor that has yet to receive FDA approval for its CRT-D device, have requested that their devices be included in any approval of CRT-D for new technology add-on payments. As we discussed in the September 7, 2001 final rule (66 FR 46915), an approval of a new technology for special payment should extend to all technologies that are substantially similar. Otherwise, our payment policy would bestow an advantage to the first applicant to receive approval for a particular new technology.

The applicant contends that, despite the approval of a similar device in May 2002, the InSync® Defibrillator System should still be considered new for several reasons: First, an ICD-9-CM code was only issued in FY 2003, which falls within the 2-year to 3-year range provided in the regulations. Second, the utilization of CRT-Ds is still growing and has not reached full utilization and, therefore, CRT-Ds remain underreported within the FY 2003 MedPAR data that are being used to recalibrate the

DRG weights for FY 2005. Finally, the applicant believes reporting of CRT-Ds may be insufficient to accurately recalibrate the DRGs because the new ICD-9-CM codes for CRT-Ds are unlikely to be used consistently and accurately by hospitals in the first year.

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

Using the March 2004 update file to the FY 2003 MedPAR file, we have identified 11,004 cases using CRT-D in the FY 2003 MedPAR database. Of these, 10,750 cases were reported in DRGs 514 and 515 (then Cardiac Defibrillator Implant With and Without Cardiac Catheter, respectively). In DRG 515, we found 3,960 cases with procedure code 00.51 (Implantation of cardiac resynchronization defibrillator, total system (CRT-D)) and 6,790 cases in DRG 514. DRG 514 is no longer valid, effective in FY 2004. In FY 2004, we assigned new cases of defibrillator implants with cardiac catheters from DRG 514 to new DRGs 535 (Cardiac Defibrillator Implant with Cardiac Catheter With Acute Myocardial Infraction (AMI) Heart Failure/Shock) and 536 (Cardiac Defibrillator Implant with Cardiac Catheter Without Acute Myocardial Infarction (AMI) Heart Failure/Shock). Using the 6,790 cases from the FY 2003 MedPAR found in DRG 514, we examined the primary diagnosis codes necessary for assignment to DRG 535

along with procedure code 00.51 and found 3,413 cases of CRT-D for DRG 535. The remaining 3,377 CRT-D cases found in DRG 514 using procedure code 00.51 fall into DRG 536. For FY 2003, the total number of cases of CRT-D found in the FY 2003 MedPAR data for DRGs 514 and 515 were 48,700. Cases reporting CRT-Ds thus represent 22 percent of all cases for these DRGs.

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

Comment: Two commenters, the applicant and another manufacturer of CRT-D devices, commented that the utilization of CRT-D is still growing and has not reached full utilization. One of the commenters further noted that industry estimates forecast that CRT-D will ultimately account for over 50 percent of the defibrillator market by 2006 (or double the amount seen in FY 2003). As a result, additional time and utilization is necessary with CRT-D before the DRGs can be recalculated to reflect the full costs of CRT-D in the DRG weights. Some commenters, including the applicant, also explained

that the volume of cases in the FY 2003 MedPAR is indicative of the breakthrough nature of the technology and the benefit it confers to heart failure patients. The fact that some hospitals were willing to absorb the costs of the technology and make CRT-D available to their patients should have no effect if the technology remains new and eligible for new technology add-on payments. In light of the above, the applicant believes the technology should be considered new under the timeframe of newness and that the existing MedPAR data are insufficient to update the DRG weights for FY 2005. Another commenter noted that over the last 12 months, the volume of patients receiving the CRT-D in the commenter's hospital has risen by 28 percent. The commenter added that for the coming year the volume of patients receiving the CRT-D is expected to rise an additional 30 percent.

MedPAC questioned if this technology still meets the newness criterion. MedPAC noted that the technology could diffuse further and represent an even greater share of cases. However, MedPAC believes it is clear that costs of the technology are already reflected in the data used to set the DRG weights. MedPAC recommended that one way to deal with this issue would be to exclude cases of the technology when it can be tracked from the calculation of the mean charges from the DRG during recalibration of the relative weights. This would avoid overpaying for the technology by including its costs in the base payment while also providing an add-on payment.

One commenter, the applicant, was concerned that MedPAC's recommendation might lead to the lowering of payment for implantable cardioverter defibrillators (ICDs).

The commenter recommended that CMS not take any action that would lower payment for a technology that already experiences inadequate payment.

Response: Although we have a large amount of cases of CRT-D reflected within the DRGs, as stated by the commenter, the potential population that can receive the CRT-D could be much larger as time elapses. While the regulations state that a technology is no longer new when data begin to become available reflecting the new technology in the DRGs, the commenter has argued that the CRT-D is not fully reflected in the DRGs since it has not reached its full market utilization. In the proposed rule, we expressed concerns regarding the extent of the data already reflected in the DRGs, which suggests that CRT-D should no longer be considered "new". However, at this point we cannot make a definite determination that the CRT-D is fully reflected within the DRGs; and therefore, we have concluded that CRT-D should be considered to meet the newness criterion.

We have responded to MedPAC's recommendation on excluding a new technology from recalibration of the relevant weight above. We will consider this recommendation as we continue to develop policy in this area.

Comment: Some commenters believed that the date of issuance of an ICD-9-CM code should start the 2- to 3-year period of a technology being new instead of the FDA approval date. The commenters explained that considering a technology new from the FDA approval date is inconsistent with the regulations in 42 CFR §412.87(b)(2). One commenter further noted that distinct hospital charge data for CRT-D only became available after the issuance of a ICD-9-CM code and CRT-D charge data did not become

publicly available until May 2004. As a result the commenter maintains that the CRT-D is still within the 2-3 year period of being considered "new". Another commenter added that even though CRT-D was approved in May of 2002, it is uncertain if hospitals adjusted their charges at that time in order to reflect the higher costs of CRT-D procedures, especially given the lack of a unique ICD-9-CM code. Furthermore, it was not possible to uniquely identify CRT-D in the data until a unique ICD-9-CM code was issued. Therefore, the commenter believes it does not seem appropriate to consider the CRT-D new from the FDA approval date of May 2002. One commenter was concerned that continued inadequate payment for the CRT-D has the potential to limit patient access to this new technology. Therefore, the commenter encouraged CMS to consider the CRT-D to meet the newness criterion.

One commenter, the applicant, added that prior to the MMA, CRT-D did not meet the cost threshold and therefore the applicant did not apply for new technology add-on payments. The commenter noted that had Congress acted earlier an application would have been submitted earlier as well. The applicant believes that finding the CRT-D to meet the newness criterion and approval of add-on payments for CRT-D is consistent with Congress' intent to ensure more new technologies qualify for add-on payments.

Response: As stated previously, we have determined that CRT-D meets the newness criterion. For a further discussion on the newness criterion regarding FDA approval dates and the issuance of ICD-9-CM codes, please see section II.E.2. of the preamble to this final rule.

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

In the September 7, 2001 final rule, we stated that the data submitted must be of a sufficient sample size to demonstrate a significant likelihood that the sample mean approximates the true mean across all cases likely to receive the new technology. Using a standard statistical methodology for determining the needed (random) sample size based on the standard deviations of the DRGs identified by the applicant as likely to include cases receiving a CRT-D, we have determined that a random sample size of 354 cases can be reasonably expected to produce an estimate within $3,500 of the true mean.[4] Of course, the data submitted, which include Medicare data from 30 hospitals, do not represent a random sample of all cases in these DRGs across all hospitals.

The manufacturer also contends that the added capability of the InSync® Defibrillator System device provides significant benefits over and above a conventional

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

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

We welcomed comments on whether this technology meets the new technology criterion, but especially about whether it meets the newness criterion in the light of the extent to which it is represented cases within the relevant DRGs. We indicated that we would determine whether to approve this technology in the light of any comments that we received and our continuing analysis.

Prior to the publication of the May 18, 2004 proposed rule, we received public comments in accordance with section 503(b)(2) of Pub. L. 108-173 regarding this application for add-on payments. Commenters noted that CRT-D has had positive clinical outcomes by reversing remodeling of the heart and improving the heart's ability to pump more efficiently. One commenter added that CRT-D has helped decrease hospitalizations and length of stay.

During the 60-day comment period for the May 18, 2004 proposed rule, we received the following public comments on this application.

Comment: The applicant submitted additional data aside from the data discussed in the proposed rule showing that CRT-D meets the cost criterion. The applicant searched the FY 2003 MedPAR for cases with procedure code 00.51 and found 3,947 cases in DRG 515, 3,396 cases in DRG 535 and 3,351 cases in DRG 536. The average standardized charge for these DRGs were $81,950 for DRG 515, $104,092 for DRG 535 and $97,250 for DRG 536. This resulted in a case weighted average standardized charge of $93,776. The case weighted threshold using the threshold amounts from Table 10 was $81,161. Based on this analysis, the applicant maintains that CRT-D meets the cost criterion since the case weighted average standardized charge is greater then the case weighted threshold. One commenter believes that the average costs of the CRT-D meet or exceed the cost threshold. The commenter added that CRT-D procedures are more complex and take longer than conventional ICD implantations. One commenter added that the DRGs do not provide adequate reimbursement for cases with a CRT-D.

Response: We also searched the latest update to the FY 2003 MedPAR and found 3960 cases in DRG 515 with an average standardized charge of $82,520, 3,413 cases in DRG 535 with an average standardized charge of $104,755 and 3,377 cases in DRG 536 with an average standardized charge of $98,329. This resulted in a case weighted average standardized charge of $94,546. Using the thresholds from table 10, the case weighted threshold for DRGs 515, 535 and 536 was $81,169. As a result, the average

standardized charge is greater than the case weighted threshold and therefore the CRT-D meets the cost criterion for new technology add-on payments.

Comment: The applicant also submitted the following comments on the substantial clinical improvement criterion. The commenter first noted that CRT-D meets the definition of substantial clinical improvement described in 42 CFR 412.87(b)(1) because prior to May 2, 2002 there was no device available that provided cardiac resynchronization therapy in combination with an implantable cardiac defibrillator, and that the introduction of the CRT-D device enabled the treatment of patients with symptomatic heart failure despite maximal medical therapy in addition to providing a potentially life saving defibrillator in those patients who are at high risk for ventricular arrhythmias. Another commenter agreed with the applicant that the CRT-D represents a substantial clinical improvement because it provides treatment for a new and different patient population (those with heart failure and high risk for ventricular arrhythmias). Two commenters further noted multiple studies that demonstrated objective and subjective clinical improvement in patients with moderate to severe heart failure when treated with CRT or CRT-D as quantified by such measures as New York Heart Association Class, 6 minute walk distance, peak oxygen uptake, left ventricular ejection fraction, and area of regurgitant mitral jet. It was also noted by the applicant that CRT-D was shown in the COMPANION study to significantly reduce all cause of mortality. One of the commenters also noted that CRT-D reduced symptoms and improved quality of life. Another commenter added that the CRT-D provides dual therapy for patients with dual indications, and that it is not simply a combination of two existing devices. One

commenter believed that there is some potential benefit from reduced hospital readmissions and cost savings to both the hospital and Medicare program when using the CRT-D.

Response: We agree that CRT-D provides a valuable treatment to Medicare beneficiaries who have refractory, symptomatic congestive heart failure despite optimal medical management and who are also at significant risk for potentially fatal ventricular arrhythmias. We recognize that prior to the advent of CRT-D patients could not have had access to the benefits of both cardiac resynchronization therapy and an implantable defibrillator. For these reasons CMS believes the CRT-D device represents a substantial clinical improvement for the purposes of a new technology add-on payment.

Comment: The applicant commented that the FDA's view of CRT-P and CRT-D devices further supports the distinction between the two technologies. The commenter explained that the FDA did not allow for the pooling of data for the Miracle trial (study of a CRT-P) and MIRACLE ICD trial (study of a CRT-D) as the studies and devices addressed different patient populations and indications. The FDA required that the safety and efficacy of the devices be proven separately as a result of the differences between the devices and because biventricular pacing was a new technology. The commenter explained that the FDA believed that the two types of CRT therapy would affect two different populations (indications for an ICD and CRT-D versus indications for a CRT-P with no arrhythmia). The commenter finally noted that the FDA listed the CRT-D as one of ten "Advances in Patient Care" in its Fiscal Year 2002 Office of Device Evaluation Annual Report. In reference to CRT-D the report stated "[t]he device, the first of its

kind, can be used to treat symptoms of advanced heart failure in certain people who already need an ICD." The commenter emphasized the FDA's language describing the device as the "first of its kind."

Response: We again agree that the CRT-D device represents a substantial clinical improvement because it is capable of treating patients with the two distinct conditions of congestive heart failure and "at high risk for sudden cardiac death," who prior to its availability could not have received the benefits of both cardiac resynchronization therapy and immediate defibrillation in the event of sustained ventricular arrhythmia. We have therefore determined that this device meets the substantial clinical improvement criterion.

Comment: The applicant submitted three different scenarios on the potential add-on payment amount for the new technology. The device consists of a defibrillator, right atrial and right ventricular leads, left ventricular lead, lead delivery system and a balloon catheter. The first scenario would pay for the device and all the leads associated with implanting the device. The second approach, which was supported by the applicant, excluded the costs of the right atrial and right ventricular leads because these items are used in ICDs whose costs are already reflected in DRGs 515, 535 and 536. The last scenario excluded all costs associated with the ICD since the DRGs have already captured all costs of an ICD in the CRT-D.

Response: After reviewing all the criteria, we have determined that CRT-D is eligible for add-on payments in FY 2005. Cases involving CRT-D that are eligible for new technology add-on payments are identified by either one of the following two

ICD-9-CM procedure codes: 00.51 (Implantation of Cardiac Resynchronization Defibrillator, Total System (CRT-D)) or 00.54 (Implantation or Replacement of Pulse Generator Device Only (CRT-D)). We agree with the commenter that option number two is the best approach to determine the costs of the CRT-D for the purpose of new technology add-on payments. Using this approach, the total costs for the device are $32,525. Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the costs of the technology or 50 percent of the costs in excess of the DRG payment for the case. As a result, the maximum add-on payment for a case involving the CRT-D is $16,262.50.

Comment: One commenter recommended that CRT-D add-on payments should expire in May of FY 2005. The commenter explained that the newness criterion should be extended to the full 2-3 year period from the FDA approval date.

Response: Predictability is an important aspect of the prospective payment system methodology. Accordingly, we believe that it is appropriate to apply a consistent payment methodology for new technologies throughout the fiscal year. Furthermore, we note that the CRT-D will still be within the 2 to 3 year period in which it can be considered new for most of FY 2005. As a result, we will make add-on payments for cases involving CRT-D for the entire FY 2005.

d. GliaSite® Radiation Therapy System (RTS)

The Pinnacle Health Group submitted an application for approval of GliaSite® Radiation Therapy System (RTS) for new technology add-on payments. GliaSite® RTS was approved by the FDA for use on April 25, 2001. The system involves several

components, including a drug called Iotrex and a GliaSite® catheter. Iotrex is an organically bound liquid form of 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 25, 2001. Technology is no longer considered new 2 to 3 years after data reflecting the costs of the technology begin to become available. Because data regarding this technology began to become available in 2001, we determined that GliaSite® RTS does not meet the criterion that a medical service or technology be considered new. Therefore, in the May 18, 2004 proposed rule, we proposed to deny approval of GliaSite® RTS for new technology add-on payments.

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

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

However, as discussed above, because GliaSite® RTS did not meet the newness criterion, we proposed to deny add-on payments for this technology in FY 2005.

Prior to the publication of the May 18, 2004 proposed rule, we received no public comments on this application for add-on payments. During the 60-day comment period for the proposed rule, we received the following public comments on this application.

Comment: Many commenters objected to the proposed denial of new technology status for Iotrex (the chemotherapy agent in the GliaSite® RTS). They stated that it represents a substantial improvement over conventional brachytherapy treatment for brain tumors by reducing the number of radioactive seeds implanted into the patient's brain (via up to 20 catheters). Commenters also stated that this therapy reduces the problems associated with conventional therapy by providing a more "conformal therapy with no target tissue underdosing, less target tissue overdosing and no healthy tissue 'hot spots.'"

Commenters also noted that this therapy is more widely available at over 140 centers starting in 2003 (whereas brachytherapy treatment is only offered at 5 centers nationwide). While more widely spread, commenters nonetheless stated that prior to 2003, when the treatment was accepted at the 140 centers noted above, "significantly fewer hospitals offered this therapy" due to a combination of licensing and safety requirements that must be met in order for providers to purchase and use this radioisotope. Commenters stated that meeting these requirements of the Nuclear Regulatory Commission or applicable State authorities governing the distribution and use of Iotrex was time-consuming, taking on average 6 to 8 months or more per hospital, and caused a significant delay in the adoption and use of this therapy, despite the FDA approval date. Commenters also stated that by denying GliaSite® RTS new technology status, CMS is not permitting appropriate payment for the device and is "likely restricting access to this therapy."

Response: The regulations clearly state that a medical service or technology may be considered new within 2 or 3 year after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). Notably, the regulations continue, "[a]fter CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion of this section." This device received FDA approval in April of 2001. Information provided by the applicant demonstrates that despite the delays caused by licensing and safety requirements, the device was available on the market no later than fall of 2001 and data began to become available at that time. The applicant's own comments indicate that since that time, a relatively large number of hospitals have adopted this therapy, with 69 hospitals having the required license halfway through FY 2002, and 118 hospitals with the required license at the end of FY 2003. Therefore, the costs of the device have already been reflected in three cycles of DRG recalibrations using costs contained in the second half of FY 2001, and captured in the entirety of FYs 2002 and 2003 MedPAR data. Since the product has been on the market since 2001, and since many hospitals that treat this disease are currently using the device, and have since early in FY 2002, this device is now beyond the 2 to 3 year period in which it can still be considered new.

Comment: One commenter noted that the DRG for craniotomy (DRGs 1 and 2) does not adequately cover the cost of the catheter and isotope. The commenter stated that

"some centers are readmitting the patients for reoperation to place the catheter" and "some are treating patients as outpatient to avoid losing money on the DRG."

Response: Since Medicare has paid for the device for the hospitals that have correctly coded the use of the product in the correct DRGs as well as in other DRGs and in other areas of our system (as disclosed by this commenter), the costs have nonetheless been accounted for in our data and the treatment cannot be considered new.

We therefore finalize the decision to deny new technology add-on status for the GliaSite® RTS (Iotrex) for FY 2005.

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

The manufacturer stated that Natrecor® represents a substantial clinical improvement over existing treatments for decompensated congestive heart failure because it provides novel clinical effects, leads to fewer complications, and improves overall clinical outcomes. Specifically, Natrecor® reduces left ventricular preload, afterload, and pulmonary capillary wedge pressure without inducing tachyphylaxis, and it causes a balanced vasodilation of veins, arteries, and coronary arteries that increases cardiac output. It has also been shown to significantly reduce dyspnea, and it blocks the rennin-aldosterone-angiotensin system, thereby reducing sodium retention and enhancing

diuresis and natriuresis. In addition, Natrecor® is not pro-arrhythmic; it does not increase cardiac work by causing tachycardia, and it does not cause electrolyte imbalances.

However, as discussed above, Natrecor® does not meet the newness criterion. Therefore, in the May 18, 2004 proposed rule, we proposed to deny add-on payments for this technology in FY 2005.

Prior to the publication of the proposed rule, we received no public comments on this application for add-on payments. During the 60-day comment period for the proposed rule, we received the following public comments on this application.

Comment: Some commenters, including the applicant, disagreed with CMS' position that Natrecor® is ineligible for an add-on payment since it is not "new". A commenter explained that in the proposed rule CMS stated that the 2-to-3 year period for collection of cost data begins when the drug or biological receives FDA approval and not when an ICD-9-CM code is issued. The commenter felt this contradicts the statutory language in section 1886 (d)(5)(K)(ii)(II) and the regulatory text in 42 CFR 412.87(b)(2). The commenter stated that that based on the statutory and regulatory text, a technology should be considered new from the date a code is issued. As a result, since Natrecor® did not receive a unique code until October 1, 2002 it should still fall within the 2-3 year period to be considered new.

The commenter further noted that heart failure patients who receive Natrecor® are more costly than patients who do not receive Natrecor®. Based on data the applicant submitted, the commenter explained that the average charge for a patient receiving Natrecor® is 47.5 percent higher than the case weighted average charge threshold of

$32,485. The commenter also added that based on data from the Premier database, even though 48 percent of all cases of Natrecor® map to DRG 127, Natrecor® has had a very small impact on DRG 127 since it represents only 1.8 percent of all charges in DRG 127 which is a result of the fact that only 8.4 percent of all patients assigned to DRG 127 received Natrecor®. As a result, the commenter disagreed with CMS' contention that charges for Natrecor® are adequately reflected in the relevant DRGs. The commenter concluded that limited Medicare reimbursement coupled with the high cost of a breakthrough biologic therapy have led to restrictions on the use of Natrecor®. Also, the number of patients that could receive Natrecor® in DRG 127 is much higher then the current figure of 8.4 percent.

Another commenter believed that CMS should provide its full evaluation of the cost and clinical data submitted by this applicant (and all other applicants) in order to provide for better insight into the agency's decision-making process. The commenter was concerned that during the comment period an application could satisfy the criterion upon which CMS had proposed to deny the application in the proposed rule, while in the final rule CMS could deny the application on a different criterion that had not been discussed in the proposed rule. As a result, the commenter recommended a full analysis of all the criteria in the proposed rule.

Response: As stated above, a technology is no longer considered new 2 to 3 years after data reflecting its costs begin to become available. Because data reflecting the costs of Natrecor® began to become available in 2001, these costs are currently reflected in the

DRG weights. For a further discussion on the newness criterion regarding FDA approval dates and the issuance of ICD-9-CM codes, please see the preamble above.

We conduct sufficient analysis on each application in order to provide sufficient opportunity to comment. We do not believe that it is necessary to provide a full analysis of all the criteria in cases where, for example, we believe that sufficient evidence is available to propose denying the application on the basis of the newness criterion. However, even in these cases we provide an account of any information submitted by the applicant in order to provide opportunity for comment.

Comment: One commenter believes that CMS should be more proactive when it comes to DRG reclassifications of new technologies. The commenter cited Natrecor® as an example of a new technology with over 10,000 cases in which the current reimbursement is inadequate. The commenter noted that after CMS denied the application for add-on payments, no consideration was given to the reclassification of the new technology. The commenter encouraged CMS to make strides to ensure that patient access to important, life threatening therapies is not threatened by inappropriate PPS payments.

Response: When reviewing new technology applications, we consider if the applicant has met all the criteria for new technology add-on payments. The applicant or anyone from the public is free to make a separate request for consideration of a new DRG assignment as we discuss in section II. B. of this final rule.

Because Natrecor® does not meet the newness criterion, we are finalizing our proposal not to approve add-on payments for this technology in FY 2005.

f. Kinetra® Implantable Neurostimulator for Deep Brain Stimulation

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

In December 2003, the device was approved by the FDA. Therefore, it qualifies under the newness criterion because FDA approval was within the statutory timeframe of

2-3 years and its costs are therefore not yet reflected in the DRG weights. Because there are no data available to evaluate costs associated with Kinetra®, we conducted the cost analysis using Soletra™, the predecessor technology used to treat this condition, as a proxy for Kinetra®. The pre-existing technology provides the closest means to track cases that have actually used similar technology and serves to identify the need and use of the new device. The manufacturer informed us that the cost of the Kinetra® device is twice the price of a single Soletra™ device. Since most patients would receive two Soletra™ devices if the Kinetra® device is not implanted, data regarding the cost of Soletra™ give a good measure of the actual costs that will be incurred. Medtronic submitted data for 104 cases that involved the Soletra™ device (26 cases in DRG 1 (Craniotomy Age > 17 With CC), and 78 cases in DRG 2 (Craniotomy Age > 17 Without CC)). These cases were identified from the FY 2002 MedPAR file using procedure codes 02.93 (Implantation, intracranial neurostimulator) and 86.09 (Other incision of skin and subcutaneous tissue). In the analysis presented by the applicant, the mean standardized charges for cases involving Soletra™ in DRGs 1 and 2 were $69,018 and $44,779, respectively. The mean standardized charge for these Soletra™ cases according to Medtronic's data was $50,839.

For the proposed rule, we used the same procedure codes to identify 187 cases involving the Soletra™ device in DRGs 1 and 2 in the FY 2003 MedPAR file. Similar to the Medtronic data, 53 of the cases were found in DRG 1, and 134 cases were found in DRG 2. The average standardized charges for these cases in DRGs 1 and 2 were $51,163 and $44,874, respectively. Therefore, the case-weighted average standardized charge for

cases that included implantation of the Soletra™ device was $46,656. The new cost thresholds established under the revised criteria in Pub. L. 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 and an additional surgery for implantation of the second generator). Therefore, the Kinetra® device reduces the number of surgeries from 3 to 2.

In the May 18, 2004 proposed rule, we indicated that, despite the improvement Kinetra® represents over its immediate predecessor, Soletra™, we had concerns about whether the device is significantly different in terms of how it achieves its desired clinical result. The stimulation mechanism by which it treats patient symptoms remains substantially the same as the predecessor device. The enhancements cited by the manufacturer are primarily to features such as control, power, monitoring, and reliability. Nevertheless, these improvements, along with the reduced number of surgeries required, may be sufficient to warrant a determination that the device represents a substantial clinical improvement. We welcomed further public comment on the issue of whether the device is sufficiently different from the previously used technology to qualify as a substantially improved treatment for the same patient symptoms.

In the proposed rule, we also invited comments concerning the cost of the device. If the new device, at twice the cost of the existing technology, merely replaces the costs

of two of the previous devices, then the charges for Kinetra® are not substantially different from current charges resulting from the use of either device alone. Because the costs for the predecessor device meet the statutory cost criterion, the successor technology would meet the criterion as well, at least under the manufacturer's assumption that a single Kinetra® costs twice as much as each of the two 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®, we stated in the proposed rule that we would expect the costs for patients who receive the new device to drop. We stated that, for those reasons, it may not be appropriate to base the cost analysis for Kinetra® on the manufacturer's assumption that total costs for Soletra™ and Kinetra® are substantially the same.

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

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

Prior to publication of the proposed rule, we received no public comments on this application. During the 60-day comment period for the proposed rule, we received the following public comments on this application.

Comment: The applicant responded to our request for comments by providing further detail on the cost of the device, how it derived the higher cost for the device and recommendations on how we might proceed if we were to approve the device for add-on payments. It noted that the device has substantially higher manufacturing costs than the predecessor device, Soletra™, which has a smaller battery and much lower production cost. The applicant also stated that the device meets the substantial clinical improvement criterion due to the much improved user outcomes for patients that receive Kinetra®as opposed to those that receive the Soletra™. In addition to the factors listed above, it noted that not only does the device reduce invasiveness and risk of surgical complications to implant the device, but the shorter operating time needed to implant one device reduces the duration of anesthesia in one episode that these patients need for surgical placement. The time to reach the desired and improved therapeutic outcome is greatly reduced. The

need for follow up care is substantially reduced and the intervals between battery replacement operations with the new device are significantly increased (anywhere from 15 months to 2 years longer, based on various comments received).

The applicant also provided data that satisfactorily answered our remaining questions with regard to the reasons for staged implantation of the device in some patients. It noted that many patients simply cannot physically tolerate the long day of surgery, and particularly the general anesthesia required to implant the generator if the procedure is all done in one day or one hospital stay. In addition, due to the nature of the brain surgery involved to place the leads, care must be given to ensure that no hemorrhages are present before proceeding with implanting the rest of the device. Other physicians noted that patient medications must also be taken into account when planning the implantation of the device. One commenter, a physician using the device in his practice, also noted the improved mobility and function of patients receiving this device and the reduced interference in daily and leisure activities for patients receiving this device over the Soletra™ generators. Other physicians noted that patients actually spend less time in the hospital under the staged method for implanting the device and tolerate the procedures much better. Some nurses noted that there are additional educational requirements associated with the Kinetra® device due to the unique patient control, but this training and the additional time to set up the initial programming of the device result in reduced follow-up visits and re-programming, and allow the patients to monitor their symptoms in the stress-free environment of the home instead of the doctor's office.

Response: We believe that sufficient evidence has been provided by the applicant to demonstrate that this device satisfies the significant clinical improvement criterion and should receive new technology add-on payment for FY 2005. We have found that, based on the new evidence provided, Kinetra® does represent a substantial clinical improvement over the previous Soletra™ device. Specifically, the increased patient control, reduced surgery, fewer complications, and elimination of environmental interference significantly improve patient outcomes. Since we stated in the proposed rule that the device meets the newness criterion, and that the device meets the cost threshold in the DRGs to which it is assigned, this determination of substantial clinical improvement warrants the approval of Kinetra® for new technology add-on payments for FY 2005.

Comment: The applicant also recommended that, if approved for add-on payment, CMS should require both the procedure code that identifies the neurostimulator device for deep brain stimulation (02.93) in addition to the code that identifies the placement of the generator in the chest cavity (86.95). In addition, it commented that any concern over double-payment if implantation occurs in a staged manner (that is, in separate inpatient admissions or in different settings that Medicare pays for) would be ameliorated if we require that both these two ICD-9-CM codes be required in a case that is mapped to either DRG 1 or 2 (Craniotomy with and without CC).

Response: We agree that this is the best approach to resolving both the reimbursement issue as well as concerns over the possibility of paying for the device twice if performed in different settings (that is, a staged implantation). We are approving new technology add-on payments for the Kinetra® device for FY 2005 in this final rule.

Cases receiving Kinetra® for Parkinson's disease or essential tremor on or after October 1, 2004 will be eligible to receive an add-on payment of up to $8,285, or half the cost of the device, which is approximately $16,570. These cases will be identified by the presence of procedure codes 02.93 (Implantation or replacement of intracranial neurostimulator leads) and 86.95 (Insertion or replacement of dual array neurostimulator pulse generator). If a claim has only the procedure code identifying the implantation of the intracranial leads, or if the claim identifies only insertion of the generator, no add-on payment will be made.

Comment: Commenters expressed disappointment that we did not approve this device in our proposed rule. However, they remarked upon the complex issues that were raised by our concerns. Specifically, commenters urged that CMS adopt and maintain a uniform standard between the inpatient PPS and the outpatient PPS, urging CMS to make consistent decisions for devices that may be used appropriately in both settings. The commenters specifically referenced different sets of language defining substantial improvements from the OPPS rules, urging the IPPS to follow the guidance of the policies set forth in the OPPS.

Response: The commenters' specific reference to the language in the November 1, 2002 outpatient prospective payment system final rule (67 FR 66781 through 66783) that refers to determinations of substantial clinical improvement where factors such as "increased battery life" and "miniaturization, might so improve convenience, durability and ease of operation" was taken out of context. The November 1, 2002 final OPPS rule states, "[n]evertheless, there may be some

improvements in the medical technology itself that are so significant that we may wish to recognize them for separate payment… even though they do not directly result in substantial clinical improvements." To date, the OPPS has only applied these explicit substantial clinical improvement criteria to pass-through device category applications. We have not yet determined whether to apply this particular standard within IPPS. However, we are approving the Kinetra® device for new technology add-on payments for FY 2005, without reference to these considerations. We will continue to consider whether to employ specific factors such as those identified for the OPPS in the IPPS.

Comment: Several commenters noted the importance of the programmability of the device, especially for patients who live at a distance from their physician and would not be able to visit frequently to adjust the level of stimulation as would be necessary with the Soletra™ device. One commenter (a physician) noted that "the problem [with the Soletra™ device] has been so severe in some patients that [he has] had to loan them a regular physician programmer so that they could do the adjustments at home." He noted further that the Soletra™ programmer is not meant for patient use and encouraged CMS to approve add-on payment for Kinetra® so he can use it in his practice.

Response: We do not know the protocol for doctor-patient programming of the Soletra™ device, however, we are approving add-on payment for Kinetra® for FY 2005.

Comment: We received one comment that cited that "the use of Kinetra® in the VA system is preferred by an almost 3 to 1 ratio versus the previous technology" whereas the usage in Medicare was only approximately 1 to 4.

Response: We do not know where the commenter received the data in this comment, as we were not given this data by the applicant. However, we are approving Kinetra® for add-on payment for FY 2005.

g. Intramedullary Skeletal Kinetic Distractor (ISKD)

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

In the May 18, 2004 proposed rule, we indicated that we had reviewed the application and technology, and we had determined that the device is not new and cannot be approved for new technology add-on payments because it came on the market on May 2, 2001. The costs of the device are thus reflected in the FY 2001 MedPAR file, as acknowledged by the manufacturer's data. As a result, the costs of the device are already reflected in the DRG weights.

The manufacturer submitted charge data for cases found in the FY 2001 MedPAR file, as well as data from several hospitals that have used the device. The manufacturer identified cases using ICD-9-CM codes 78.35 (Limb lengthening procedure, femur) and 78.37 (Limb lengthening, tibia/fibula). These procedure codes occur in four DRGs:

DRGs 210 and 211 (Hip and Femur Procedures Except Major Joint Procedures Age > 17, With and Without CC, respectively) and DRGs 218 and 219 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur Age > 17, With and Without CC). The average charges for cases involving these procedure codes identified by the applicant were not standardized. The average charges provided for DRGs 210, 211, 218, and 219 were $26,692, $18,187, $32,959 and $20,228, respectively. The manufacturer then added the cost of the device, which the manufacturer states is $6,750. The manufacturer projects that, in FY 2005, there will be 9 cases in DRG 210, 4 cases in DRG 211, 28 cases in DRG 218, and 19 cases in DRG 219, which results in a case-weighted threshold of $22,347. Thus, according to the manufacturer's data, because the case-weighted average standardized charges of $27,003 for the technology are greater than the cost threshold of $22,347 for these projected 60 cases, the ISKD would qualify for new technology add-on payments.

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

partial weight bearing during the lengthening process and resume some activities of normal living.

However, because the device is already captured in our DRG weights, in the May 18, 2004 proposed rule, we proposed to deny the application for the ISKD device for new technology add-on payments for FY 2005.

Prior to publication of the proposed rule, we received no public comments on this application. During the 60-day comment period for the proposed rule, we received the following public comments on this application.

Comment: The applicant noted that it was very disappointed with CMS' proposal to deny add-on payments for this device. It stated that, although the device may be paid for in the DRG system, so few cases have received the device that the costs related to the device are not accurately reflected in the data used to recalibrate the DRG weights. It argues that the low volume of cases that have received the device has been a direct result of underpayment for the device and that CMS is denying this treatment to beneficiaries by not paying more for this device. The applicant also stated that if we had asked for market data in the application, it would have provided that information to us sooner, and would have had the opportunity to present its argument that the device did, in fact, have a delay between FDA approval and coming to the market. It stated that the "delay between FDA approval and commercial availability was due to a halt in production while certain changes on the ISKD were validated." It also noted that the company "conducted a comprehensive review of its sales database" and has determined that the first commercial

sales of the device were made in February 2002, and as such, the costs of the device were not included in the FY 2001 MedPAR.

Response: This device has been on the market for more than the 2- to 3-year period for which new technology add-on payments are allowed. Even though there may have been a delay in commercial availability of the device, the company stated that sales were made in February of 2002. We note that we are not using strictly the FY 2001 MedPAR as our basis for determining newness in FY 2005, but are denying add-on payments to those products that were on the market prior to midway into FY 2002. Products that were in use prior to April of 2002 have data for more than half of FY 2002 so that the costs of the new technology were included in the DRG recalibration in subsequent years. We have been making payments for the ISKD device since it came on the market and data reflecting the cost of the device are therefore already reflected in the DRG weights. Therefore, we cannot find that the device is new and we are finalizing our proposal to deny this applicant new technology add-on payments.

h. Acticon™ Neosphincter

American Medical Systems submitted an application for approval of the Acticon™ Neosphincter for new technology add-on payments for FY 2005. The Acticon™ Neosphincter is a small, fluid-filled prosthesis that is completely implanted within the body. The Acticon™ Neosphincter prosthesis has been developed to treat severe fecal incontinence (the accidental loss of solid or liquid stool at least weekly). It is designed to mimic the natural process of bowel control and bowel movements. The prosthesis consists of three components: an occlusive cuff implanted around the anal

canal, a pressure-regulating balloon implanted in the prevesical space, and a control pump with septum implanted in the scrotum. All components are connected with color-coded, kink-resistant tubing.

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

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

The applicant states in its application that the Acticon™ Neosphincter represents a substantial clinical improvement for the following reasons: (1) there is no other existing device in the United States that can be used to treat severe fecal incontinence; and (2) self-treatment for severe fecal incontinence has proven to be largely unsuccessful and surgical options have historically been more limited, including sphincteroplasty or muscle transposition.

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

Prior to the publication of the May 18, 2004 proposed rule, we received public comments in accordance with section 50(b)(2) of Pub. L. 108-173 regarding this application for add-on payments.

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

accident at any time. However, because we concluded that the Acticon™ Neosphincter is no longer new, we proposed that it is not eligible for add-on payments.

During the 60-day comment period for the May 18, 2004 proposed rule, we received the following public comments on this application.

Comment: One commenter, the applicant, commented that the Acticon™ Neosphincter should still be considered new under the newness criterion since the device received FDA approval on December 18, 2001 and ICD-9-CM codes (49.75 and 49.76) became effective October 1, 2002. The commenter believes that only after the ICD-9-CM codes became available did data begin to reflect the costs of the technology in the DRGs. Based on the issuance of the codes, there is only 1 ½ years of data and this is the first year CMS is using data with the new ICD-9-CM codes that reflect the Acticon™ Neosphincter within the DRGs. As a result, the commenter maintains that the Acticon™ Neosphincter is still "new" under 42 CFR 412.87(b)(2).

The commenter also noted that the standardized charges per case of $16,758 are actually the standardized costs per case. The correct average charge per case based on the data submitted is $41,396.

Response: As stated above, a technology can be considered new only 2 to 3 years after data reflecting the costs of the technology begin to become available. Data on the costs of this technology began to become available after the December 2001 FDA approval and the costs of this technology are currently reflected in the DRG weights. As a result, the Acticon™ Neosphincter does not meet the newness criterion. For a further

discussion regarding the effect of FDA approval dates and the issuance of ICD-9-CM codes upon our evaluation of the newness criterion, please see the preamble above.

Also, in reference to the cost data, we appreciate the commenter pointing out this error and agree that the average case weighted standardized charge is $41,396. Because the average case weighted standardized charge is greater then the average case weighted threshold of $14,426, the commenter maintains that the Acticon™ Neosphincter meets the cost criterion. However, because the Acticon™ Neosphincter does not meet the newness criterion, we are denying add-on payments for this technology in FY 2005.

We are finalizing our proposal not to approve this technology for add-on payments for FY 2005.

i. TandemHeart™ Percutaneous Left Ventricular Assist System

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

On November 11, 2000, FDA approved the AB-180 XC Blood Pump (also known as the TandemHeart™ pVAD) as a single use, disposable centrifugal blood pump designed to circulate blood through an extracorporeal circuit. On May 23, 2003, FDA approved the CardiacAssist Transseptal Cannula Set for transseptal 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 the FDA approved the Cardiac Arrest Transseptal Cannula Set in May 2003. Therefore, the costs of the TandemHeart™ pVAD are not adequately reflected within the DRGs. As a result, we consider the TandemHeart™ pVAD to be new under our criterion.

As stated above, according to the manufacturer, approximately 60 TandemHeart™ pVADs have been used since the FDA approved the Cardiac Assist Transseptal Cannula Set in May 2003 (not all of these have been used in Medicare beneficiaries). However, only two actual cases were submitted by the applicant with an

ICD-9-CM code of 37.65 (Implant of an external pulsatile heart assist system) used to identify the device. As stated in the September 7, 2001 final rule (66 FR 46916), data submitted by the applicant must be of a sufficient sample size to demonstrate a significant likelihood that the true mean across all cases likely to receive the technology will exceed the threshold established by CMS. We indicated in the proposed rule that, because we lack a significant sample of data reflecting the costs of this technology, we could not accurately determine the average charge per case for the TandemHeart™ pVAD. Neither could we determine whether this technology meets our cost criterion. We indicated that if we received sufficient data to complete our analysis in time for inclusion in the final rule, we would assess whether this technology meets the cost criterion.

In response to this request, the manufacturer and applicant submitted supplementary data on the TandemHeart™ pVAD. We received a total of 11 actual cases that used the Tandem Heart. Although these cases are approximately 18 percent of all TandemHeart™ pVAD cases, we cannot consider this a significant sample of cases to determine if the Tandem Heart meets the cost criterion. Of the 11 cases submitted, the variance in charges from the lowest charge per case to highest charge per case was close to 1 million dollars. Such a large variance in charges per case will require us to consider many more cases in excess of the 11 cases submitted and the 60 total cases that have used the device since its inception before we can determine if the TandemHeart™ pVAD meets the cost criterion. Also, because this is a small pool of cases, one unrepresentative case could skew the results of the data. As a result, because there are insufficient data for

us to determine whether the TandemHeart™ pVAD meets the cost criterion, we are denying add-on payments for this technology in FY 2005.

Although we are not approving this application because we did not have sufficient data to determine whether TandemHeart™ pVAD meets the cost criterion, in the proposed rule we noted that the applicant submitted information on the substantial clinical improvement criterion. The applicant stated in its application that the TandemHeart™ pVAD represents a substantial clinical improvement because, at present, the only alternative to intra-aortic balloon pump support is the surgical implantation of a ventricular assist device. The TandemHeart™ pVAD is the only therapeutic intervention that is capable of achieving effective circulatory support to stabilize cardiogenic shock patients that could be placed via a percutaneous approach. In the proposed rule, we indicated that we would present a full analysis of this technology under the significant improvement criterion if we received sufficient data in time for this final rule to evaluate whether the technology met the cost criterion. For this final rule, as we have determined above, the TandemHeart™ pVAD does not meet the cost criterion and therefore we are not presenting our full analysis of this technology under the substantial improvement criterion. However, we note, although the TandemHeart™ pVAD appears to be a promising new technology for providing circulatory support in profound, refractory left ventricular failure, our review of the submitted literature did not find that adequate clinical experience or clinical evidence exists to demonstrate substantial clinical improvement to the degree we feel is necessary to warrant a new technology special add-on payment. As a result of this and the fact that there are insufficient data to determine

whether the TandemHeart™ pVAD meets the cost criterion, we are denying add-on payments in FY 2005 for this technology.

Nevertheless, we encourage the manufacturers of the TandemHeart™ pVAD device to continue their efforts to compile objective clinical data that demonstrate its clinical efficacy, particularly with regard to improved clinical outcomes in patients with this very serious, life threatening condition. Because the device only became available for use in May 2003, it could remain eligible for consideration for new technology add-on payments in FY 2006.

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

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

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

The System 100 consists of: (1) 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 commercially applicable venous catheters. According to the applicant, although the System 100 was first approved by FDA in June 2002, the System 100 was not used by hospitals until August 2002 because it took a substantial amount of time to market and sell the device to hospitals. As a result, the applicant believes that the System 100 should still be considered new. The applicant has presented data and evidence demonstrating that the System 100 was not marketed until August 2002. Therefore, we also believe August 1, 2002 is the relevant date for determining the availability of the System 100.

The applicant estimates that 308 patients (approximately 120 cases per year) have used the System 100 since its inception and the potential population for use of the device is 60,000 cases per year. These 308 cases represent a small percentage of the potential number of cases that can utilize the System 100. Therefore, the System 100 is not adequately reflected within the DRG weights (as discussed in the September 7, 2001 final rule (66 FR 46914)). In addition, the System 100 is within the 2 to 3 year period contemplated under §412.87(b)(2) of the regulations. Therefore, the System 100 could be considered new. However, the ultrafiltration process that the System 100 employs can also be considered to be a type of hemodialysis, which is an old and well-established

technology. In the proposed rule, we indicated that we have concerns about whether new technology add-on payments should be extended to a well-established technology, even when a new clinical application is developed for that technology. As discussed above, in the September 7, 2001 final rule (66 FR 46915), we noted that if an existing technology is used for treating patients not expected to be assigned to the same DRG as the patients already receiving the technology, it may be considered for approval if it also meets the other cost and clinical improvement criteria. In this case, the device does treat a different patient population of congestive heart failure than the patient population for renal dialysis. Under the policy described in the September 7, 2001 final rule, this technology may be considered new for the purposes of determining whether it qualifies for add-on payments. However, in the proposed rule, we indicated that we have some concerns about whether this is an appropriate result, and about whether technologies that have been in use for many years, in some cases decades, should be able to qualify for add-on payments for new technologies. Therefore, we invited comments on whether this technology should be considered new, and on the general issue of whether existing technologies should be approved for add-on payments when new applications are developed for these technologies and whether special standards regarding, for example, clinical improvement, should be applied in such cases.

Comment: One commenter, the applicant, explained that the System 100 should still be considered new for numerous additional reasons. The commenter explained that System 100 has received numerous patents issued from the United States Patent Office for many aspects of the technology thus demonstrating its uniqueness and newness. The

commenter also added that the technology should be considered new since the FDA recognized the features of the technology, such as proprietary design of the filter assembly and its unique low flow capability, as a different technology because the device can be used in a different patient population. The commenter further explained that no other technology operates in this low flow range using automatic pressure control alogorithims and peripheral vascular access while delivering ease of use and patient safety.

Some commenters recommended that CMS maintain the criteria and definition established in the September 7, 2001 Federal Register (66 FR 46915) that if an existing technology is used for treating patients not expected to be assigned to the same DRG as the patients already receiving the technology, it may be considered for approval if it also meets the other cost and clinical improvement criterion. As a result, the commenters maintain that according to the September 7, 2001 final rule the System 100 meets these criteria and should be approved for new technology add-on payments.

Response: We appreciate the commenter's comments on the newness criterion. As noted above, we do not employ FDA guidelines to determine what drugs, devices or technologies qualify for new technology add-on payments. We also do not consider patents issued by the United States Patent Office as an indicator of a new technology. For a more detailed discussion of the criteria for newness and substantial clinical improvement please see the September 7, 2001 Federal Register (66 FR 46914).

We will continue to review the policy stated in our September 7, 2001 rule. We invite further public comment on this issue in the interim.

The applicant submitted five sets of data to demonstrate that the System 100 meets the cost criterion. Of these five, three sets of data were flawed in the analysis of the cost criterion. Therefore, as in the proposed rule, we discuss only the data that are most accurate and relevant. It is important to note at the outset of the cost analysis that the console is reusable and is, therefore, a capital cost. Only the circuits and catheters are components that represent operating expenses. Section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act, which makes no mention of any add-on payments for a new medical service or technology. Therefore, it is not appropriate to include capital costs in the add-on payments for a new medical service or technology and these costs should also not be considered in evaluating whether a technology meets the cost criterion. The applicant has applied for add-on payments for only the circuits and catheter, which represent the operating expenses of the device. However, in the proposed rule we stated our belief that the catheters cannot be considered new technology in any sense. As a result, we considered only the UF 500 disposable blood circuit as relevant to the evaluation of the cost criterion.

The applicant commissioned Covance to search the FY 2002 MedPAR file. The applicant used a combination of diagnosis codes to determine which cases could potentially use the System 100. Covance found 27,589 cases with the following

combination of ICD-9-CM diagnosis codes: 428.0 through 428.9 (Heart Failure), 402.91 (Unspecified with Heart Failure), or 402.11 (Hypertensive Heart Disease with Heart Failure), in combination with 276.6 (Fluid Overload) and 782.3 (Edema). The 27,589 cases were found among 281 DRGs with 49.4 percent of cases mapped across DRGs 88, 89, 127, 277 and 316. The applicant eliminated those DRGs with less than 150 cases, which resulted in a total of 22,024 cases that could potentially use the System 100. The case-weighted average standardized charge across all DRGs was $14,534. The case-weighted threshold across all DRGs was $17,789. Although the case-weighted threshold is greater than the case-weighted standardized charge, it is necessary to include the standardized charge for the circuits used in each case. In order to establish the charge per circuit, the manufacturer submitted data regarding 51 actual cases that used the System 100. Based on these 51 cases, the standardized charge per circuit was $2,209. The manufacturer also stated that an average of two circuits are used per case. Therefore, adding $4,418 for the charge of the two circuits to the case-weighted average standardized charge of $14,534 results in a total case-weighted standardized charge of $18,952. This is greater than the case-weighed threshold of $17,789. In the May 18, 2004 proposed rule, we welcomed comments from the public on the charge information submitted by the applicant for the circuits.

Comment: One commenter noted that we stated, "[c]atheters cannot be considered new technology in any sense." The commenter stated that this language on catheters is unduly broad and it is possible that the introduction of a new catheter could represent a substantial clinical improvement. The commenter also noted that a catheter

could be considered new under CMS policy specified in the September 7, 2001 **Federal Register** (66 FR 46915) that discusses if the new use of an existing technology is for treating patients not expected to be assigned to the same DRG, it may be considered for approval of new technology add-on payments.

Response: We thank the commenter for pointing this out and we agree that in a certain circumstance a catheter could be considered a new technology under our current policy. We also note that we are continuing to review our policy regarding whether a new use of an existing technology may be considered for approval of new technology add-on payments.

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

The applicant contends that the System 100 represents a substantial clinical improvement for the following reasons: It removes excess fluid without the use of diuretics; it does not lead to electrolyte imbalance, hemodynamic instability or worsening

renal function; it can restore diuretic responsiveness; it does not adversely affect the renin-angiotensin system; it reduces hospital length of stay for the treatment of congestive heart failure, and it requires only peripheral venous access. In the proposed rule we stated our belief that there was some basis for concluding that the System 100 represents a substantial clinical improvement over current standard treatment of fluid overload in congestive heart failure. However, in the May 18, 2004 proposed rule, we also invited comment on whether the data submitted are indeed adequate to demonstrate significant clinical improvement.

Prior to the publication of the May 18, 2004 proposed rule, we received public comments in accordance with section 503(b)(2) of Pub. L. 108-173 regarding this application for add-on payments. Several commenters noted that the System 100 provides physicians a new treatment option for patients with fluid overload who are unresponsive to diuretics and has been documented in clinical studies and other published articles to effectively treat fluid overload. Another commenter noted that patients who have been treated with the System 100 seem to have improved health versus those who have lingered on diuretic therapy or have been treated by hemodialysis. The commenter also noted that the System 100 reduces hospital stays. Other commenters noted that the System 100 is safer for those patients in terms of reduced electrolyte imbalance and renal dysfunction and is a major step forward in the treatment of decompensated heart failure.

We considered these comments in our evaluation in the proposed rule of whether the System 100 meets this substantial clinical improvement criterion. During the 60-day

comment period for the proposed rule, we received the following comments on this application.

Comment: One commenter, the applicant, illustrated that there remains a growing unmet clinical need for effective treatment of the congestive heart failure population. The need for new technologies to treat fluid overload is demonstrated through data from the ADHERE registry which states that the percentage of heart failure patients discharged but still symptomatic of fluid retention is 39 percent. The registry had other notable facts and concluded that chronic diuretic therapy is due to fluid overload seen in patients with and without renal insufficiency and is an independent predictor of poor clinical outcomes and higher resource utilization. The commenter concluded that the emerging knowledge of congestive heart failure patients suffering from fluid overload demonstrates the need for efficient and effective fluid removal such as the System 100.

Some commenters also commented that the System 100 meets the established criteria for new technology since it is clearly and distinctly new and different from any currently available technology and provides clinical services to patients who previously were ineligible for this kind of therapy, and treats a different patient population--heart failure versus renal failure. Furthermore, these commenters also noted that patients with fluid overload are treated in a different DRG than patients who have renal failure.

The applicant also noted that there are some clinical trials that have demonstrated the clinical safety and effectiveness as well as cost effectiveness of the System 100 in treating patients with fluid overload.

Response: We thank the commenters for their comments on this criterion. After careful review of all available information, we have determined that although we recognize the potential benefit of this new technology for Medicare beneficiaries (as stated by the commenter), we do not believe there is sufficient objective clinical evidence to determine that the System 100 meets the substantial clinical improvement criterion (such as a large prospective, randomized clinical trial), given the prevalence of congestive heart failure in the Medicare population. For example, a large prospective, randomized clinical trial that demonstrates improved outcomes, especially in morbidity and mortality, when compared to standard therapy for this sub-population of Medicare patients with congestive heart failure was not submitted. As a result, we are denying add-on payments for this technology for FY 2005.

III. Changes to the Hospital Wage Index

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts "for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level." In accordance with the broad discretion conferred under the Act, we currently define hospital labor market areas based on the definitions of statistical areas established by the Office of Management and Budget (OMB). A detailed discussion of the FY 2005 hospital wage index based on the

statistical areas, including OMB's revised definitions of Metropolitan Areas, appears under section III.B of this preamble.

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

As discussed below in section III.G. of this preamble, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating the wage index. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The budget neutrality adjustment for FY 2005 is discussed in section II.B. of the Addendum to this final rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix

adjustment to the wage index. A discussion of the initial collection of these data and the occupational mix adjustment that we are applying beginning October 1, 2004 (the FY 2005 wage index) appears under section III.C. of this preamble.