DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412 and 413

[CMS–1470–F]

RIN 0938–AL89

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 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 costs to implement changes arising from our continuing experience with these systems. In addition, in the Addendum to this final rule, we are describing 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, 2003. 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 on a cost basis subject to these limits.

Among other 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; the introduction of updated wage data used to compute the wage index; the approval of new technologies for add-on payments; changes to the policies governing postacute care transfers; payments to hospitals for the direct and indirect costs of graduate medical education; pass-through payments for nursing and allied health education programs; determination of hospital beds and patient days for payment adjustment purposes; and payments to critical access hospitals (CAHs).

EFFECTIVE DATES: The provisions of this final rule, except the provisions of § 412.230(e)(2)(ii)(A) (because it grants an exemption) and § 412.278(f)(2)(i), are effective on October 1, 2003. The provisions of § 412.230(e)(2)(ii)(A) and § 412.278(f)(2)(i) are effective on August 1, 2003. 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 this rule on August 1, 2003.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

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Acronyms

AHIMA American Health Information Management Association
AHA American Hospital Association
CAH Critical access hospital
CBSAs Core Based Statistical Areas
CC Complication or comorbidity
CMS Centers for Medicare & Medicaid Services
CMSA Consolidated Metropolitan Statistical Areas
COBRA Consolidated Omnibus Reconciliation Act of 1985, Pub. L. 99–272
CPI Consumer Price Index
CRNA Certified registered nurse anesthetist
DRG Diagnosis-related group
DSH Disproportionate share hospital
FDA Food and Drug Administration
FQHC Federally qualified health center
FTE Full-time equivalent
FY Federal fiscal year
GME Graduate medical education
HIPC Health Information Policy Council
HIPAA Health Insurance Portability and Accountability Act, Pub. L. 104–191
HHA Home health agency
ICD–9–CM International Classification of Diseases, Ninth Revision, and Clinical Modification
ICD–10–PCS International Classification of Diseases Tenth Edition, and Procedure Coding System
IME Indirect medical education
IPPS Acute care hospital inpatient prospective payment system
IRF Inpatient Rehabilitation Facility
LDP Labor, delivery, and postpartum
LTC–DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
MCE Medicare Code Editor
MDC Major diagnostic category
MDH Medicare-dependent small rural hospital
MedPAC Medicare Payment Advisory Commission
MedPAR Medicare Provider Analysis and Review File
MEI Medicare Economic Index
MGCRB Medicare Geographic Classification Review Board
MPFS Medicare Physician Fee Schedule
MSA Metropolitan Statistical Area
NECMA New England County Metropolitan Areas
NCHS National Center for Health Statistics
NCVHS National Committee on Vital and Health Statistics
O.R. Operating room
PPS Prospective payment system
PRA Per resident amount
ProPAC Prospective Payment Assessment Commission
PRRB Provider Reimbursement Review Board
RCE Reasonable compensation equivalent

RHC Rural health center
RRC Rural referral center
SCH Sole community hospital
SNF Skilled nursing facility
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248
UHDDS Uniform Hospital Discharge Data Set

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

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

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

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

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

2. Hospitals and Hospital Units Excluded From the IPPS

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

facilities (IRFs)), psychiatric hospitals and units, and LTCHs, as discussed below. Children's hospitals and cancer hospitals continue to be paid under reasonable cost-based reimbursement.

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

a. Inpatient Rehabilitation Facilities

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

b. LTCHs

Under the authority of sections 123(a) and (c) of Public Law 106–113 and section 307(b)(1) of Public Law 106–554, LTCHs are being transitioned from being paid for inpatient hospital services based on a blend of reasonable cost-based reimbursement under section 1886(b) of the Act to fully Federal prospective rates during a 5-year period, beginning with cost reporting periods that start on or after October 1, 2002. For cost reporting periods beginning on or after October 1, 2006, LTCHs will be paid under the fully Federal prospective payment rate (the June 6, 2003 LTCH PPS final rule (68 FR 34122)). LTCHs may elect to be paid based on full PPS payments instead of a blended payment in any year during the 5-year transition period. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O.

c. Psychiatric Hospitals and Units

Sections 124(a) and (c) of Public Law 106–113 provide for the development of a per diem PPS for payment for inpatient hospital services furnished in psychiatric hospitals and units under the Medicare program, effective for cost reporting periods beginning on or after October 1, 2002. This system must include an adequate patient classification system that reflects the differences in patient resource use and costs among these hospitals and maintain budget neutrality. We are in the process of developing a proposed rule, to be followed by a final rule, to implement the PPS for psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs).

3. Critical Access Hospitals

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

4. Payments for Graduate Medical Education

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

B. Summary of the Provisions of the May 19, 2003 Proposed Rule

On May 19, 2003, we published a proposed rule in the **Federal Register** (68 FR 27154) that set forth proposed changes to the Medicare IPPS for operating costs and for capital-related costs in FY 2004. We also set forth proposed changes relating *to* payments for GME costs, payments to CAHs, and payments to providers classified as psychiatric hospitals and units that continue to be excluded from the IPPS and paid on a reasonable cost basis. These changes were proposed to be effective for discharges occurring on or after October 1, 2003.

The following is a summary of the major changes that we proposed and the issues we addressed in the May 19, 2003 proposed rule:

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:

- Expansion of the number of DRGs that are split on the basis of the presence or absence of complications or comorbidities (CCs). The DRGs we proposed to split were: DRG 4 (Spinal Procedures) into proposed new DRGs 531 and 532 (Spinal Procedures With and Without CC, respectively); DRG 5 (Extracranial Vascular Procedures) into proposed new DRGs 533 and 534 (Extracranial Vascular Procedures With and Without CC, respectively); DRG 231 (Local Excision and Removal of Internal Fixation Devices Except Hip and Femur) into proposed new DRGs 537 and 538 (Local Excision and Removal of Internal Fixation Devices Except Hip and Femur With and Without CC, respectively); and DRG 400 (Lymphoma and Leukemia With Major O.R. Procedure) into proposed new DRGs 539 and 540 (Lymphoma and Leukemia With Major O.R. Procedure With and Without CC, respectively).
- Creation of a new DRG for patients with an intracranial vascular procedure and an intracranial hemorrhage. The DRG we proposed to create was DRG 528 (Intracranial Vascular Procedure With a Principal Diagnosis of Hemorrhage).
- Creation of two new DRGs, differentiated on the basis of the presence or absence of a CC, for craniotomy patients with only a vascular shunt procedure. The DRGs we proposed to create were DRGs 529 and 530 (Ventricular Shunt Procedure With CC and Without CC, respectively).
- Creation of two new DRGs to differentiate current DRG 514 (Cardiac Defibrillator Implant With Cardiac Catheterization) on the basis of whether the patient does or does not experience any of the following symptoms: acute myocardial infarction, heart failure, or shock. The new DRGs we proposed were DRG 535 (Cardiac Defibrillator Implant With Cardiac Catheterization and With Acute Myocardial Infarction, Heart Failure, or Shock) and DRG 536 (Cardiac Defibrillator Implant With Cardiac Catheterization and Without Acute Myocardial Infarction, Heart Failure, or Shock)
- Changes in the DRG assignment of certain congenital anomalies that currently result in patients being assigned to newborn DRGs even when the patient is actually an adult. We also proposed adding to the list of major problems in newborns that affect DRG assignment.
- Modification of DRG 492 (Chemotherapy With Acute Leukemia as

Secondary Diagnosis) to include in this DRG cases receiving high-dose Interleukin-2 (IL–2) chemotherapy for patients with advanced renal cell cancer and advanced melanoma.

We also presented our analysis of applicants for add-on payments for high-cost new medical technologies and proposed a revision to the high-cost threshold for a new technology or medical service to qualify for add-on payments.

- We proposed to continue to make add-on payments for Xigris.
- We discussed new applications for add-on payments for FY 2004.
- We proposed to reduce the high-cost threshold for a new technology or medical service to qualify for add-on payments from 1 standard deviation above the geometric mean standardized charge for cases in the DRGs to which the new technology is assigned to 75 percent of 1 standard deviation.

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 in this section included the following:

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

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

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

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

4. PPS for Capital-Related Costs

We discussed the payment requirements for capital-related costs. We did not propose any changes to the policies on payments to hospitals for capital-related costs.

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

We discussed the following proposed revisions and clarifications concerning excluded hospitals and hospital units and CAHs:

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

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

In the Addendum to the May 19, 2003 proposed rule, we proposed changes to the amounts and factors for determining the FY 2004 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 2004 for hospitals and hospital units excluded from the PPS.

7. 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.

8. 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 2004 for the following:

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

9. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, the Medicare Payment Advisory Commission (MedPAC) is required to submit a report to Congress, no later than March 1 of each year, that reviews and makes recommendations on Medicare payment policies. In the proposed rule, we discussed the MedPAC recommendations concerning hospital inpatient payment policies and presented our response to those recommendations. For further information relating specifically to the MedPAC March 1 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's Web site at: *http://www.medpac.gov.*

C. Public Comments Received in Response to the May 19, 2003 IPPS Proposed Rule

We received approximately 4,200 timely items of correspondence containing multiple comments on the May 19, 2003 proposed rule. Summaries of the public comments and our responses to those comments are set forth below under the appropriate heading.

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

B. DRG Reclassification

1. General

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

For FY 2003, cases are assigned to one of 510 DRGs in 25 major diagnostic categories (MDCs). Most MDCs are based on a particular organ system of the body. For example, MDC 6 is Diseases and Disorders of the Digestive System. This approach is used because clinical care is generally organized in accordance with the organ system affected. However, some MDCs are not constructed on this basis because they involve multiple organ systems (for example, MDC 22 (Burns)). The table below lists the 25 MDCs.

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

In general, cases are assigned to an MDC based on the patient's principal diagnosis before assignment to a DRG. However, for FY 2003, there are eight DRGs to which cases are directly assigned on the basis of ICD–9–CM procedure codes. These DRGs are for heart, liver, bone marrow, lung, simultaneous pancreas/kidney, and pancreas transplants (DRGs 103, 480, 481, 495, 512, and 513, respectively) and for tracheostomies (DRGs 482 and 483). Cases are assigned to these DRGs before they are classified to an MDC.

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

Generally, nonsurgical procedures and minor surgical procedures 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 having 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, cases are classified into the appropriate DRG by the Medicare GROUPER software program. The GROUPER program was developed as a means of classifying each case into a DRG on the basis of the diagnosis and procedure codes and, for a limited number of DRGs, demographic information (that is, sex, age, and discharge status).

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

The records for all Medicare hospital inpatient discharges are maintained in the Medicare Provider Analysis and Review (MedPAR) file. The data in this file are used to evaluate possible DRG classification changes and to recalibrate the DRG weights. However, in the July 30, 1999 IPPS final rule (64 FR 41500), we discussed a process for considering non-MedPAR data in the recalibration process. In order for us to consider the feasibility of 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 19, 2003 proposed rule, we proposed numerous changes to the DRG classification system for FY 2004. The changes we proposed to the DRG classification system for FY 2004, 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 2004 GROUPER version 21.0 and effective for discharges occurring on or after October 1, 2003. Unless otherwise noted in this final rule, our DRG analysis is based on data from the March 2002 update of the FY 2002 MedPAR file, which contains hospital bills received through March 31, 2002, for discharges in FY 2002.

2. Review of DRGs for a Split Based on Presence or Absence of a CC

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

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

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

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

The following four DRGs meet these criteria: DRG 4 (Spinal Procedures) and

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

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

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

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

Therefore, we proposed to establish the following new DRGs: proposed DRG 531 (Spinal Procedures With CC) and proposed DRG 532 (Spinal Procedures Without CC) in MDC 1; proposed DRG 533 (Extracranial Procedures With CC) (the proposed rule incorrectly included ''Vascular'' in the title) and proposed DRG 534 (Extracranial Procedures Without CC) (the proposed rule incorrectly included ''Vascular'' in the title) in MDC 1; proposed DRG 537 (Local Excision and Removal of Internal Fixation Devices Except Hip and Femur With CC) and proposed DRG 538 (Local Excision and Removal of Internal Fixation Devices Except Hip and Femur Without CC) in MDC 8; and proposed DRG 539 (Lymphoma and Leukemia With Major O.R. Procedure With CC) and DRG 540 (Lymphoma and Leukemia With Major O.R. Procedure Without CC) in MDC 17. We proposed that DRGs 4, 5, 231, and 400 would become invalid.

Comment: Seven commenters supported the proposed expansion of the number of DRGs related to spinal procedures and extracranial vascular procedures and the removal of internal fixation devices. One commenter commended CMS for the proposed change to payments for implanting spinal code stimulation devices. Referring to proposed new DRGs 531 and 532, the commenter stated that most inpatients receiving a spinal cord stimulator implant have a comorbid condition, which adds significantly to the cost of care and can serve as a barrier to patient access. Another commenter specifically supported the new DRGs 533 and 534 for extracranial vascular procedures.

One commenter expressed support for CMS' recognition of cost differences within a given DRG based on the presence or absence of a CC and encouraged CMS to continue to consider secondary diagnoses that can have a substantial effect on hospital resources when restructuring DRGs based on cost considerations.

Response: We appreciate the support for these proposals and are adopting them as final without further modification.

We are establishing new DRGs 531, 532, 533, 534, 537, 538, 539, and 540, effective for discharges occurring on or after October 1, 2003. As a result of establishing these new DRGS, DRGs 4, 5, 231, and 400 are invalid, effective October 1, 2003. We will continue to monitor whether additional DRGs should be split based on the presence or absence of a CC.

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

a. Revisions of DRGs 1 and 2

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

Therefore, we conducted an analysis of the charges for various procedures and diagnoses within DRGs 1 and 2 to assess whether further changes to these DRGs may be warranted. Currently, the average charges for cases assigned to DRGs 1 and 2 are approximately $55,000 and $30,000, respectively. In the May 19, 2003 proposed rule, we proposed to create two separate new DRGs for: (1) cases with an intracranial vascular procedure and a principal diagnosis of an intracranial hemorrhage; and (2) craniotomy cases with a ventricular shunt procedure (absent another procedure). The former set of cases are much more expensive than those presently in DRGs 1 and 2; the latter set of cases are much less expensive.

(1) Intracranial Vascular Procedures

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

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

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

We indicated that proposed new DRG 528 would have the following principal diagnoses:

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

And operating room procedures:

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

(2) Ventricular Shunt Procedures

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

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

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

We indicated that proposed new DRG 529 would consist of any principal diagnosis in MDC 1 (erroneously cited as MDC 5 in the proposed rule), with the presence of a CC and one of the following operating room procedures:

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

We proposed that the proposed new DRG 530 would consist of any principal diagnosis in MDC 1 (erroneously cited as MDC 5 in the proposed rule) with one of the operating room procedures listed above for the proposed new DRG 529, but without the presence of a CC.

Comment: Four commenters supported the proposed creation of two DRGs to capture ventricular shunt procedures. Ten commenters supported the proposed creation of new DRG 528 for an intracranial vascular procedure with a principal diagnosis of hemorrhage.

Two commenters requested that CMS verify its GROUPER analysis and clarify in the final rule the estimated number of cases that will be assigned to DRG 528. One commenter also believed that CMS is underestimating the volume of hemorrhagic cases that would be assigned to this new DRG. The commenter indicated that its analysis of MedPAR 2001 data demonstrated 1,550 cases.

Response: We conducted an analysis based on later available MedPAR data and found 1,596 cases that would be assigned to DRG 528 (based on a full year of MedPAR data). This volume is consistent with the commenter's analysis, although different MedPAR files were used in the analysis. In the proposed rule (68 FR 27161), we reported 917 cases based on preliminary data (6 months' worth of cases) that we analyzed when we considered the proposed change in the DRG classification. There were actually 1,354 cases grouped to the proposed new DRG 528 for the proposed rule.

Comment: One commenter suggested the creation of a new companion DRG to DRG 528 for intracranial vascular procedures for unruptured cerebral aneurysms. The commenter was concerned that the charges for endovascular repair of unruptured aneurysms is higher than other procedures currently assigned to DRG 2.

Response: The average charges for unruptured aneurysm cases varied according to the DRG to which the cases were assigned. The average charges for these cases in DRG 1 were slightly higher than the overall charges for that DRG, of approximately $69,682 and $54,900, respectively. However, we found that these charges are consistent with the variation of charges within this DRG and, therefore, did not propose a change in the DRG reclassification. Similarly, for cases assigned to DRG 2, we found the average charges of approximately $36,077 are consistent with the overall average charges of that DRG of approximately $32,000. We will continue to monitor these cases.

Comment: Three commenters requested a change to the DRG assignment of cases involving implantation of GLIADEL® chemotherapy wafers to treat brain tumors.[2] One of the commenters offered two options: create a new DRG or reassign these cases to DRG 484 (Craniotomy for Multiple Significant Trauma). The commenter cited an example in which CMS has in the past grouped together in the same DRG cases that are clinically dissimilar but similar in resource intensity when there were no other options available. For FY 1998 (62 FR 45974), coronary stent cases were moved from DRG 112 (Percutaneous Cardiovascular Procedures) to DRG 116 (Other Permanent Cardiac Pacemaker Implant or PTCA with Coronary Artery Stent Implant). In that instance, CMS concluded that, although coronary artery stent cases are not clinically similar to the pacemaker cases in DRG 116, the resource consumption of these

[2] We also discuss this issue later in this preamble under section II.E.3.b. relative to the application for new technology add-on payments for the GLIADEL® wafer.

cases is very similar. The commenter contended that, absent another appropriate craniotomy DRG, the same argument could be applied to assigning cases with GLIADEL® wafer to DRG 484.

In a comment on the proposed rule, the manufacturer of this implant provided estimated FY 2003 average costs and charges for these cases. Its report indicated that the costs of the cases of $24,280 would be the same for cases assigned to DRG 1 and DRG 2, and the charges of the cases of $50,394 would be the same for both DRGs. The manufacturer requested that we analyze the available data in the FY 2003 MedPAR file to identify GLIADEL® cases. The manufacturer believed these data support the need for a DRG change.

One commenter agreed with our determination that this technology is currently reflected within the DRG weights and does not meet the definition of a new technology.

Response: In our analysis of the data from the March 2003 update of the FY 2003 MedPAR file, we found a total of 61 cases in which the ICD–9–CM procedure code 00.10 (Implantation of a chemotherapeutic 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. Consistent with the GROUPER logic for these DRGs that splits cases based on the presence or absence of CCs, we found that the average standardized charges in DRGs 1 and 2 were approximately $64,864 and $42,624, respectively. We believe that while the charges for GLIADEL® wafer cases may be higher than the average standardized charges for DRG 2, they are within the normal variation of the overall charges within each DRG.

We note that the DRGs are a system of averages, and there is expected to be variation in the average charges for different procedures and services across all DRGs. Hospitals are expected to be able to finance some higher cost procedures with lower cost procedures within the same DRG as well as across DRGs. Although the average charges of the cases we identified in our analysis are somewhat higher than the average charges of all cases in these DRGs, they are within the range of other procedures included in these DRGs. By way of comparison, we are creating a new DRG for cases with an intracranial vascular procedure and a principal diagnosis of an intracranial hemorrhage on the basis of our analysis that showed the average charges for these cases were $113,884. This is approximately $59,000 more than the average charges in DRG 1 (more than the total charges for the GLIADEL® cases reported by the commenter) and approximately $84,000 more than the average charges in DRG 2.

We also are concerned that there may be insufficient volume of cases to warrant the establishment of a new DRG for this technology. Thus, before considering the creation of a new DRG for these cases, we would like to review a full year of data, as well as consider alternative options if they appear warranted. It would also be necessary to provide opportunity for public comment on any potential changes to the DRG assignment of these cases before proceeding with a final change.

Currently, DRG 484 includes complex, multiple significant trauma cases; that is, patients with a principal diagnosis of trauma and at least two significant trauma diagnosis codes (either as principal or secondary diagnosis) from different body site categories. While this DRG includes craniotomy, it is assigned to MDC 24 (Multiple Significant Trauma). While the treatment for glioblastoma multiforme is significant, we do not believe these cases are clinically similar to other cases currently assigned to DRG 484.

We also are concerned that there may be insufficient volume to warrant the establishment of a new DRG for this technology, and we would like to review a full year of data, as well as consider alternative options if they appear warranted. It also would be necessary to provide opportunity for public comment on any potential changes before proceeding with a final change.

Comment: Two commenters pointed out a typographical error in our proposal. The commenters indicated that we proposed new DRGs 529 and 530 for placement in MDC 5; the correct MDC should have been MDC 1.

Response: We agree with the commenters and have corrected this placement, as indicated in the discussion above.

After consideration of the comments received, we are adopting as final the three new proposed DRGs 528, 529, and 530. These DRGS will be effective for discharges occurring on or after October 1, 2003.

b. DRG 23 (Nontraumatic Stupor and Coma)

In DRG 23 (Nontraumatic Stupor and Coma), there are currently six principal diagnoses identified by the following ICD–9–CM diagnosis codes: 348.4, Compression of the brain; 348.5, Cerebral edema; 780.01, Coma; 780.02, Transient alteration of awareness; 780.03, Persistent vegetative state; and 780.09, Other alteration of consciousness. Code 780.02 is often used to describe the diagnosis of psychiatric patients rather than the diagnosis of patients with severe neurological disorders. The treatment plan for a patient with ''transient alteration of awareness'' is clinically very different from the treatment plan for a coma patient. Furthermore, many patients with this diagnosis are treated in psychiatric facilities rather than in acute care hospitals.

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

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

Comment: An organization representing hospitals supported our proposed change, while other commenters opposed the change. The commenters who opposed the change stated that code 780.02 is included in the ICD–9–CM chapter for signs and symptoms of ill-defined conditions. The commenters believed that since this code is included in a chapter with ill-defined conditions, it would be inappropriate to move the code to DRG 429. The commenters stated that this

code does not describe a mental disorder; and disagreed with our statement in the proposed rule that code 780.02 was similar to codes 293.81 and 293.82. The commenters further stated that they disagreed with our assertion that many patients with a diagnosis of transient alteration of awareness are treated in psychiatric facilities.

Response: Our review of claims data indicates that code 780.02 is a frequent diagnosis for patients admitted to psychiatric hospitals. Many patients are likely to present with transient alteration of awareness at the time of admission to a psychiatric hospital. The cause of this transient alteration is likely to be diagnosed during the stay, leading to the assignment of another, more specific principal diagnosis.

However, in many patients, this is not the case, and no underlying cause for the transient alteration of awareness is determined. When a more definitive diagnosis cannot be made, the patient is left with the diagnosis of alteration of awareness. We recognize the difficulty in assigning symptoms such as these to the most appropriate DRG. However, we will note that the average charges for DRG 23 (where the code is currently assigned) and DRG 429 are similar.

Therefore, we are proceeding with the assignment of code 780.02 to DRG 429 based on a review of psychiatric hospital data as well as a clinical comparison of cases already assigned to DRG 429.

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

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

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

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

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

We received two comments in support of this change. Therefore, we are adopting as final our proposal to remove code 37.64 from DRGs 478 and 479 and assign it to DRGs 110 and 111.

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

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

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

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

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

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

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

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

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

shock as a principal diagnosis. We proposed to establish new DRG 535 (Cardiac Defibrillator Implant With Cardiac Catheterization and With Acute Myocardial Infarction, Heart Failure, or Shock) and new DRG 536 (Cardiac Defibrillator Implant With Cardiac Catheterization and Without Acute Myocardial Infarction, Heart Failure, or Shock). Proposed new DRG 536 would exclude the following principal diagnosis codes from MDC 5 associated with acute myocardial infarction, heart failure, or shock.

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

(2) Cardiac Resynchronization Therapy (CRT)

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

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

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

When the CRT–D generator (code 00.54) and one of the cardioverter/defibrillator leads are replaced, the case currently is assigned to DRG 115 (Permanent Cardiac Pacemaker Implant with AMI, Heart Failure, or Shock or AICD Lead or Generator Procedure). The commenter recommended that we include the combination of codes 37.95 and 00.54 as a combination that would result in assignment to DRG 514 or DRG 515, as do other combinations of generators and leads. Our medical advisors agree with this recommendation. As discussed previously, we proposed to delete DRG 514 and replace it with proposed new DRGs 535 and 536. Therefore, we proposed to add codes 37.95 and 00.54 to the list of procedure combinations that would result in assignment to DRG 515 or new proposed DRGs 535 and 536.

Comment: Several commenters supported our proposed revision to DRG 514 so that it would be split based on the presence or absence of a principal diagnosis of acute myocardial infarction, heart failure, or shock.

One commenter pointed out a typographical error in the proposed rule in the code number cited for the procedure, Implantation of automatic cardioverter/defibrillator lead(s) only. The code number should have been 37.95 instead of 39.75.

Response: We appreciate the support for our proposed revision of DRG 514. We have corrected the code number for Implantation of automatic cadioverter/defibrillator lead(s) only to 37.95 in the description of this issue above.

Comment: Several commenters supported the addition of codes 37.95 and 00.54 to the list of procedure combinations that would lead to an assignment of DRG 515 and new DRGs 535 and 536. However, one commenter suggested that, in addition to this combination, codes 37.97 (Replacement of automatic cardioverter/defibrillator lead(s) only and 00.54 also should be added to the procedure combination list under DRG 515 and new DRGs 535 and 536. The commenter pointed out that both procedures would involve the insertion of a pulse generator and a lead so that resources required are equivalent to those for a total system implant.

Response: We agree with the commenter that the combination of codes 37.97 and 00.54 also would involve the implantation of a pulse generator and a lead. Therefore, in this final rule, we are adding the combination of procedure codes 37.97 and 00.54 to the list of procedure combinations that will lead to assignment to DRG 515 and new DRGs 535 and 536.

Comment: One commenter recommended that CMS also consider modifying DRGs 115 and 116 to recognize more combination groups of devices and leads. Specifically, the commenter recommended adding the following combination of codes to the list of procedure combinations under DRGs 115 and 116:

- 00.53, Implantation or replacement of CRT–P pulse generator only
- 37.74, Implantation or replacement of epicardial pacemaker lead.

Response: DRGs 115 and 116 have one of the most complex assignment structures of all the DRGs. The DRG logic for DRGs 115 and 116 involves three separate combinations of code groups that can possibly lead to these DRG assignments. Before making a

modification to one of the combination groups (particularly the procedure combinations), we believe we should analyze the impact of a modification to the currently existing types of device, lead, and diagnosis combinations. In the future, we will undertake a close review of DRGs 115 and 116 to determine if additional modifications, such as the one suggested, are needed.

Comment: Two commenters supported the proposal to restructure DRG 514 through the creation of new DRGs 535 and 536. One of the commenters supported the division of these new DRGs based on the presence or absence of acute myocardial infarction, heart failure, or shock. However, the commenter believed that this new structure would lead to significant confusion among hospital coders with respect to the coding of CRT–Ds. The commenter stated that hospital coders may be confused when a patient is admitted with one diagnosis, but then develops an acute myocardial infarction, heart failure, or shock after the admission but prior to discharge. In these cases, the acute myocardial infarction, heart failure, or shock would be a secondary diagnosis. The split of DRGs 535 and 536 is based on these conditions when they are the principal diagnosis (reason for the hospital admission). To eliminate the potential for misunderstanding, the commenter requested that the definition of DRG 535 be modified so that patients who receive CRT–D devices are assigned to DRG 535 when an ICD–9–CM diagnosis code for heart failure is present as either a principal or secondary diagnosis.

Response: We appreciate the support from the commenters for our proposal to modify DRG 514 through the creation of new DRGs 535 and 536. We note that the issue of coding the implantation of CRT–Ds has been covered through extensive articles in the American Hospital Association's *Coding Clinic for ICD–9–CM.* In the past, the coding of cases with acute myocardial infarction, heart failure, or shock has not been problematic for hospital coding specialists. However, should the DRG modifications lead to coding questions on CRT–D cases, we will ask the American Hospital Association to provide additional guidance in its *Coding Clinic for ICD–9–CM.* Furthermore, the DRG splits for an acute myocardial infarction, heart failure, or shock, which currently are included in DRGs 115 and 116, are based on these conditions being the principal diagnosis. As a result, this is a longstanding DRG logic precedent. We do not believe that replicating the logic used for splitting DRGs 115 and 116 and using it for DRGs 535 and 536 would create confusion for hospital coders. Rather, we believe hospital coders would easily recognize this type of longstanding DRG logic.

Comment: Another commenter supported the proposal to split DRG 514 into DRGs 535 and 536 based on the presence or absence of acute myocardial infarction, heart failure, or shock. The commenter stated that this split would ensure greater consistency within the DRG system and ensure adequate payment to hospitals for the higher costs patients receiving implantable cardioverter-defibrillator implants. However, the commenter recommended that DRG 515 undergo a similar split based on the presence or absence of acute myocardial infarction, heart failure, or shock. The commenter stated that the creation of these additional new DRGs would fully align payment logic across all pacemaker and implantable cardioverter-defibrillator implant devices. The manufacturer also believed that differences between average charges and average length of stay for these cases within DRG 515 would warrant this additional splitting of the DRG.

Response: We appreciate the support for the revisions involving DRGs 514, 535, and 536. However, when we examined the data for DRGs 514 and 515, we found that there were almost three times as many cases with an acute myocardial infarction, heart failure, or shock cases in DRG 515 as in DRG 514. Those cases in DRG 514 with a principal diagnosis of an acute myocardial infarction, heart failure, or shock, had average charges approximately 20 percent greater than the average charges for all cases in DRG 514. However, cases with a principal diagnosis of an acute myocardial infarction, heart failure, or shock in DRG 515 had average charges that were only about 10 percent greater than all cases in this DRG. Therefore, there is a significantly greater need for the DRG split for DRG 514. We will continue to examine cases within this area, and specifically DRG 515, to determine if additional DRG refinements are needed in the future.

Comment: One commenter, who supported the revisions to DRG 514 through the new DRGs 535 and 536, expressed concern about our coverage decisions on automatic implantable cardioverter-defibrillators. The commenter believed the coverage was extremely restricted.

Response: We appreciate the support of the commenter for new DRGs 535 and 536. We will share the concerns relating to coverage decisions on automatic implantable cardioverter-defibrillators with our coverage staff.

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

Prior to the issuance of the proposed rule, we received a comment that two codes for cervical fusion of the spine are not included within DRG 519 (Cervical Spinal Fusion With CC) and DRG 520 (Cervical Spinal Fusion Without CC). The two cervical fusion codes are:

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

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

We did not receive any comments on this proposal. Therefore, we are adopting as final our proposal to remove codes 81.01 and 81.31 from DRGs 497 and 498 and reassign them to DRGs 519 and 520, effective for FY 2004.

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

a. Nonneonate Diagnoses

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

Prior to the publication of the proposed rule, we received a recommendation to move the following congenital anomaly codes from MDC 15 and reassign them to other appropriate MDCs based on the body system being treated:

- 758.9, Chromosome anomaly, not otherwise specified
- 759.4, Conjoined twins

- 759.7, Multiple congenital anomalies, not elsewhere classified
- 759.81, Prader-Willi syndrome
- 759.83, Fragile X syndrome
- 759.89, Specified congenital anomalies, not elsewhere classified
- 759.9, Congenital anomaly, not otherwise specified
- 779.7, Periventricular leukomalacia
- 795.2, Abnormal chromosomal analysis

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

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

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

Comment: Several commenters supported all of the proposed changes relating to congenital anomalies. One commenter supported the changes in general, but mentioned several concerns. While this commenter agreed that it was feasible to move these congenital conditions out of MDC 15, the commenter suggested that those patients who are still in the neonatal period (first 28 days of life) when admitted should continue to be classified to MDC 15.

In addition, this commenter questioned whether the proposed DRG assignments were correct for codes 759.4 (Conjoined twins), code 759.7 (Multiple congenital anomalies, not elsewhere classified), and 759.89 (Specified congenital anomalies, not elsewhere classified). The commenter stated that although the proposed DRG assignments for these three DRGs may be appropriate based on the body system being treated for most cases, these DRGs do not necessarily reflect the body system affected or being treated. The commenter did not suggest alternative DRG assignments.

Response: We acknowledge the commenter's point that, for a minority of cases, the admission will, in fact, be in the neonatal period. However, the majority of cases will continue to be patients well beyond the neonatal period. The proposed DRG modifications will correct the majority of inappropriate DRG assignments that occur when adults are assigned to MDC 15 (Newborns and Other Neonates with Conditions Originating in the Perinatal Period). In the future, we will examine other means to further refine this area, such as making new DRG assignments for congenital anomalies based on the age of the patient. However, at this point, we are attempting to resolve the problems created for the majority of patients.

Regarding the commenter's concern that codes 759.4, 759.7, and 759.89 may not always be appropriately assigned according to our proposal, the commenter did not suggest an alternative. The commenter agreed that many cases with these three codes will be assigned to the appropriate body system by using our proposed DRG assignments. We recognize that reassignment of these codes will not resolve all problems, and some cases may be assigned to the wrong body system based on the patient's actual condition. However, we note that these three codes are vague and do not specify a precise congenital anomaly by body system. Therefore, we had to rely on our medical advisors to determine the most appropriate DRG for the majority of cases. Our main concern was to correct the DRG assignment that resulted in adults being assigned to a neonatal DRG when they had a congenital anomaly. We will continue to examine the data for these cases to determine if additional modifications are needed in the future.

Therefore, we are adopting the proposed revisions as final without modification.

b. Heart Failure Codes for Newborns and Neonates

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

Prior to the publication of the proposed rule, we received correspondence suggesting that the following diagnosis codes for heart failure, which are currently in MDC 5, be added to the list of secondary diagnosis of major problems for neonates under MDC 15.

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

These heart failure-related diagnosis codes were new codes as of October 1, 2002. They were an expansion of the previous 4-digit codes for heart failure and provided additional detail about the specific type of heart failure. The codes for heart failure that existed prior to October 1, 2002, are classified as secondary diagnoses of major problems within MDC 15 and are currently assigned to DRGs 387 and DRG 389. We stated in the proposed rule that these other heart failure diagnosis codes should be included as principal diagnosis of major problem codes within MDC 15. However, these heart failure codes are currently listed in the secondary, not principal, diagnoses of major problems within MDC 15.

We agree that diagnosis codes 428.20 through 428.43 listed in the chart above should be included as secondary diagnosis of major problem codes within MDC 15, as are the other heart failure codes. Therefore, we proposed to add them to DRG 387 and 389.

Comment: Several commenters supported the proposal to add codes 428.20 through 428.43 (codes for heart failure that became effective October 1, 2002, listed in the chart above) to DRGs 387 and 389. The commenters agreed that the heart failure codes created on October 1, 2002, should be assigned to DRGs 387 and 389 in the same fashion as were those heart failure codes created prior to October 1, 2002.

One commenter indicated that we incorrectly described the addition of diagnosis codes 428.20 through 428.43 listed in the chart to the list of ''principal'' diagnosis of major problem codes. The commenter stated that we should have indicated that these codes would be added to the list of ''secondary'' diagnoses of major problem codes because this category is where the other heart failure codes are currently assigned.

Response: We agree that the codes should have been described as an addition to the list of secondary diagnoses of major problem codes within DRGs 387 and 389. We have clarified this point in the description above.

Comment: One commenter who supported the addition of the heart failure-related diagnosis codes (428.20 through 428.43) to DRGs 387 and 389, asked for clarification of how diagnoses for combined codes that include congestive heart failure will be handled. The commenter mentioned code 402.91 (Hypertensive heart disease with heart failure, unspecified benign or malignant) as an example.

Response: We will conduct an additional review of DRGs 387 and 389 to determine if additional codes should be added to the list of secondary diagnoses of major problems for FY 2005. We encourage commenters to send their recommendations to us to assist in this review.

We are adopting our proposal as final, with the clarification that the major problem codes are secondary, not principal, codes. Accordingly, we are adding codes 428.20 through 428.43 listed above to the list of secondary diagnoses of major problem codes within DRGs 387 and 389.

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

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

High-dose IL–2 therapy is performed only in very specialized treatment settings, such as an intensive care unit or a bone marrow transplant unit. This therapy requires oversight by oncology health care professionals experienced in the administration and management of patients undergoing this intensive treatment because of the severity of the side effects. Unlike most cancer therapies, high-dose IL–2 therapy is associated with predictable toxicities that require extensive monitoring. Often patients require one-on-one nursing or physician care for extended portions of their stay.

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

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

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

According to industry sources, the wholesale cost of IL–2 is approximately $700 per vial. Dosages range between 15 and 20 vials per treatment, or between $10,500 and $14,000 per patient, per cycle, for the cost of the IL–2 drug alone. There is no ICD–9–CM procedure code that currently identifies patients receiving this therapy. Therefore, it is not possible to identify directly these cases in the MedPAR data. Currently, this therapy is coded using the more general ICD–9–CM code 99.28 (Injection or infusion of biologic response modifier). When we addressed this issue previously in the August 1, 2000 IPPS final rule (65 FR 47067) by examining cases for which procedure code 99.28

was present, our analysis was inconclusive due to the wide range of cases identified (1,179 cases across in 136 DRGs). However, recent data collected by the industry on 30 Medicare beneficiaries who received high-dose IL–2 therapy during FY 2002 show average charges for these cases of approximately $54,000.

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

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

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

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

- V58.1, Encounter for chemotherapy
- V67.2, Followup examination following chemotherapy

And one of the following secondary diagnoses:

- 204.00, Acute lymphoid leukemia without mention of remission
- 204.01, Acute lymphoid leukemia with remission
- 205.00, Acute myeloid leukemia without mention of remission
- 205.01, Acute myeloid leukemia with remission
- 206.00, Acute monocytic leukemia without mention of remission
- 206.01, Acute monocytic leukemia with remission
- 207.00, Acute erythremia and erythroleukemia without mention of remission
- 207.01, Acute erythremia and erythroleukemia with remission
- 208.00, Acute leukemia of unspecified cell type without mention of remission
- 208.01, Acute leukemia of unspecified cell type without mention of remission

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

In the proposed rule, we indicated that we would monitor cases with procedure code 00.15 as these data became available, and consider potential further refinements to DRG 492 as necessary.

Comment: Five commenters supported our proposed change. One commenter who opposed the proposed change believed that classifying high-dose IL–2 therapy as chemotherapy would be a violation of coding advice published in the American Hospital Association's coding publication, *Coding Clinic for ICD–9–CM*, because IL–2 therapy is a biologic response modifier and is considered immunotherapy, not chemotherapy. Therefore, the commenter asserted that the use of either V58.1 or V67.2 as principal diagnosis codes for these cases would result in erroneous coding advice. The commenter added that *Coding Clinic, Fourth Quarter,* page 51, indicates that when a patient is admitted for immunotherapy, the code for the neoplasm should be assigned as the principal diagnosis.

Response: We acknowledge the commenter's points concerning correct selection of principal diagnosis, as well as the advice published previously in *Coding Clinic*. However, the discussion of this topic has raised some concerns among the Cooperating Parties of AHA's Editorial Advisory Board. The advice given in the Fourth Quarter 1994 *Coding Clinic* predates the new treatment technology now available, which calls into question the correctness of the published advice. Therefore, this topic will be included on the agenda of an upcoming AHA Editorial Advisory Board meeting for further discussion and clarification. It is likely that new instructions will be issued in the next several months to clarify these coding instructions.

Therefore, in anticipation of this clarification, we are adopting as final the proposed changes to DRG 492. We will continue to monitor this DRG for shifts in resource consumption and validity of DRG assignment, and will specifically monitor code 00.15 for appropriate placement in DRG 492.

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

a. Implantable Devices

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

Currently, if these diagnosis codes are reported alone without an O.R. procedure, the case would be assigned to DRG 467 (Other Factors Influencing Health Status). However, if an O.R. procedure is reported with the principal diagnosis of V53.01, V53.02, or V53.09, the case would be assigned to DRG 461 (O.R. Procedure with Diagnoses of Other Contact with Health Services).

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

Because the procedures that are routinely used with these codes are in MDC 1, we believe it would be

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

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

We received three comments that supported our proposal to move diagnosis codes V53.01, V53.02, and V53.09 from MDC 23 to MDC 1. Accordingly, we are adopting as final the proposed reassignment, effective for discharges occurring on or after October 1, 2003.

b. Malignancy Codes

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

We agree that code V10.48 should have been included in the list of history of malignancy codes within DRG 465. Therefore, we proposed to add it to the list of secondary diagnoses in DRG 465.

We received several comments that supported this DRG modification. Accordingly, we are adopting the proposal as final without modification.

9. Medicare Code Editor (MCE) Change

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

We received a request to examine the MCE edit ''Adult Diagnosis—Age Greater than 14'' because currently the edit rejects claims for patients under age 15 who are being treated for gall bladder disease. We reviewed this issue with our pediatric consultants and determined that, although incidence is rare, gallbladder disease does occur in patients under age 15. Therefore, in the May 19, 2003 proposed rule, we proposed to modify the MCE by removing the following codes from the edit ''Adult Diagnosis—Age Greater Than 14'':

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

Comment: Four commenters agreed in general with our decision to remove the above listed codes from the MCE in the edit ''Adult Diagnosis—Age Greater than 14.'' However, one commenter recommended that all ICD–9–CM codes in the 575 through 577 range be removed from the edit and listed several codes that appeared to be missing from our list. These codes were 575.4 (Perforation of gallbladder), 577.0 (Acute pancreatitis), and 577.1 (Chronic pancreatitis). In addition, three commenters pointed out that code 574.90 had been erroneously listed twice with different narrative descriptions.

Response: We appreciate the commenters' interest in the correctness of the MCE. We also have received many telephone calls and e-mails concerning the typographical error with code 574.90. We have corrected the list above to reflect the correct code number, 574.91. As noted, the second narrative listing in the proposed rule correctly described code 574.91, not 574.90 (68 FR 27166).

With regard to the comment concerning the absence of codes 575.4 and 577.0 from the above list, we note that these codes are not included in the MCE edit. That is, these codes were never part of the MCE edit. With regard to code 577.1, this code is the last one on the list and was printed correctly in the proposed rule (68 FR 27166, third column).

Accordingly, we are adopting as final the proposal to remove the listed codes from the MCE edit ''Adult Diagnosis—Age Greater than 14,'' with the correction of the fifth digit of code 574.91 (Calculus of gallbladder and bile duct without cholecystitis with obstruction).

10. Surgical Hierarchies

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

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

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

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

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

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

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

Based on the preliminary recalibration of the DRGs, in the May 19, 2003 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, MDC 1 (Diseases and Disorders of the Nervous System), MDC 5 (Diseases and Disorders of the Circulatory System), MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue), and MDC 17 (Myeloproliferative Disease and Disorders, Poorly Differentiated Neoplasms for Lymphoma and Leukemia) as follows:

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

In the proposed rule, we were unable to test the effects of the proposed revisions to the surgical hierarchy and reflect these changes in the proposed relative weights because the revised GROUPER software was unavailable at the time the proposed rule was published. 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 resources used for each surgical class. We have now tested the proposed surgical hierarchy changes using the revised GROUPER software, and are reflecting the final changes in the DRG relative weights in this final rule. Further, as discussed in section II.C. of the preamble of this final rule, the final recalibrated weights are different from the proposed weights because they were based on more complete data.

Based on a test of the proposed revisions using the March 2003 update of the FY 2002 MedPAR file and the revised GROUPER software, we have found that the proposed change in the pre-MDC DRGs to reorder DRG 513 (Pancreas Transplant) above DRG 12 (Simultaneous Pancreas/Kidney Transplant) was not supported by the data. If this proposal were finalized, no cases would be assigned to DRG 512. The other proposed revisions are still supported by the data.

Comment: Two commenters expressed support for the proposed

change in the surgical hierarchy. Another commenter requested a change in the surgical hierarchy for a case in which a spinal fusion with subsequent debridement is performed during the same admission. This case is assigned to DRG 217 (Wound Debridement and Skin Graft Except Hand, for Musculoskeletal and Connective Tissue Disease). The commenter requested that this case be reassigned to DRG 497 (Spinal Fusion Except Cervical With CC) because it has a higher DRG weight than DRG 217.

Response: The surgical hierarchy places a patient with multiple procedures in the most resource intensive class, but this does not necessarily mean that the patient is assigned to the most resource intensive DRG. In this scenario, one surgical class is actually one DRG, and another surgical class is back and neck procedures. These classes encompass 7 DRGs (DRGs 496–500 and DRGs 519 and 520). The average charges for DRG 217 are approximately $15,000 more than the back and neck procedures class. DRG 217 is hierarchically ordered higher in the surgical group than DRG 497, which is the reason the case is assigned to DRG 217.

Therefore, we are adopting the proposed changes in MDCs 1, 5, 8, and 17 as final. We are not making any changes in the pre-MDC DRGs.

11. Refinement of Complications and Comorbidities (CC) List

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. 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. As we proposed in the May 19, 2003 proposed rule, we are not deleting any of the diagnosis codes on the CC list.

As explained in the May 19, 1989 proposed rule (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), 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.[3]

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, 2003. (See section II.B.13. 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.

Tables 6G and 6H in the Addendum to this final rule contain the revisions to the 13 CC Exclusions List that will be effective for discharges occurring on or after October 1, 2003. Each table shows the principal diagnoses with changes to the excluded CCs. Each of these principal diagnoses is shown with an asterisk, and the additions or deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis.

CCs that are added to the list are in Table 6G—Additions to the CC Exclusions List. Beginning with discharges on or after October 1, 2003, the indented diagnoses 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, 2003, the indented diagnoses will be recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

Comment: One commenter indicated that it was unable to provide meaningful comments on Tables 6G and 6H because of formatting errors in the printed tables. In addition, the commenter suggested that the changes in the tables should not be effective until a revised version was made available for public comment.

Response: We apologize for the errors in the format of the tables, which were printer's errors. However, we note that the tables did contain the correct codes, even though the format of the columns was distorted. Therefore, we do not believe a delay in the effective date of the changes is warranted.

Copies of the original CC Exclusions List applicable to FY 1988 can be obtained from the National Technical Information Service (NTIS) of the Department of Commerce. It is available in hard copy for $133.00 plus shipping and handling. A request for the FY 1988 CC Exclusions List (which should include the identification accession number (PB) 88–133970) should be made to the following address: National Technical Information Service, United States Department of Commerce, 5285 Port Royal Road, Springfield, VA 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, 2000, 2002, and 2003) and those in Tables 6G and 6H of this final rule for FY 2004 must be incorporated into the list purchased from NTIS in order to obtain the CC Exclusions List applicable for discharges occurring on or after October 1, 2003. (**Note:** There was no CC Exclusions List in FY 2001 because we did not make changes to the ICD–9–CM codes for FY 2001.)

Alternatively, the complete documentation of the GROUPER logic,

[3] See the September 30, 1988 final rule (53 FR 38485) for the revision made for the discharges occurring in FY 1989; the September 1, 1989 final rule (54 FR 36552) for the FY 1990 revision; the September 4, 1990 final rule (55 FR 36126) for the FY 1991 revision; the August 30, 1991 final rule (56 FR 43209) for the FY 1992 revision; the September 1, 1992 final rule (57 FR 39753) for the FY 1993 revision; the September 1, 1993 final rule (58 FR 46278) for the FY 1994 revisions; the September 1, 1994 final rule (59 FR 45334) for the FY 1995 revisions; the September 1, 1995 final rule (60 FR 45782) for the FY 1996 revisions; the August 30, 1996 final rule (61 FR 46171) for the FY 1997 revisions; the August 29, 1997 final rule (62 FR 45966) for the FY 1998 revisions; the July 31, 1998 final rule (63 FR 40954) for the FY 1999 revisions, the August 1, 2000 final rule (65 FR 47064) for the FY 2001 revisions; the August 1, 2001 final rule (66 FR 39851) for the FY 2002 revisions; and the August 1, 2002 final rule (67 FR 49998) for the FY 2003 revisions.) In the July 30, 1999 final rule (64 FR 41490), we did not modify the CC Exclusions List for FY 2000 because we did not make any changes to the ICD–9–CM codes for FY 2000.

including the current CC Exclusions List, is available from 3M/Health Information Systems (HIS), which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. The current DRG Definitions Manual, Version 20.0, is available for $225.00, which includes $15.00 for shipping and handling. Version 21.0 of this manual, which includes the final FY 2004 DRG changes, is available for $225.00. These manuals may be obtained by writing 3M/HIS at the following address: 100 Barnes Road, Wallingford, CT 06492; or by calling (203) 949–0303. Please specify the revision or revisions requested.

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

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

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

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

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

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

We annually conduct a review of procedures producing assignment to DRG 468 or DRG 477 on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these DRGs into one of the surgical DRGs for the MDC into which the principal diagnosis falls. The data are arrayed two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical DRGs for the MDC in which the diagnosis falls. Based on this year's review, we did not identify any necessary changes in procedures under DRG 477. Therefore, we did not propose moving any procedures from DRG 477 to one of the surgical DRGs in this final rule.

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

We received several comments of support for our proposal to assign code 50.29 to DRGs 170 and 171 in MDC 6. Therefore, we are adopting the proposal as final without modification. As a result, code 50.29 will not result in assignment to DRG 468 when this procedure is performed on patient with a principal diagnosis in MDC 6.

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

We also annually review the list of ICD–9–CM procedures that, when in combination with their principal diagnosis code, result in assignment to DRGs 468, 476, and 477, to ascertain if any of those procedures should be reassigned from one of these 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 our review this year, we did not propose moving any procedures from DRG 476 to DRGs 468 or 477, or from DRG 477 to DRGs 468 or 476.

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

- 38.21, Biopsy of blood vessel
- 77.42, Biopsy of scapula, clavicle and thorax [ribs and sternum]
- 77.43, Biopsy of radius and ulna
- 77.44, Biopsy of carpals and metacarpals
- 77.45, Biopsy of femur
- 77.46, Biopsy of patella

- 77.47, Biopsy of tibia and fibula
- 77.48, Biopsy of tarsals and metatarsals
- 77.49, Biopsy of other bones
- 92.27, Implantation or insertion of radioactive elements

We note that the above codes being moved from DRG 468 to DRGs 476 and 477 were erroneously listed in the May 19, 2003 proposed rule under section II.B.12.c., which related to adding diagnosis or procedure codes to MDCs, instead of section II.B.12.b., which discussed the reassignment of procedures among DRGs 468, 476, and 477. We regret any inconvenience this inadvertent listing may have caused.

Comment: One commenter asked us to consider moving procedure code 51.23, Laparoscopic cholecystectomy, from DRG 468 and adding it to DRG 477. The commenter indicated that this procedure is often performed in the outpatient setting.

Response: We believe that the commenter's request has merit. We will perform the necessary data analysis and will consider proposing this change in next fiscal year's rule if we find that the data support this change.

c. Adding Diagnosis or Procedure Codes to MDCs

Based on our review this year, we did not propose adding any diagnosis codes to MDCs in this final rule. We did not receive any comments on the proposal.

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

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

The ICD–9–CM Manual contains the list of valid diagnosis and procedure codes. (The ICD–9–CM Manual is available from the Government Printing Office on CD–ROM for $23.00 by calling (202) 512–1800.) The NCHS has lead responsibility for the ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the above process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as 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 2004 at a public meeting held on December 6, 2002, and finalized the coding changes after consideration of comments received at the meetings and in writing by January 10, 2003. Those coding changes are announced in Tables 6A and 6B of this final rule. Copies of the minutes of the procedure codes discussions at the Committee's 2002 meetings can be obtained from the CMS Web site: *http://www.cms.gov/paymentsystems/icd9/.* The minutes of the diagnoses codes discussions at the 2002 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.

The first of the 2003 public meetings was held on April 3, 2003. In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include all proposals discussed and approved at the April meeting as part of the code revisions effective the following October. Because the proposed rule was published after the April meeting, we were able to include all new procedure codes that were approved subsequent to that meeting in Table 6B of the Addendum to the proposed rule, including the DRG assignments. However, the National Center for Health Statistics (NCHS) created and finalized three new severe acute respiratory syndrome (SARS) related codes after the proposed rule was published. These new codes, which were not listed in Table 6A of the Addendum to the proposed rule, have been included in Table 6A of the Addendum to this final rule. The new codes are as follows:

- 079.82, SARS-associated coronavirus
- 480.3, Pneumonia due to SARS-associated coronavirus
- V01.82, Exposure to SARA-associated coronavirus

These new codes have been identified with a footnote (1) in Table 6A of the Addendum to this final rule.

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

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

Questions and comments concerning the procedure codes should be addressed to: Patricia E. Brooks, Co-Chairperson; ICD–9–CM Coordination and Maintenance Committee; CMS, Center for Medicare 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: *pbrooks1@cms.hhs.gov.*

The ICD–9–CM code changes that have been approved will become effective October 1, 2003. The new ICD–9–CM codes are listed, along with their DRG classifications, in Tables 6A and 6B (New Diagnosis Codes and New Procedure Codes, respectively) in the Addendum to this 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. Accordingly, in the May 19, 2003 proposed rule, we only solicited comments on the proposed DRG classification of these new codes.

Comment: One commenter expressed concern about the MDC and DRG designations for new diagnosis code 752.89 (Other specified anomalies of genital organs) that was included in

Table 6A of the Addendum to the proposed rule. We had proposed assigning this new code to MDC 12 (Diseases and Disorders of the Male Reproductive System), and DRG 352 (Other Male Reproductive System Diagnoses). The commenter pointed out that this new code could apply to both males and females. Its predecessor code was assigned to MDC 12, DRG 352, as well as to MDC 13 (Diseases and Disorders of the Female Reproductive System) and DRGs 358 (Uterine and Adnexa Procedure for Non-Malignancy with CC), 359 (Uterine and Adnexa Procedure for Non-Malignancy without CC), and 369 (Menstrual and Other Female Reproductive System Disorders).

Response: The commenter is correct. Diagnosis code 752.89 would apply to both males and females and should have been included in both MDC 12 and MDC 13. In this final rule, we are assigning diagnosis code 752.89 to MDC 13 under DRGs 358, 359, and 369 and have modified Table 6A of the Addendum to this final rule accordingly.

Comment: One commenter pointed out a typographical error for the code title for V15.87. The commenter indicated that the word ''membrance'' should be changed to ''membrane''; that is, the title should read ''History of Extracorporeal Membrane Oxygenation (ECMO).''

Response: We agree with the commenter and have corrected the title in Table 6A of the Addendum to this final rule.

For codes that have been replaced by new or expanded codes, the corresponding new or expanded diagnosis codes are included in Table 6A. New procedure codes are shown in Table 6B. Diagnosis codes that have been replaced by expanded codes or other codes or have been deleted are in Table 6C (Invalid Diagnosis Codes). These invalid diagnosis codes will not be recognized by the GROUPER beginning with discharges occurring on or after October 1, 2003. Table 6D contains invalid procedure codes. Revisions to diagnosis code titles are in Table 6E (Revised Diagnosis Code Titles), which also includes the DRG assignments for these revised codes. Table 6F includes revised procedure code titles for FY 2004.

The Department of Health and Human Services has been actively working on the development of new coding systems to replace the ICD–9–CM. In December 1990, the National Committee on Vital and Health Statistics (NCVHS) issued a report noting that, while the ICD–9–CM classification system had been responsive to changing technologies and identifying new diseases, there was concern that the ICD classification might be stressed to a point where the quality of the system would soon be compromised. The ICD–10–CM (for diagnoses) and the ICD–10–PCS (for procedures) were developed in response to these concerns. These efforts have become increasingly important because of the growing number of problems with the ICD–9–CM, which was implemented 24 years ago.

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

Comment: Several commenters supported the move to ICD–10–CM and ICD–10–PCS as national coding standards. One commenter representing hospitals supported moving to these systems expeditiously. The commenter stated that ICD–10–CM and ICD–10–PCS are a vast improvement over ICD–9–CM and would provide greater specificity and detail in coding. Another commenter believed that the new systems would offer immediate and long-term benefits for specifying illness severity and accommodating a diverse array of new technologies that warrant expedited assignment under the DRG system.

Response: We appreciate the support from many in the health care industry for ICD–10–CM and ICD–10–PCS. We agree with the importance of having and maintaining medical coding systems that accurately capture the patient's conditions and medical procedures. We also agree that ICD–9–CM is seriously constrained because of its structure and space limitations. We recognize that over 30 countries have implemented ICD–10 to better capture medical conditions. Countries such as Canada and Australia have successfully implemented ICD–10 without serious ramifications to their data or reimbursement systems. We agree that it is important to capture information on new technologies. It is becoming increasingly difficult to do so using ICD–9–CM. We will continue working with NCVHS and the health care industry to determine if these new systems should be named as national coding standards.

14. Other Issues

In addition to the specific topics discussed in section II.B.1. through 13. of this preamble, we considered a number of other DRG-related issues in the May 19, 2003 proposed rule. Below is a summary of the issues that were addressed.

a. Cochlear Implants

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

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

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

$25,052 for noncochlear implant cases), this difference is much less than the $36,000 and $85,000 differences for heart assist systems cited above.

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

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

Accordingly, for the reasons cited above, we did not propose to change the DRG assignment of cochlear implants in the May 19, 2003 proposed rule. However, we did encourage public comments as to whether a new DRG for cochlear implants (or some other solution) is warranted.

Comment: Several commenters urged CMS to reassign cochlear implantation procedures to a DRG that has a weight appropriate to reflect the costs of cochlear implantation. The commenters stated that while a hospital's acquisition cost of the device itself averages approximately $23,800, the proposed payment for FY 2004 is approximately $8,233. While most cochlear implants have been and will continue to be performed on an outpatient basis, a small, but significant portion, particularly for Medicare beneficiaries, need to be conducted as an inpatient procedure. The commenters stated that the low volume of inpatient cases is a direct result of the inadequate payment rate.

The commenters stated that cochlear implantation is clinically incongruent and economically inconsistent with the other procedures in DRG 49. The commenters believed that cochlear implants do not meaningfully affect the weighting of DRG 49 and proposed two options: Create a new DRG specifically for cochlear implants, or reassign cochlear implants cases to DRG 482 (Tracheostomy for Face, Mouth, and Neck Diagnoses).

Response: We requested public input on possible solutions for these cases because we recognize the data indicate the charges for these cases are much higher than for other cases in DRG 49. However, we are concerned that the options suggested by commenters are not workable solutions. As we alluded to in the proposed rule, we have concerns about creating a new DRG for this procedure. We appreciate the point made by commenters that only those patients requiring inpatient care would receive the procedure in an inpatient setting, even if the DRG payment were increased. However, as we have stated previously, we are reluctant to create new DRGs 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. Hospitals are generally able to offset any losses on such procedures through corresponding payment advantages from other, less expensive procedures.

The second option suggested, to reassign these cases to DRG 482, is inconsistent with the structure of that DRG, which requires that a tracheostomy be performed in order to be assigned to this DRG. Assigning cochlear implants to this DRG would fundamentally alter its structure, which could not be done without first proposing such a change for public review and comment.

However, as we indicated above, we recognize the disparity in average charges for these cases compared to other cases in DRG 49, and will continue to evaluate possible reclassification options for FY 2005.

b. Burn Patients on Mechanical Ventilation

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

In the August 1, 2002 final rule, we modified DRGs 482 and 483 to recognize code 96.72 (Continuous mechanical ventilation for 96 consecutive hours or more) for the first time in the DRG assignment (67 FR 49996). We noted that many patients assigned to DRG 483 did not have code 96.72 recorded. We believed this was due, in part, to the limited number of procedure codes (six) that can be submitted on the current billing form, and the fact that code 96.72 did not affect the DRG assignment (prior to FY 2003). We stated that we would give future consideration to further modifying DRGs 482 and 483 based on the presence of code 96.72. We anticipate that cases of patients receiving 96 or more hours of continuous mechanical ventilation are more expensive than other tracheostomy patients. Once code 96.72 is reported more frequently, we will be better able to assess the need for future revisions to DRGs 482 and 483.

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

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

We received one comment from an organization representing coders that agreed with the importance of reporting code 96.72 and the need for further education on this issue. We will continue to monitor our data to assess

the payment for burn patients on mechanical ventilation in the future.

c. Multiple Level Spinal Fusion

Prior to the publication of the proposed rule, we received a comment recommending the establishment of new DRGs that would differentiate between the number of levels of vertebrae involved in a spinal fusion procedure. The commenter noted that the ICD–9–CM Coordination and Maintenance Committee discussed adding a new series of codes to identify multiple levels of spinal fusions at its December 6, 2002 meeting.

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

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

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

The analysis found that increasing the levels fused from 1 to 2 levels to 3 or more levels increased the mean standardized charges by 38 percent for lumbar/thoracic fusions, and by 47 percent for cervical fusions. The commenter then recommended redefining the spinal fusion DRGs to differentiate between 1 to 2 level spinal fusions and multilevel spinal fusions.

The following current spinal fusion DRGs separate cases based on whether or not a CC is present: DRG 497 (Spinal Fusion Except Cervical With CC) and DRG 498 (Spinal Fusion Except Cervical Without CC); and DRG 519 (Cervical Spinal Fusion With CC) and DRG 520 (Cervical Spinal Fusion Without CC). The difference in charges associated with the current CC split is only slightly greater than the difference attributable to the number of levels fused as found by the commenter's analysis. Therefore, in the May 19, 2003 proposed rule, we did not propose to redefine these DRGs to differentiate on the basis of the number of levels fused.

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

Comment: Several commenters supported our proposal to wait for data using the new ICD–9–CM procedure codes for multiple level spinal fusions prior to making revisions to the spinal fusion DRGs. One commenter representing hospitals supported our proposal to continue with the current DRG classification system until sufficient data are available to evaluate a potential DRG change. Several commenters expressed their appreciation for the creation of the new codes for multiple level spinal fusion. They recognized the difficult challenge that was involved in developing this new classification system as part of ICD–9–CM.

One commenter requested us to proceed with a DRG revision for multiple level spinal fusion without waiting for data using the new codes. This commenter stated that there are significant costs involved with increased instrumentation and hardware when multiple level spinal fusions are performed, and requested that we consider using non-MedPAR data to establish relative weights for new DRGs based on the levels of vertebrae involved. In addition, the commenter stated that there is a need to distinguish between fusions and refusions within the DRGs. The commenter stated that refusions vary significantly due to the existence of scar tissue and implants that need to be removed and replaced. Further, the commenter recommended that we split DRG 496 Combined anterior/posterior spinal fusion based on the presence or absence of a complication or comorbidity.

Response: We appreciate the support of commenters that we wait for data from the reporting of the new codes for multiple level spinal fusion prior to proposing revisions to the spinal DRGs (rather than using non-MedPAR data prior to the availability of data using the new codes). We also appreciate the comments concerning the extensive effort it took on our part to develop a set of ICD–9–CM codes that could capture this type of information. We believe it is important to carefully examine hospital data prior to making any revisions for multiple level spinal fusions. Therefore, we will look at this data as we receive it and evaluate any need for DRG revisions. We will consider all the points raised by the commenters as we consider additional DRG revisions for spinal fusions in the future.

d. Heart Assist System Implant

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

When we reviewed the FY 2002 MedPAR data, we identified only 21 cases in DRG 103 that listed a procedure code indicating the use of any heart assist system. We do not believe that 21 cases is a sufficient number of cases to support creation of an additional DRG. Therefore, in the May 19, 2003 proposed rule, we did not propose a change to the structure of either DRG 103 or DRG 525.

Comment: Two commenters argued that procedure code 37.66 (Implant of an implantable, pulsatile heart assist system) does not fit clinically or financially with the following other procedure codes in DRG 525:

- 37.62, Implant of other heart assist system,
- 37.63, Replacement and repair of heart assist system,
- 37.65, Implant of an external, pulsatile heart assist system
- 37.66, Implant of an implantable, pulsatile heart assist system.

One commenter indicated that, according to an analysis that it performed, Medicare data on procedure code 37.66 demonstrates that average charges ($342,725) and length of stay

(40.1 days) are significantly higher than data on all other procedures in DRG 525 (average charges ranging from $112,748 to $190,672) and (average length of stay ranging from 10.9 to 16.7). According to the commenter, the implantable pulsatile technology represents a different class of device and procedure (long-term support) compared to the less resource intensive, short-term devices used in other procedures in DRG 525.

The commenters requested three possible alternatives for the reclassification of procedure code 37.66: (1) Create a unique DRG for this procedure; (2) add this procedure code to DRG 103 (Heart Transplant); or (3) add a new technology add-on payment for code 37.66 to DRG 525.

Response: In response to comments we received on the creation of new DRG 525 last year, we noted that these four codes represent the most expensive cases in MDC 5 (67 FR 49991). However, the specific point made by the commenters this year, that procedure code 37.66 is significantly different in terms of clinical procedures and resource utilization from the other procedures in DRG 525, was not raised prior to this year's proposed rule.

While we recognize the significant disparities referenced by the commenter warrant further consideration, the potential solutions suggested by the commenter are significant changes to the DRG system that warrant public comment. In particular, the reassignment of code 37.66 to DRG 103 would result in inclusion of nontransplant cases in this existing single-procedure DRG. Therefore, in light of the significant impacts of each of the commenters' suggestions on the structure of the DRGs involved and the need to submit any such significant impacts to public review and comment, we are not changing DRG 525 for FY 2004. We appreciate the commenter bringing this issue to our attention. We will evaluate whether to make further changes to DRG 525 in light of the information that there is significant disparity in the costs of the different procedures included in the DRG. We note that the outlier payment policy will help to offset extraordinarily expensive costs.

Furthermore, the volume and mix of cases in this DRG is likely to change over the next year. Currently, CMS has approved the use of LVADs in two instances. They can be used as either a bridge to heart transplant or for support of blood circulation postcardiotomy (the period following open-heart surgery). In these two applications, the LVAD is used as temporary mechanical circulatory support. CMS is currently reviewing a request for expanded coverage for these devices as destination (or permanent) therapy for end-stage heart failure patients who are not candidates for heart transplantation. Destination therapy means that the patient will use the LVAD for the remainder of his or her life.

We believe it will be helpful to have data on the resources and volume associated with any potential destination therapy cases prior to revising DRG 525.

e. Drug-Eluting Stents

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

In the absence of MedPAR data reflecting the use of drug-eluting stents, it was necessary to undertake several calculations to establish the FY 2003 DRG relative weights for these two new DRGs. First, based on prices in countries where drug-eluting stents were already being used compared to the average price of nondrug-eluting stents in those countries, we calculated a price differential of approximately $1,200. When we apply average overall hospital charge markups to this technology (based on weighted average cost-to-charge ratios), we estimated that the charge differential between nondrug-eluting and drug-eluting stents would be approximately $2,664 per stent. However, we recognize that some cases involve more than one stent. Using an average of 1.5 stents per procedure, we estimated that the net incremental charge for cases that would receive drug-eluting stents is $3,996.

In order to determine accurately the DRG relative weights for these two new DRGs relative to all other DRGs, we also must estimate the volume of drug-eluting stent cases likely to occur. We used the manufacturer's estimate that as many as 43 percent of current stent patients will receive drug-eluting stents during FY 2003 to calculate the FY 2003 DRG relative weights, although we prorated this percentage since the new DRGs did not become active until April 1, 2003.[4]

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

Comment: In response to our statement in the proposed rule that we would use the best available data to establish the FY 2004 relative weights for DRGs 526 and 527, one commenter (the manufacturer of the only FDA-approved drug-eluting stents at this time) commissioned an independent accounting firm to collect costs, charges, and utilization data from hospitals on drug-eluting and nondrug-eluting stents.

The data were collected from a randomized, statistically significant sample of United States hospitals with interventional cardiac catherization laboratories. First, the firm identified those hospitals that performed coronary angioplasty on Medicare beneficiaries. The method used to identify these hospitals was first to review MedPAR data to isolate those hospitals with average volume in DRGs with a placement of coronary artery stent, ICD–9–CM procedure code (36.06). From this list of hospitals, it was necessary to eliminate those that appeared to have quality issues with the data. This resulted in a list of 1,033 hospitals for the ''population'' group from which the sample was drawn.

A sample size sufficient to achieve a confidence level of 95 percent that the results would be within 5 percent of the actual distribution (assuming a normal distribution) was then determined, and a randomized selection within each state identified 279 hospitals. An additional 30 hospitals from a preliminary phase of the study were added because these hospitals had already supplied nondrug-eluting stent data and had committed to supply drug-

[4] Even though the DRG became active on April 1, 2003, we expect that hospitals did not use this technology before FDA approval. (We intend to identify and review any cases with the code 36.07 that occurred prior to FDA approval.) Therefore, no payments are expected to have been made under these DRGs for cases occurring before FDA approval.

eluting stent data. Therefore, the total sample size for the survey instrument was 309 hospitals.

At the time of the survey, 83 of the selected hospitals had not yet received shipments of the drug-eluting stents and, hence, were not able to complete the survey because they had no cost or charge data for drug-eluting stents. The final number of completed surveys was 119 (or 53 percent of the sample).

The survey was designed to collect data regarding costs, charges, and utilization for drug-eluting stents at three different points in time: currently; October 1, 2003; and at full-maturity (defined as that point in time in which the hospital has achieved a stable and consistent usage of the drug-eluting stent). The data were submitted (including a sample of invoices) under a request for confidential treatment under the Freedom of Information Act.

Based on the data collected, the commenter recommended that CMS increase the harge differential between nondrug-eluting and drug-eluting stents to create a payment differential of $3,024. This represents the cost per case differential between nondrug-eluting stent and drug-eluting stent cases anticipated by surveyed hospitals on October 1, 2003. The current cost differential reported by the sample of hospitals was $2,721. The commenter estimated that our proposed methodology results in a payment differential of $1,451 and $1,495 between DRGs 516 and 526, and DRGs 517 and 527, respectively. The surveyed hospitals reported average current and anticipated stents used per case of 1.4 and 1.5, respectively. Average projected utilization of drug-eluting stents relative to all stents was reported in the survey to currently be 33 percent, and by October 1, 2003, utilization is projected to be 69 percent.

Another commenter noted that the actual cost per stents is 59 percent higher than our projection of $1,200. The commenter also noted that most cases use 2 stents instead of the projected 1.5 stents, and, therefore, the net incremental charge difference should be $5,554 instead of the $3,996 projected by CMS.

Response: The data submitted was extensively detailed and helped us better understand the costs, charges, and utilization for all types of stents. As noted above, we stated in the proposed rule that we would use the best available data at the time of the final rule to establish the FY 2004 relative weights for DRGs 526 and 527, and these data are much more detailed and current than any other sources available to us at this time. These data are extremely useful to assess the appropriateness of our proposed methodology to determine the relative weights for DRGs 526 and 527.

The commenter recommended that CMS establish a payment differential between DRGs for nondrug-eluting stents and drug-eluting stents of $3,024 to account for the estimated cost difference between the two types of stents. However, the DRG relative weights are established using the average charges per case of each DRG relative to the national average. Therefore, we examined the charge per case data from the sample.

The commenter referred to a mean charge differential per case of $5,721, based on anticipated costs per drug-eluting stent on October 1, 2003. However, we do not believe it is appropriate to use anticipated October 1, 2003 charges for several reasons. First, these data cannot be substantiated. As noted above, we received a sampling of current invoices that allowed us to verify the current costs per drug-eluting stent. These invoices cannot verify the $300 average per stent cost increase that reportedly will occur between the time the survey was conducted and October 1, 2003. Second, for all other DRGs, we are using charge data reflective of FY 2002 charges. Although we are establishing the FY 2004 relative weights in this final rule, using anticipated FY 2004 charge data would result in 2-year later charge data being used to establish the DRG 526 and 527 relative weights, while FY 2002 charge data are used to establish all other relative weights. Therefore, we believe the current data more closely approximate the data used to determine the FY 2004 relative weights for the remainder of the DRGs. Finally, hospitals must rely upon the manufacturer of the only currently available drug-eluting stents for information on future pricing. We believe this raises questions as to the validity of the data due to the lack of independently verifiable pricing data for the future.

Therefore, we are basing our evaluation of our proposed methodology on the sample data from the current period. The commenter reported a mean differential in charges per case of $4,859 for the current period. However, we are concerned that the mean differential in charges per case is unduly influenced by extraordinarily high charge markups reported on the part of some hospitals. For example, one hospital reported charging $28,000 per drug-eluting stent, while its costs per stent were only $3,023. This same hospital reported charges of $9,500 for nondrug-eluting stents, with costs per stent of $1,010. To control the distorting impact such a hospital would have on the mean charge differential, we examined the geometric mean charge differential based on current charges per case.

The survey data showed that, for seven hospitals, the charge per case was higher for nondrug-eluting stent cases. In order to calculate the geometric mean differential charge per case, it was necessary to remove these seven negative differentials. The result was a current geometric mean differential charge per case of $4,186. As an alternative to removing these seven negative numbers, we set them to a $1 differential, and calculated a geometric mean differential charge per case of $2,291. Based on the range of these results, we believe our proposed charge differential of $3,996 represents a reasonable approximation of the differential in charges per case, and we are proceeding to establish the DRG relative weights for DRGs 526 and 527 for FY 2004 using this amount.

We note that there is a difference between CMS and the commenter on the current cost difference between drug-eluting stents and nondrug-eluting stents (our estimate began with a $1,200 per stent differential, while the survey found a $2,721 current differential). It appears that the reason our charges per case for drug-eluting stents and nondrug-eluting stents are not substantially different from the charges in the survey data, despite the discrepancy in the cost differential, is due to the fact that hospitals are not marking up drug-eluting stents by the same proportion as nondrug-eluting stents. From the data submitted by the commenter, we found the average charge increase for nondrug-eluting stents is 183 percent. The average charge increase for drug-eluting stents is 124 percent. This lower markup reduces the differential in charges relative to the actual costs hospitals may incur.

Based on data submitted to us last year by the commenter, we proposed that 43 percent of stent cases from DRGs 516 and 517 would be reassigned to DRGs 526 and 527. However, based on the survey data, for FY 2004 we are changing our estimate to assume that 69 percent of coronary stent cases will be reassigned from DRGs 516 and 517 to DRGs 526 and 527, respectively. We note that, although this percentage is based on anticipated utilization on October 1, 2003, it is not based on data that is only available from the manufacturer. We are continuing to assume a utilization rate of 1.5 stents per case.

Comment: Many commenters argued that the proposed payment for drug-eluting stents is inadequate and asked that CMS consider the data it has received to date from hospital claims to determine whether the proposed FY 2004 payment rate for drug-eluting stents is adequate. Other commenters requested that CMS use the most current United States data available (as opposed to data from the United Kingdom) to establish the DRG weights for FY 2004.

Some commenters noted that current DRG weights account for 1.5 stents per case, but that the number of stents per case is expected to rise because the insertion of drug-eluting stents is more technically challenging in comparison to competitive products. The commenters also noted that because drug-eluting stents are able to treat smaller vessels, more diffuse disease in diabetics, and longer lesions, a rise is expected in the stent per patient ratio. The commenters asked that CMS adjust its ratio of 1.5 stents per case to an amount closer to 2 stents per case when recalibrating the DRG weights. Another commenter explained that, based on their analysis, an average of 1.7 drug-eluting stents is used per procedure and the average cost per drug-eluting stent is $3,195. The commenter requested that these amounts be used to compute the relative weights for DRGs 526 and 527. The commenter also noted that the payment rates for FY 2003 are higher than the payment rates for FY 2004 due to the decline in the DRG relative weights.

One commenter suggested as an alternative to increasing the weights for drug-eluting stents that payment be contingent on the type and number of stents used per procedure. The commenter recommended that CMS set up revenue codes to indicate the type and number of stents used per case and make payment approximately $1,000 above the cost per stent.

Another commenter also noted that the demand from hospitals for drug-eluting stents is much higher than the projected 43 percent of coronary artery stent cases. The commenter estimated that 85 to 90 percent of all stent cases should be reassigned from DRGs 516 and 517 to DRGs 526 and 527. Another commenter explained that drug-eluting stents, compared with nondrug-eluting stents, have already been shown to decrease angiographic restenosis in coronary arteries by more than half, which should reduce the need for repeat procedure rates from 20 percent of cases to less than 5 percent. As a result, demand for drug-eluting stents is expected to increase and the commenter estimated that 70 percent of all coronary artery stent cases will involve the use of drug-eluting stents. Therefore, 70 percent of all stent cases should be moved to DRGs 526 and 527 to account for drug-eluting stents instead of the 43 percent proposed by CMS.

One commenter explained that there are many added costs of using drug-eluting stents, such as that the area of blockage to be treated is to be predilated with an angioplasty balloon before and after implanting the stent, the use of intravascular ultrasound to ensure proper positioning and deployment of stents in certain cases, and increased length of time a patient spends in the cardiac catheterization laboratory. The commenter also added that percutaneous transluminal coronary angioplasty volume is expected to increase due to obesity, smoking, sedentary lifestyle, and diabetes. Therefore, the commenter recommended that CMS ensure that drug-eluting stents are adequately paid.

Response: As described above, we used data submitted to us from a survey of U.S. hospitals to evaluate our proposed methodology. Our analysis indicates that the proposed charge differential and the number of stents per procedure in our methodology are appropriate. However, we have increased our assumed utilization rate of drug-eluting stents to 69 percent from 43 percent, based on these data.

With respect to the decline in the proposed FY 2004 DRG relative weights compared to FY 2003, every year we recalibrate the DRG weights comparing the average charge per DRG to all other DRGs. The weights of one DRG can change for numerous reasons (for example, increase or decrease in total cases or increase or decrease in charges) and cause weights from other DRGs to increase or decrease due to budget neutrality.

As we proposed, we are maintaining DRGs 526 and 527 for FY 2004, and adopting the same methodology to establish the relative weights as we used for FY 2003. We have used the best available data to establish the final FY 2004 relative weights for DRGs 526 and 527 included in this final rule. We will continue to evaluate the appropriate assignment of these cases in the future.

Comment: One commenter recommended that CMS move drug-eluting stents to DRGs 516 and 517 and adjust the weights, because CMS should not provide a financial incentive for hospitals to favor one therapy when other alternatives with equal or better outcomes are available. The commenter stated further that CMS should not create an incentive that promotes a more expensive treatment for which risks and benefits are not yet completely known. Another commenter suggested that drug-eluting stents should receive add-on payments for new technology instead of receiving their own DRG payment.

Response: We explained our rationale for creating new DRGs 525 and 526 (instead of assigning these cases to DRGs 516 or 517 or approving a new technology add-on) in the August 1, 2002 IPPS final rule (67 FR 50005) and refer the commenters to that rule for our response. We appreciate the commenter's continual input and interest in these issues.

f. Artificial Anal Sphincter

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

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

170 and DRG 171 are higher weighted than DRGs 157 and 158.

In the May 19, 2003 proposed rule, we did not propose to assign these cases to DRGs 170 and 171. Although we recognized that the data submitted by the commenter appear to show this procedure is associated with above average costs in the DRGs to which these cases are assigned, we stated that we believe the current assignment is the most clinically appropriate at this time. As noted above, the procedure codes to identify the implantation, revision, or removal of these devices were effective beginning on October 1, 2002. Therefore, we proposed to monitor the costs of these cases using actual Medicare cases with these codes included from the FY 2003 MedPAR that will be used for the FY 2004 DRG relative weights.

Comment: Two commenters expressed concern that the procedures for insertion and removal of an artificial anal sphincter are assigned to DRG groupings that do not cover the cost of the device. In addition, one commenter stated that, as the surgeon must operate on two distinct areas of the patient's body, these procedures are more resource-intensive and, therefore, are not clinically coherent with other procedures of low complexity in DRGs 157 and 158.

Response: As noted above, the codes describing the implantation, revision, or removal of artificial anal sphincters were created for use beginning on October 1, 2002. Therefore, we do not have data on cases assigned to codes 49.75 and 49.76. Accordingly, we are not making any changes to the DRG assignments of these codes at this time. However, we will continue to monitor this procedure in the upcoming MedPAR data and will, in the future, consider modifications relating to DRG assignment(s) if warranted.

C. Recalibration of DRG Weights

As we proposed, in this final rule we used the same basic methodology for the FY 2004 recalibration as we did for FY 2003 (August 1, 2002 IPPS final rule (67 FR 50008). That is, we recalibrated the DRG weights based on charge data for Medicare discharges using the most current charge information available (the FY 2002 MedPAR file).

The MedPAR file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2002 MedPAR data used in this final rule include discharges occurring between October 1, 2001 and September 30, 2002, based on bills received by CMS through March 31, 2003, from all hospitals subject to the IPPS and short-term acute care hospitals in Maryland (which is under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2002 MedPAR file includes data for approximately 11,496,239 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. This is a change from the recalibration methodology in the proposed rule, where hospitals that subsequently became CAHs were included in the data. In this final rule, we changed the recalibration methodology for consistency with our change that excluded these CAHs from the data used to construct the wage index.

The methodology used to calculate the DRG relative weights from the FY 2002 MedPAR file is as follows:

- To the extent possible, all the claims were regrouped using the DRG classification revisions discussed in section II.B. of this preamble.
- The transplant cases that were used to establish the relative weight for heart and heart-lung, liver, and lung transplants (DRGs 103, 480, and 495) were limited to those Medicare-approved transplant centers that have cases in the FY 2000 MedPAR file. (Medicare coverage for heart, heart-lung, liver, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average charge for the DRG and before eliminating statistical outliers.
- 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 (1.45726) so that the average case weight after recalibration is equal to the average case weight before recalibration. This adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS.

As noted below in section IV.A.2. of the preamble of this final rule, we are expanding the transfer policy applicable to postacute care transfers to a total of 29 DRGs (the current 10 DRGs, minus 2, plus 21 additional DRGs), beginning in FY 2004. Because we count a transfer case as a fraction of a case as described above in the recalibration process, the expansion of the postacute care transfer policy to additional DRGs affects the relative weights for those DRGs. Therefore, we calculated the final FY 2004 normalization factor comparing: the case-mix using the final FY 2004 DRG relative weights in which we treated postacute care transfer cases in the additional DRGs for the postacute transfer policy for FY 2004 as a fraction of a case with the case-mix using the FY 2003 DRG relative weights without treating cases in these additional DRGs as transfer cases.

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

Comment: Commenters questioned the fact that the proposed weights for several DRGs declined from the prior fiscal year.

Response: As described above, the relative weight for each DRG is

calculated by comparing the average charge for cases within each DRG (after removing statistical outliers) with the national average charge per case. Therefore, there are several factors that can cause a shift in the relative weight of a DRG from one fiscal year to the next. For example, even though the average charges of cases within a particular DRG may have increased, if they did not increase by an equal or greater percentage than the national average, the DRG relative weight would decline. In this final rule, the weights for 223 DRGs for FY 2004 decline from those for FY 2003 (all but 38 DRGs by less than 5 percent), while the weights for 299 DRGs for FY 2004 increased from those for FY 2003 (all but 39 DRGs by less than 5 percent).

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: One commenter expressed concern that the impact of the proposed DRG recalibration is a $3 million decrease in payments to its hospitals. The commenter was hopeful that the budget neutrality adjustment to ensure that the normalization of DRG weights is achieved will somehow restore the estimated negative impact.

Response: As explained above and in the proposed rule, section 1886(d)(4)(C)(iii) of the Act requires that the changes made through DRG reclassification and recalibration be made in a manner that assures that the aggregate payments are neither greater than nor less than the aggregate payment that would have been made without the changes. However, this requirement refers to aggregate national payments. Therefore, for individual hospitals, the impacts of these changes may be either positive or negative.

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

1. Background

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

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

As we explained in the May 19, 2003 IPPS proposed rule (68 FR 27173), we proposed revisions to the LTC–DRG classifications and relative weights and indicated that we would finalize them in the IPPS final rule, to be effective October 1, 2003 through September 30, 2004. The final LTC–DRGs and relative weights for FY 2004 in this final rule are based on the IPPS DRGs (GROUPER version 21.0) discussed in section II. of this final rule.

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, under this final rule, we will use the IPPS version 21.0 GROUPER for FY 2004 to process LTCH PPS claims. The changes to the IPPS DRG classification system for FY 2004 (Grouper 21.0) are discussed in section II.B. of this preamble.

Under the LTCH PPS, we determine relative weights for each of the IPPS DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCH patients. In a departure from the IPPS, as we discussed in both the May 19, 2003 proposed rule (68 FR 27174) and the June 6, 2003 LTCH PPS final rule (68 FR 34132), 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. In order to deal with the large number of low volume LTC–DRGs (LTC–DRGs with fewer than 25 cases), as we discussed in the May 19, 2003 proposed rule (68 FR 27176), we group those low volume LTC–DRGs into 5 quintiles based on average charge per discharge. (A listing of the composition of low volume quintiles for the FY 2004 LTC–DRGs (based on FY 2002 MedPAR data) appears in section II.D.3. of this final

rule.) 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 in section II.D.4. of this preamble.

b. Patient Classifications Into DRGs

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

As discussed above in section II.B. of this preamble, the 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 a 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 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 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 2004 LTC–DRG Relative Weights

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

As we stated in the August 30, 2002 LTCH PPS final rule (67 FR 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 LTC–DRG relative weights in determining payment to LTCHs for each case.

Under the LTCH PPS, relative weights for each LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each LTC–DRG that represents the resources needed by an average inpatient LTCH case in that LTC–DRG. For example, cases in a LTC–DRG with a relative weight of 2 will, on average, cost twice as much as cases in a LTC–DRG with a weight of 1.

b. Data

To calculate the LTC–DRG relative weights for FY 2004 in this final rule, we obtained total Medicare allowable charges from FY 2002 Medicare hospital bill data from the December 2002 update of the MedPAR file, and we used Version 21.0 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 2004 LTC–DRG

relative weights based on the best available data for this final rule.

As we discussed in the May 19, 2003 proposed rule (68 FR 27151), 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 2004 LTC–DRG relative weights, we have excluded the data of the 22 all-inclusive rate providers and the 3 LTCHs that are paid in accordance with demonstration projects.

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

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

As we noted above, we are using LTCH claims data from the FY 2002 MedPAR file for the determination of the FY 2004 LTC–DRG relative weights. Since at the time (FY 2002) LTCHs were still reimbursed under the reasonable cost-based system, some LTCHs also had submitted multiple bills for Medicare payment for the same stay. Thus, in certain LTCHs, hospital personnel were apparently still reporting a different principal diagnosis on each bill since, under the reasonable cost-based reimbursement system in FY 2002, payment was not dependent upon principal diagnosis as it is under a DRG-based system. Therefore, as we explained in the May 19, 2003 proposed rule (68 FR 27151), we are following the same methodology outlined above to determine the appropriate diagnosis and procedure codes for those multiple bill LTCH cases in the FY 2002 MedPAR files, and we are using these codes to group each LTCH case to a LTC–DRG for FY 2004. Since the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002 (FY 2003), we believe that this problem will be self-correcting as LTCHs submit more completely coded data in the future.

c. Hospital-Specific Relative Value Methodology

By nature LTCHs often specialize in certain areas, such as ventilator-dependent patients and rehabilitation and wound care. Some case types (DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. Such nonarbitrary distribution of cases with relatively high (or low) charges in specific LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, we use a hospital-specific relative value method to calculate the LTC–DRG relative weights instead of the methodology used to determine the DRG relative weights under the IPPS described above in section II.C. of this preamble. We believe this method will remove this hospital-specific source of bias in measuring LTCH average charges. Specifically, we reduce the impact of the variation in charges across providers on any particular LTC–DRG relative weight by converting each LTCH's charge for a case to a relative value based on that LTCH's average charge.

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

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

Multiplying by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight in a LTCH with higher average costs than they would at a LTCH with low average costs which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. Because we standardize charges in this manner, we count charges for a Medicare patient at a LTCH with high average charges as less resource intensive than they would be at a LTCH with low average charges. For example, a $10,000 charge for a case in a LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case in a LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

d. Low Volume LTC–DRGs

In order to account for LTC–DRGs with low volume (that is, with fewer than 25 LTCH cases), in accordance with the methodology discussed in the May 19, 2003 proposed rule (68 FR 27176), 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 FY 2002 MedPAR file, we identified 173 LTC–DRGs that contained between 1 and 24 cases. This list of LTC–DRGs was then divided into one of the five low volume quintiles, each containing a minimum of 34 LTC–DRGs (173/5 = 34 with 3 LTC–DRGs as the remainder). For FY 2004, as we described in that same proposed rule, we are making an assignment to a specific low volume quintile by sorting the 173 low volume LTC–DRGs in ascending order by average charge. Since the number of LTC–DRGs with less than 25 LTCH cases is not evenly divisible by five, the average charge of the low volume LTC–DRG was used to determine which low volume quintile received the additional LTC–DRG. After sorting the 173 low volume LTC–DRGs in ascending order, we grouped the first fifth (34) of low volume LTC–DRGs with the lowest average charge into Quintile 1. The highest average charge cases are grouped into Quintile 5. Since the average charge of the 69th LTC–DRG in the sorted list is closer to the previous LTC–DRG's average charge (assigned to Quintile 2) than to the average charge of the 70th LTC–DRG in the sorted list (to be assigned to Quintile 3), we placed it into Quintile 2. This process was repeated through the remaining low volume LTC–DRGs so that 3 low volume quintiles contain 35 LTC–DRGs and 2 low volume quintiles contain 34 LTC–DRGs.

In order to determine the relative weights for the LTC–DRGs with low volume for FY 2004, in accordance with the methodology described in the May 19, 2003 proposed rule (68 FR 27176), 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 2004. 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
44	ACUTE MAJOR EYE INFECTIONS.
46	OTHER DISORDERS OF THE EYE AGE >17 W CC.
47	OTHER DISORDERS OF THE EYE AGE >17 W/O CC.
65	DYSEQUILIBRIUM.
66	EPISTAXIS.
69	OTITIS MEDIA & URI AGE >17 W/O CC.
93	INTERSTITIAL LUNG DISEASE W/O CC.
95	PNEUMOTHORAX W/O CC.
149	MAJOR SMALL & LARGE BOWEL PROCEDURES W/O CC.
178	UNCOMPLICATED PEPTIC ULCER W/O CC.
192	PANCREAS, LIVER & SHUNT PROCEDURES W/O CC.
273	MAJOR SKIN DISORDERS W/O CC.
276	NON-MALIGANT BREAST DISORDERS.
284	MINOR SKIN DISORDERS W/O CC.
305	KIDNEY, URETER & MAJOR BLADDER PROC FOR NON–NEOPL W/O CC.
311	TRANSURETHRAL PROCEDURES W/O CC.
319	KIDNEY & URINARY TRACT NEOPLASMS W/O CC.
326	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W/O CC.
342	CIRCUMCISION AGE >17.
344	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES FOR MALIGNANCY.
348	BENIGN PROSTATIC HYPERTROPHY W CC.
349	BENIGN PROSTATIC HYPERTROPHY W/O CC.
367	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM W/O CC.
376	POSTPARTUM & POST ABORTION DIAGNOSES W/O O.R. PROCEDURE.
399	RETICULOENDOTHELIAL & IMMUNITY DISORDERS W/O CC.
414	OTHER MYELOPROLIF DIS OR POORLY DIFF NEOPL DIAG W/O CC.
428	DISORDERS OF PERSONALITY & IMPULSE CONTROL.
431	CHILDHOOD MENTAL DISORDERS.
432	OTHER MENTAL DISORDER DIAGNOSES.
433	ALCOHOL/DRUG ABUSE OR DEPENDENCE, LEFT AMA.
467	OTHER FACTORS INFLUENCING HEALTH STATUS.
511	NON-EXTENSIVE BURNS W/O CC OR SIGNIFICANT TRAUMA.
538	LOCAL EXCISION AND REMOVAL OF INTERNAL FIXATION DEVICES EXCEPT HIP AND FEMUR WITHOUT CC.
540	LYMPHOMA AND LEUKEMIA WITH MAJOR O.R. PROCEDURE WITHOUT CC.
	Quintile 2
21	VIRAL MENINGITIS.
22	HYPERTENSIVE ENCEPHALOPATHY.
31**	CONCUSSION AGE >17 W CC.
53	SINUS & MASTOID PROCEDURES AGE >17.
61	MYRINGOTOMY W TUBE INSERTION AGE >17.
72	NASAL TRAUMA & DEFORMITY.
84	MAJOR CHEST TRAUMA W/O CC.
128	DEEP VEIN THROMBOPHLEBITIS.

TABLE 1.—COMPOSITION OF LOW VOLUME QUINTILES—Continued

LTC-DRG	Description
177	UNCOMPLICATED PEPTIC ULCER W CC.
185	DENTAL & ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AGE >17.
193	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W CC.
194*	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W/O CC.
200	HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR NON-MALIGNANCY.
206***	DISORDERS OF LIVER EXCEPT MALIG,CIRR,ALC HEPA W/O CC.
208***	DISORDERS OF THE BILIARY TRACT W/O CC.
211	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W/O CC.
232	ARTHROSCOPY.
237	SPRAINS, STRAINS, & DISLOCATIONS OF HIP, PELVIS & THIGH.
275	MALIGNANT BREAST DISORDERS W/O CC.
301	ENDOCRINE DISORDERS W/O CC.
309	MINOR BLADDER PROCEDURES W/O CC.
323	URINARY STONES W CC, &/OR ESW LITHOTRIPSY.
324	URINARY STONES W/O CC.
339	TESTES PROCEDURES, NON-MALIGNANCY AGE 17.
341	PENIS PROCEDURES.
420	FEVER OF UNKNOWN ORIGIN AGE >17 W/O CC.
421	VIRAL ILLNESS AGE >17.
454	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W CC.
455	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W/O CC.
465	AFTERCARE W HISTORY OF MALIGNANCY AS SECONDARY DIAGNOSIS.
502	KNEE PROCEDURES W PDX OF INFECTION W/O CC.
506	FULL THICKNESS BURN W SKIN GRAFT OR INHAL INJ W CC OR SIG TRAUMA.
507*	FULL THICKNESS BURN W SKIN GRAFT OR INHAL INJ W/O CC OR SIG TRAUMA.
508	FULL THICKNESS BURN W/O SKIN GRAFT OR INHAL INJ W CC OR SIG TRAUMA.
509	FULL THICKNESS BURN W/O SKIN GRAFT OR INH INJ W/O CC OR SIG TRAUMA.
510	NON-EXTENSIVE BURNS W CC OR SIGNIFICANT TRAUMA.
529	VENTRICULAR SHUNT PROCEDURES WITH CC.
	QUINTILE 3
31*	CONCUSSION AGE >17 W CC.
32*	CONCUSSION AGE >17 W/O CC.
63	OTHER EAR, NOSE, MOUTH & THROAT O.R. PROCEDURES.
83	MAJOR CHEST TRAUMA W CC.
117	CARDIAC PACEMAKER REVISION EXCEPT DEVICE REPLACEMENT.
129	CARDIAC ARREST, UNEXPLAINED.
158	ANAL & STOMAL PROCEDURES W/O CC.
194**	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W/O CC.
197	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W CC.
218	LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE >17 W CC.
223	MAJOR SHOULDER/ELBOW PROC, OR OTHER UPPER EXTREMITY PROC W CC.
225	FOOT PROCEDURES.
226**	SOFT TISSUE PROCEDURES W CC.
233	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W CC.
234	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W/O CC.
257	TOTAL MASTECTOMY FOR MALIGNANCY W CC.
262	BREAST BIOPSY & LOCAL EXCISION FOR NON-MALIGNANCY.
295	DIABETES AGE 0–35.
299	INBORN ERRORS OF METABOLISM.
317	ADMIT FOR RENAL DIALYSIS.
325	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W CC.
347***	MALIGNANCY, MALE REPRODUCTIVE SYSTEM, W/O CC.
352	OTHER MALE REPRODUCTIVE SYSTEM DIAGNOSES.
369	MENSTRUAL & OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS.
394	OTHER O.R. PROCEDURES OF THE BLOOD AND BLOOD FORMING ORGANS.
402	LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W/O CC.
408	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W OTHER O.R. PROC.
410	CHEMOTHERAPY W/O ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS.
419	FEVER OF UNKNOWN ORIGIN AGE >17 W CC.
447	ALLERGIC REACTIONS AGE >17.
449	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W CC.
450*	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W/O CC.
473	ACUTE LEUKEMIA W/O MAJOR O.R. PROCEDURE AGE >17.
497	SPINAL FUSION W CC.
498*	SPINAL FUSION W/O CC.
503	KNEE PROCEDURES W/O PDX OF INFECTION.
507**	FULL THICKNESS BURN W SKIN GRFT OR INHAL INJ W/O CC OR SIG TRAUMA.
518	PERCUTANEOUS CARDIVASCULAR PROC W/O CORONARY ARTERY STENT OR AMI.
532	SPINAL PROCEDURES WITHOUT CC.

TABLE 1.—COMPOSITION OF LOW VOLUME QUINTILES—Continued

LTC-DRG	Description
	QUINTILE 4
119	VEIN LIGATION & STRIPPING.
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG.
125	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG.
150	PERITONEAL ADHESIOLYSIS W CC.
152	MINOR SMALL & LARGE BOWEL PROCEDURES W CC.
157	ANAL & STOMAL PROCEDURES W CC.
161	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >7 W CC.
171	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W/O CC.
191	PANCREAS, LIVER & SHUNT PROCEDURES W CC.
195	CHOLECYSTECTOMY W 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.
227	SOFT TISSUE PROCEDURES W/O CC.
228	MAJOR THUMB OR JOINT PROC,OR OTH HAND OR WRIST PROC W CC.
230	LOCAL EXCISION & REMOVAL OF INT FIX DEVICES OF HIP & FEMUR.
266***	SKIN GRAFT &/OR DEBRID EXCEPT FOR SKIN ULCER OR CELLULITIS W/O CC.
292	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W CC.
308	MINOR BLADDER PROCEDURES W CC.
310	TRANSURETHRAL PROCEDURES W CC.
312	URETHRAL PROCEDURES, AGE >17 W CC.
360	VAGINA, CERVIX & VULVA PROCEDURES.
424	O.R. PROCEDURE W PRINCIPAL DIAGNOSES OF MENTAL ILLNESS.
427	NEUROSES EXCEPT DEPRESSIVE.
443	OTHER O.R. PROCEDURES FOR INJURIES W/O CC.
479***	OTHER VASCULAR PROCEDURES W/O CC.
486	OTHER O.R. PROCEDURES FOR MULTIPLE SIGNIFICANT TRAUMA.
493	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W CC.
494*	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W/O CC.
498**	SPINAL FUSION W/O CC.
500	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W/O CC.
505	EXTENSIVE 3RD DEGREE BURNS W/O SKIN GRAFT.
517	PERCUTANEOUS CARDIVASCULAR PROC W NON-DRUG ELUTING STENT W/O AMI.
519	CERVICAL SPINAL FUSION W CC.
531	SPINAL PROCEDURES WITH CC.
537	LOCAL EXCISION AND REMOVAL OF INTERNAL FIXATION DEVICES EXCEPT HIP AND FEMUR WITH CC.
	QUINTILE 5
1	CRANIOTOMY AGE >17 W CC.
8***	PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W/O CC.
32**	CONCUSSION AGE >17 W/O CC.
40	EXTRAOCULAR PROCEDURES EXCEPT ORBIT AGE >17.
75	MAJOR CHEST PROCEDURES.
77	OTHER RESP SYSTEM O.R. PROCEDURES W/O CC.
108	OTHER CARDIOTHORACIC PROCEDURES.
110	MAJOR CARDIOVASCULAR PROCEDURES W CC.
115	PRM CARD PACEM IMPL W AMI, HRT FAIL OR SHK, OR AICD LEAD OR GNRTR P.
116	OTH PERM CARD PACEMAK IMPL OR PTCA W CORONARY ARTERY STENT IMPLNT.
118	CARDIAC PACEMAKER DEVICE REPLACEMENT.
148	MAJOR SMALL & LARGE BOWEL PROCEDURES W CC.
154	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W CC.
168	MOUTH PROCEDURES W CC.
201	OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES.
261	BREAST PROC FOR NON-MALIGNANCY EXCEPT BIOPSY & LOCAL EXCISION.
268	SKIN, SUBCUTANEOUS TISSUE & BREAST PLASTIC PROCEDURES.
288	O.R. PROCEDURES FOR OBESITY.
304	KIDNEY, URETER & MAJOR BLADDER PROC FOR NON-NEOPL W CC.
345	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROC EXCEPT FOR MALIGNANCY.
365	OTHER FEMALE REPRODUCTIVE SYSTEM O.R. PROCEDURES.
401	LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W CC.
406	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R.PROC W CC.
441	HAND PROCEDURES FOR INJURIES.
450**	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W/O CC.
471	BILATERAL OR MULTIPLE MAJOR JOINT PROCS OF LOWER EXTREMITY.
482	TRACHEOSTOMY FOR FACE, MOUTH & NECK DIAGNOSES.
488	HIV W EXTENSIVE O.R. PROCEDURE.
494**	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W/O CC.
499	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W CC.

TABLE 1.—COMPOSITION OF LOW VOLUME QUINTILES—Continued

LTC-DRG	Description
501	KNEE PROCEDURES W PDX OF INFECTION W CC.
515	CARDIAC DEFIBRILATOR IMPLANT W/O CARDIAC CATH.
533	EXTRACRANIAL VASCULAR PROCEDURES WITH CC.
536	CARDIAC DEFIB IMPLANT WITH CARDIAC CATH WITHOUT AMI/HF/SHOCK.

* One of the original 173 low volume LTC–DRGs initially assigned to a different low volume quintile; reassigned to this low volume quintile in addressing nonmonotonicity (*see* step 5 below).

** One of the original 173 low volume LTC–DRGs initially assigned to this low volume quintile; reassigned to a different low volume quintile in addressing nonmonotonicity (*see* step 5 below).

*** One of the original 173 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 2004 LTC–DRG Relative Weights

As we noted previously, the FY 2004 LTC–DRG relative weights are determined in accordance with the methodology described in the May 19, 2003 proposed rule (68 FR 27179). 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 2004 LTC–DRG relative weights can be determined. After grouping the cases in the appropriate LTC–DRG, we calculate the relative weights for FY 2004 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 2004 LTC–DRG relative weights.

Step 1—Remove Statistical Outliers

The first step in the calculation of the FY 2004 LTC–DRG relative weights is to remove statistical outlier cases. As we discussed in the May 19, 2003 proposed rule (68 FR 27179), 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 2004 LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, as we discussed in the May 19, 2003 proposed rule (68 FR 27179), cases with a length of stay 7 days or less do not belong in a LTCH because such stays do not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH. If we were to include stays of 7 days or less in the computation of the FY 2004 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 2004 LTC–DRG relative weights, we remove LTCH cases with a length of stay of 7 days or less.

Step 3—Adjust Charges for the Effects of Short-Stay Outliers

The third step in the calculation of the FY 2004 LTC–DRG relative weights is to adjust each LTCH's charges per discharge for short-stay outlier cases (that is, a patient with a length of stay that is less than or equal to five-sixths the average length of stay of the LTC–DRG).

As we discussed in the May 19, 2003 proposed rule (68 FR 27179), 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 that same proposed rule, 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 a 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 since it results in more appropriate payments for all LTCH cases.

Step 4—Calculate the FY 2004 LTC–DRG Relative Weights on an Iterative Basis

As we discussed in the May 19, 2003 proposed rule (68 FR 27180), 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 2004 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 2004 LTC–DRG Relative Weights to Account for Nonmonotonically Increasing Relative Weights

As explained in section II.B. of this preamble, the FY 2004 CMS DRGs, upon which the FY 2004 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 19, 2003 proposed rule (68 FR 27180), the value of monotonically increasing relative weights rises as the resource use increases (for example, from uncomplicated to more complicated). The presence of CCs in a 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 a LTC–DRG ''without CCs'' (which is based on only one principal diagnosis and no relevant secondary diagnoses). Currently, the LTCH claims data include both accurately coded cases without complications and cases that have complications (and cost more) but were not coded completely. Both types of cases are grouped to a LTC–DRG ''without CCs'' since only one principal diagnosis was coded. Since LTCHs were previously paid under cost-based reimbursement, which is not based on patient diagnoses, 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 2002 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 2004.

We believe this anomaly may be due to coding that may not have fully reflected all comorbidities that were present. Specifically, LTCHs may have failed to code relevant secondary diagnoses, which resulted in cases that actually had CCs being classified into a ''without CC'' LTC–DRG. It would not be appropriate to pay a lower amount for the ''with CC'' LTC–DRG. Therefore, as we discussed in the May 19, 2003 proposed rule (68 FR 27180), we grouped both the cases ''with CCs'' and ''without CCs'' together for the purpose of calculating the FY 2004 LTC–DRG relative weights in this final rule. We continue to employ this methodology to account for nonmonotonically increasing relative weights until we have adequate data to calculate appropriate separate weights for these anomalous LTC–DRG pairs. We expect that, as was the case when we first implemented the IPPS, this problem will be self-correcting, as LTCHs submit more completely coded data in the future.

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 December 2002 update of the FY 2002 MedPAR file, we identified three of the types of nonmonotonic LTC–DRG pairs.

The first category of nonmonotonically increasing relative weights for FY 2004 LTC–DRG pairs ''with and without CCs'' contains 1 pair 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 that type of nonmonotonic LTC–DRG pair, as discussed in the May 19, 2003 proposed rule (68 FR 27180), 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 2004, LTC–DRGs 180 and 181 are in this category.

The second category of nonmonotonically increasing relative weights for LTC–DRG pairs with and without CCs consists of 7 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 19, 2003 proposed rule (68 FR 27181), 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 would have the same relative weight. For FY 2004, in this final rule, the following LTC–DRGs are in this category: LTC–DRGs 31 and 32 (low volume quintile 3); LTC–DRGs 193 and 194 (low volume quintile 2); LTC–DRGs 226 and 227 (low volume quintile 4); LTC–DRGs 449 and 450 (low volume quintile 3); LTC–DRGs 493 and 494 (low volume quintile 4); LTC–DRGs 497 and 498 (low volume quintile 3); and LTC–DRGs 506 and 507 (low volume quintile 2).

The third category of nonmonotonically increasing relative weights for LTC–DRG pairs with and without CCs consists of 6 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 we discussed in the May 19, 2003 proposed rule (68 FR 27181), 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. For FY 2004, in this final rule, the following LTC–DRGs are in this category: LTC–DRGs 7 and 8; LTC–DRGs 205 and 206; LTC–DRGs 207 and 208; LTC–DRGs 265 and 266; LTC–DRGs 346 and 347; and LTC–DRGs 478 and 479.

Step 6—Determine a FY 2004 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 December 2002 update of the FY 2002 MedPAR file. Of the 518 LTC–DRGs for FY 2004, we identified 167 LTC–DRGs for which there were no LTCH cases in the database. That is, based on data from the FY 2002 MedPAR file used in this final rule, no patients who would have been classified to those LTC–DRGs were treated in LTCHs during FY 2002 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 167 LTC–DRGs using the methodology described in steps 1 through 5 above. However, since patients with a number of the diagnoses under these LTC–DRGs may be treated at LTCHs beginning in FY 2004, we assign relative weights to each of the 167 ''no volume'' LTC–DRGs based on clinical similarity and relative costliness to one of the remaining 354 (518 − 167 = 351) LTC–DRGs for which we are able to determine relative weights, based on FY 2002 claims data.

As there are currently no LTCH cases in these ''no volume'' LTC–DRGs, as we discussed in the May 19, 2003 proposed rule (68 FR 27181), we determine relative weights for the 167 LTC–DRGs with no LTCH cases in the FY 2002 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: First, we crosswalk the no volume LTC–DRGs by matching them to other similar LTC–DRGs for which there were LTCH cases in the FY 2002 MedPAR file based on clinical similarity and intensity of use of resources as determined by care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, post-operative care, and length of stay. We assign the 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 2004 LTC–DRGs and the FY 2004 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 2004 is shown below in Table 2.

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

LTC-DRG	Description	Cross-walked LTC-DRG	Low volume quintile assigned
2	CRANIOTOMY AGE > 17 W/O CC	1	Quintile 5
3	CRANIOTOMY AGE 0–17	1	Quintile 5
6	CARPAL TUNNEL RELEASE	251	Quintile 1
26	SEIZURE & HEADACHE AGE 0–17	25	Quintile 2
30	TRAUMATIC STUPOR & COMA, COMA <1 HR AGE 0–17	29	Quintile 3
33	CONCUSSION AGE 0–17	25	Quintile 2
36	RETINAL PROCEDURES	47	Quintile 1
37	ORBITAL PROCEDURES	47	Quintile 1
38	PRIMARY IRIS PROCEDURES	47	Quintile 1
39	LENS PROCEDURES WITH OR WITHOUT VITRECTOMY	47	Quintile 1
41	EXTRAOCULAR PROCEDURES EXCEPT ORBIT AGE 0–17	47	Quintile 1
42	INTRAOCULAR PROCEDURES EXCEPT RETINA, IRIS & LENS	47	Quintile 1
43	HYPHEMA	47	Quintile 1
45	NEUROLOGICAL EYE DISORDERS	46	Quintile 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 3
51	SALIVARY GLAND PROCEDURES EXCEPT SIALOADENECTOMY	63	Quintile 3
52	CLEFT LIP & PALATE REPAIR	63	Quintile 3
54	SINUS & MASTOID PROCEDURES AGE 0–17	63	Quintile 3
55	MISCELLANEOUS EAR, NOSE, MOUTH & THROAD PROCEDURES	63	Quintile 3
56	RHINOPLASTY	72	Quintile 2
57	T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17	63	Quintile 3
58	T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0–17	63	Quintile 3
59	TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17	63	Quintile 3
60	TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0–17	63	Quintile 3
62	MYRINGOTOMY W TUBE INSERTION AGE 0–17	63	Quintile 3
67	EPIGLOTTITIS	63	Quintile 3
70	OTITIS MEDIA & URI AGE 0–17	69	Quintile 1
71	LARYNGOTRACHEITIS	97	Quintile 1
74	OTHER EAR, NOSE, MOUTH & THROAT DIAGNOSES AGE 0–17	69	Quintile 1
81	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE 0–17	69	Quintile 1
91	SIMPLE PNEUMONIA & PLEURISY AGE 0–17	90	Quintile 2
98	BRONCHITIS & ASTHMA AGE 0–17	97	Quintile 1
104	CARDIAC VALVE & OTHER MAJOR CARDIOTHORACIC PROC W CARDIAC CATH	110	Quintile 5
105	CARDIAC VALVE & OTHER MAJOR CARDIOTHORACIC PROC W/O CARDIAC CATH	110	Quintile 5

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

LTC-DRG	Description	Cross-walked LTC-DRG	Low volume quintile assigned
106	CORONARY BYPASS W PTCA	110	Quintile 5
107	CORONARY BYPASS W CARDIAC CATH	110	Quintile 5
109	CORONARY BYPASS W/O PTCA OR CARDIAC CATH	110	Quintile 5
111	MAJOR CARDIOVASCULAR PROCEDURES W/O CC	110	Quintile 5
137	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE 0–17	136	Quintile 2
146	RECTAL RESECTION W CC	148	Quintile 5
147	RECTAL RESECTION W/O CC	148	Quintile 5
151	PERITONEAL ADHESIOLYSIS W/O CC	150	Quintile 4
153	MINOR SMALL & LARGE BOWEL PROCEDURES W/O CC 155 STOMACH, ESOPHAGEAL & DUODENAL.	152	Quintile 4
155	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W/O CC	171	Quintile 4
156	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE 0–17	171	Quintile 4
159	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W CC	161	Quintile 4
160	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W/O CC	161	Quintile 4
162	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W/O CC	178	Quintile 1
163	HERNIA PROCEDURES AGE 0–17	178	Quintile 1
164	APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W CC	148	Quintile 5
165	APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W/O CC	149	Quintile 1
166	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W CC	148	Quintile 5
167	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W/O CC	149	Quintile 1
169	MOUTH PROCEDURES W/O CC	72	Quintile 2
184	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE 0–17	183	Quintile 2
186	DENTAL & ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AGE 0–17	185	Quintile 2
187	DENTAL EXTRACTIONS & RESTORATIONS	185	Quintile 2
190	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE 0–17	189	Quintile 2
196	CHOLECYSTECTOMY W C.D.E. W/O CC	197	Quintile 3
198	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W/O CC	197	Quintile 3
199	HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR MALIGNANCY	200	Quintile 2
212	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE 0–17	211	Quintile 2
219	LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE >17 W/O CC	218	Quintile 3
220	LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE 0–17	218	Quintile 3
224	SHOULDER, ELBOW OR FOREARM PROC, EXC MAJOR JOINT PROC, W/O CC	234	Quintile 3
229	HAND OR WRIST PROC, EXCEPT MAJOR JOINT PROC, W/O CC	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
258	TOTAL MASTECTOMY FOR MALIGNANCY W/O CC	257	Quintile 3
259	SUBTOTAL MASTECTOMY FOR MALIGNANCY W CC	257	Quintile 3
260	SUBTOTAL MASTECTOMY FOR MALIGNANCY W/O CC	257	Quintile 3
267	PERIANAL & PILONIDAL PROCEDURES	158	Quintile 3
279	CELLULITIS AGE 0–17	78	Quintile 3
282	TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE 0–17	281	Quintile 2
286	ADRENAL & PITUITARY PROCEDURES	53	Quintile 2
289	PARATHYROID PROCEDURES	53	Quintile 2
290	THYROID PROCEDURES	53	Quintile 2
291	THYROGLOSSAL PROCEDURES	53	Quintile 2
293	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W/O CC	63	Quintile 3
298	NUTRITIONAL & MISC METABOLIC DISORDERS AGE 0–17	297	Quintile 2
303	KIDNEY, URETER & MAJOR BLADDER PROCEDURES FOR NEOPLASM	304	Quintile 5
306	PROSTATECTOMY W CC	310	Quintile 4
307	PROSTATECTOMY W/O CC	310	Quintile 4
313	URETHRAL PROCEDURES, AGE >17 W/O CC	311	Quintile 1
314	URETHRAL PROCEDURES, AGE 0–17	311	Quintile 1
322	KIDNEY & URINARY TRACT INFECTIONS AGE 0–17	326	Quintile 1
327	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE 0–17	326	Quintile 1
328	URETHRAL STRICTURE AGE >17 W CC	311	Quintile 1
329	URETHRAL STRICTURE AGE >17 W/O CC	311	Quintile 1
330	URETHRAL STRICTURE AGE 0–17	311	Quintile 1
333	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE 0–17	332	Quintile 1
334	MAJOR MALE PELVIC PROCEDURES W CC	345	Quintile 5
335	MAJOR MALE PELVIC PROCEDURES W/O CC	345	Quintile 5
336	TRANSURETHRAL PROSTATECTOMY W CC	341	Quintile 2
337	TRANSURETHRAL PROSTATECTOMY W/O CC	341	Quintile 2
338	TESTES PROCEDURES, FOR MALIGNANCY	339	Quintile 2
340	TESTES PROCEDURES, NON-MALIGNANCY AGE 0–17	339	Quintile 2
343	CIRCUMCISION AGE 0–17	339	Quintile 2
351	STERILIZATION, MALE	339	Quintile 2
353	PELVIC EVISCERATION, RADICAL HYSTERECTOMY & RADICAL VULVECTOMY	365	Quintile 5
354	UTERINE, ADNEXA PROC FOR NON-OVARIAN/ADNEXAL MALIG W CC	365	Quintile 5
355	UTERINE, ADNEXA PROC FOR NON-OVARIAN/ADNEXAL MALIG W/O CC	365	Quintile 5
356	FEMALE REPRODUCTIVE SYSTEM RECONSTRUCTIVE PROCEDURES	360	Quintile 4
357	UTERINE & ADNEXA PROC FOR OVARIAN OR ADNEXAL MALIGNANCY	360	Quintile 4

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

LTC-DRG	Description	Cross-walked LTC-DRG	Low volume quintile assigned
358	UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W CC	360	Quintile 4
359	UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W/O CC	360	Quintile 4
361	LAPAROSCOPY & INCISIONAL TUBAL INTERRUPTION	149	Quintile 1
362	ENDOSCOPIC TUBAL INTERRUPTION	149	Quintile 1
363	D&C, CONIZATION & RADIO-IMPLANT, FOR MALIGNANCY	367	Quintile 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
377	POSTPARTUM & POST ABORTION DIAGNOSES W O.R. PROCEDURE	367	Quintile 1
378	ECTOPIC PREGNANCY	369	Quintile 3
379	THREATENED ABORTION	376	Quintile 1
380	ABORTION W/O D&C	376	Quintile 1
381	ABORTION W D&C, ASPIRATION CURETTAGE OR HYSTEROTOMY	376	Quintile 1
382	FALSE LABOR	376	Quintile 1
383	OTHER ANTEPARTUM DIAGNOSES W MEDICAL COMPLICATIONS	376	Quintile 1
384	OTHER ANTEPARTUM DIAGNOSES W/O MEDICAL COMPLICATIONS	376	Quintile 1
385	NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY	367	Quintile 1
386	EXTREME IMMATURITY	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	376	Quintile 1
392	SPLENECTOMY AGE >17	194	Quintile 2
393	SPLENECTOMY AGE 0–17	194	Quintile 2
396	RED BLOOD CELL DISORDERS AGE 0–17	399	Quintile 1
405	ACUTE LEUKEMIA W/O MAJOR O.R. PROCEDURE AGE 0–17	404	Quintile 2
407	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R. PROC W/O CC	408	Quintile 3
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	420	Quintile 2
446	TRAUMATIC INJURY AGE 0–17	445	Quintile 2
448	ALLERGIC REACTIONS AGE 0–17	455	Quintile 2
451	POISONING & TOXIC EFFECTS OF DRUGS AGE 0–17	455	Quintile 2
481	BONE MARROW TRANSPLANT	394	Quintile 3
484	CRANIOTOMY FOR MULTIPLE SIGNIFICANT TRAUMA	1	Quintile 5
485	LIMB REATTACHMENT, HIP AND FEMUR PROC FOR MULTIPLE SIGNIFICANT TR	209	Quintile 4
491	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF UPPER EXTREMITY	209	Quintile 4
492	CHEMOTHERAPY W ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS	410	Quintile 3
496	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION	210	Quintile 4
504	EXTENSIVE 3RD DEGREE BURNS W SKIN GRAFT	468	Quintile 5
516	PERCUTANEOUS CARDIOVASCULAR PROCEDURE W AMI	518	Quintile 3
520	CERVICAL SPINAL FUSION W/O CC	498	Quintile 3
525	HEART ASSIST SYSTEM IMPLANT	468	Quintile 5
526	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W AMI	517	Quintile 4
527	PERCUTANEOUS CARVIOVASCULAR PROC W DRUG-ELUTING STENT W/O AMI	517	Quintile 4
528	INTRACRANIAL VASCULAR PROCEDURES WITH PDX HEMORRHAGE	1	Quintile 5
530	VENTRICULAR SHUNT PROCEDURES WITHOUT CC	529	Quintile 2
534	EXTRACRANIAL VASCULAR PROCEDURES WITHOUT CC	500	Quintile 4
535	CARDIAC DEFIB IMPLANT WITH CARDIAC CATH WITH AMI/HF/SHOCK	515	Quintile 5
539	LYMPHOMA AND LEUKEMIA WITH MAJOR O.R. PROCEDURE WITH CC	401	Quintile 5

To illustrate this methodology for determining the relative weights for the 164 LTC–DRGs with no LTCH cases, we are providing the following examples, which refer to the no volume LTC–DRGs crosswalk information for FY 2004 provided above in Table 2:

Example 1: There were no cases in the FY 2002 MedPAR file used for this 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 2004 relative weights, would display similar clinical and resource use. Therefore, we assign the same relative weight of LTC–DRG 178 of 0.4964 (Quintile 1) for FY 2004 (Table 11 in the Addendum to this final rule) to LTC–DRG 163.

Example 2: There were no LTCH cases in the FY 2002 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 (0.7318; *see* Table 11 in the Addendum to this final rule) would be low volume quintile 2 (0.7372; *see* Table 11 in the Addendum to this final rule). Therefore, we assign LTC–DRG 91 a relative weight of 0.7372 for FY 2004.

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 2004 because Medicare will only cover these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified.

Based on our research, 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. Since we use the same GROUPER program for LTCHs as is used under the IPPS, removing these LTC–DRGs would be administratively burdensome.

Again, we note that as this system is dynamic, it is entirely possible that the number of 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 2004.

E. Add-On Payments for New Services and Technologies

1. Background

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

Section 412.87(b)(1) of our existing regulations provides that a new technology will be an appropriate candidate for an additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries (*see* the September 7, 2001 final rule (66 FR 46902)). Section 412.87(b)(3) provides that, to receive special payment treatment, new technologies meeting this clinical definition must be demonstrated to be inadequately paid otherwise under the DRG system. As discussed below, for applicants for new technology add-on payments for FY 2005, we are establishing the criteria that will be applied to assess whether technologies would be inadequately paid under the DRGs 75 percent of 1 standard deviation (based on the logarithmic values of the charges and transformed back to charges) beyond the geometric mean standardized charge for all cases in the DRGs to which the new technology is assigned (or the case-weighted average of all relevant DRGs, if the new technology occurs in many different DRGs). Table 10 in the Addendum to this final rule lists the qualifying criteria by DRG, based on the discharge data that we used to calculate the FY 2004 DRG weights. The thresholds that are published in this final rule for FY 2004 will be used to evaluate applicants for new technology add-on payments during FY 2005.

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

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

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

the annual proposed rule, the Web site also lists the tracking forms completed by each applicant.

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

The report language accompanying section 533 of 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, we account for projected payments under the new technology provision during the upcoming fiscal year at the same time we estimate the payment effect of changes to the DRG classifications and recalibration. The impact of additional payments under this provision would then be included in the budget neutrality factor, which is applied to the standardized amounts and the hospital-specific amounts.

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

To balance appropriately the Congress' intent to increase Medicare's payments for eligible new technologies with concern that the total size of those payments not result in significantly reduced payments for other cases, we set a target limit for estimated add-on payments for new technology under the provisions of sections 1886(d)(5)(K) and (L) of the Act at 1.0 percent of estimated total operating prospective payments.

If the target limit is exceeded, we would reduce the level of payments for approved technologies across the board, to ensure estimated payments do not exceed the limit. Using this approach, all cases involving approved new technologies that would otherwise receive additional payments would still receive special payments, albeit at a reduced amount. Although the marginal payment rate for individual technologies would be reduced, this reduction would be offset by large overall payments to hospitals for new technologies under this provision.

Comment: Some commenters asked that CMS ensure that the necessary software changes be made to accommodate newly approved technologies so that hospitals experience no delay in receiving add-on payments for new technologies. Commenters noted that, at the time they prepared their comments, it was unclear whether hospitals were receiving any new technology add-on payments for FY 2003. Given that $74.8 million was carved out of the FY 2003 standardized amount, it is critical that a reliable system be put in place to ensure that hospitals receive these add-on payments.

Response: We regret the delay any hospital may be experiencing in receiving add-on payments for FY 2003. On December 13, 2002, we issued Program Memorandum A–02–124 that requested fiscal intermediaries to implement the new technology payment mechanism into the claims processing system by April 1, 2003. The changes outlined in this program memorandum were delayed until July 16, 2003, in order to ensure that the claims processing system could properly process these add-on payments.

Comment: Several commenters pointed out that new ICD–9–CM codes are being created for procedures that were not typically captured and reported using ICD–9–CM coding. The commenters specifically mentioned the creation of new codes for types of drugs. Commenters are concerned about the types of medical record documentation that may be required for the administration of these drugs to be assigned an ICD–9–CM code. They asked if a physician order for a drug and a notation on a medical sheet that a nurse had in fact injected the drug were sufficient documentation. The commenters indicated that further guidance is needed regarding documentation requirements for ICD–9–CM codes for new services and technologies that have not traditionally been reported through the use of ICD–9–CM coding.

One commenter recommended that the approval process for new technologies be revised to include a requirement that the applicant must barcode such item with appropriate detailed information. The commenter stated that the use of barcoding would reduce medical errors. The commenter also was concerned that the limit of 6 procedure codes that can be reported on the billing form may become problematic as more new technologies are approved in the future.

Response: We have asked the AHA to schedule this topic for discussion by the Cooperating Parties for ICD–9–CM and the Editorial Advisory Board for Coding Clinic for ICD–9–CM. AHA agrees that this is a timely topic and has scheduled it for discussion in one of its upcoming ICD–9–CM meetings.

We would like to explore further the commenter's suggestion to require applicants for new technology add-on payments to barcode the technology. We recognize the potential limitations of the current claims form, as well as the overall limitations of ICD–9–CM. As we have stated previously, we believe ICD–10–PCS offers great potential improvement for more specific coding that may limit the use of multiple ICD–9–CM codes to identify certain classes of patients.

Comment: Commenters asked that CMS present a full and clear accounting for estimated and actual new technology add-on payments and their impact on the DRG base rate in each proposed and final rule in order to ensure that hospitals receive these add-on payments in full. Another commenter recommended that, similar to outlier payments, CMS should report every year on the extent to which the actual add-on payments per case exceeded or were lower than the amount removed from the standardized amounts.

One commenter was concerned that additional payments might be carved out of the standardized amount for new technologies to ensure budget neutrality, and those payments might not be made because CMS' projection of spending for the add-on payments was too high or because hospitals failed to bill properly for add-on payments. The commenter recommended that CMS

split the budget neutrality adjustment for DRG reclassification and recalibration into two components in order to isolate the reduction associated with add-on payments for new technologies.

Commenters did not agree that add-on payments for new technology should be budget neutral, and explained that the purpose of having additional payments for high-cost items was to compensate a hospital for its unrecovered cost. Because of budget neutrality, these high-cost items are not being properly paid. The commenter also noted that these high-cost items are also the cause of a higher than expected outlier payment.

One commenter recommended that CMS develop a separate pool of money to fund new technology and remove it from the budget neutrality calculation. The commenter explained that, while the technology is new, there should be money set aside and accessed only by those hospitals utilizing that technology.

Response: When we approve a new technology for add-on payments, we conduct an analysis based on the latest data available to estimate the total add-on payments that will be made for the new technology during the upcoming fiscal year and include the results in the annual proposed and final rules. Analyses of technologies approved for add-on payments for FY 2004 are presented below. These analyses include our analysis of available FY 2003 MedPAR data on the utilization of Xigris® and the basis for our estimated payments for new technologies approved for FY 2004. We also discuss this analysis in our description of budget neutrality in section II.A.4.a. of the Addendum to this final rule. We note that, based on our analysis, we have reduced considerably our estimate of add-on payments for Xigris® from the FY 2003 level, which led to a smaller budget neutrality offset to the standardized amounts.

As we stated above, the Congressional Report language accompanying section 533 of Pub. L. 106–554 clearly indicated Congress' intent that this provision be implemented in a budget neutral manner. Therefore, Congress is the appropriate body to consider concerns about the budget neutrality of this provision.

We do not believe it necessary to establish a separate budget neutrality calculation or pool for these payments. The amount of the payments is clearly identified in the final rule. Like all of the budget neutrality calculations, it is a prospective estimate.

Comment: Commenters recommended that CMS eliminate the use of case-weighted averages in the calculation of the cost threshold for technologies that occur in more than one DRG. The commenter believed that the goal of add-on payments is to provide adequate payment for new technologies in the DRGs in which the technology is used. The commenter added that the use of a case-weighted average biases the cost threshold against technologies that occur in more than one DRG and places hospitals at a disadvantage in DRGs where the threshold would otherwise be met except for application of the case-weighted average.

Commenters argued that our criteria for what is considered a new technology is not consistent with section 1886(d)(5)(K)(ii)(II) of the Act. The commenter stated that this provision was intended to provide for the collection of data with respect to the costs of a new medical service or technology for a period of not less than 2 years and not more than 3 years, ''beginning on the date on which an inpatient hospital code is issued with respect to the service or technology.'' Therefore, the commenter recommended that, instead of no longer considering technologies new because the related charges are already captured in the MedPAR data, CMS should only view a technology as ineligible on the grounds that it is no longer new if the agency can specifically identify a significant sample of cases involving use of the technology in the MedPAR data. One commenter noted that sufficient charge data to assess whether the new technology meets the cost threshold criterion are often only available through the MedPAR data after the new ICD–9–CM code becomes effective. Some commenters also recommended that CMS raise the add-on payment amount from 50 percent of the cost of the new technology to an 80-percent or 100-percent marginal cost factor.

Another commenter asked CMS to provide established clinical requirements or criteria that would control substantial clinical improvement determinations.

One commenter recommended that CMS deem products that fall within one of the following categories designated by the FDA to have met the substantial clinical improvement criterion: Drugs or biologicals that obtain fast track or accelerated approval; and drugs or biologicals approved after priority review or approved for orphan indication. The commenter recommended that CMS defer to the clinical expertise of the FDA with respect to these products and find that any product falling in the above categories satisfy the substantial clinical improvement criterion without further CMS analysis.

In addition, many commenters addressed the proposed change to the cost threshold criterion. (We are addressing these comments in our discussion of specific proposals later in this section of the preamble.)

Response: We appreciate the interest of the many stakeholders in ensuring that Medicare beneficiaries have full access to improvements in medical technology. We have previously discussed our position on each of the issues raised by the commenters on the proposed rule in detail in the September 7, 2001 final rule (66 FR 46905) and the August 1, 2002 final rule (67 FR 50009). Our rationales for these policies have not changed since we discussed them in those final rules, and we did not propose changes to these policies in the May 19, 2003 proposed rule. Therefore, readers are referred to the September 7, 2001 final rule and the August 1, 2002 final rule for our responses to these comments. However, we will continue to assess each of these policies and would appreciate the commenters' continued input on these issues.

Comment: One commenter suggested that CMS conduct a historical review of technologies that would have likely met the ''new'' and substantial improvement criteria and determine the relationship between the costs of those items and the new technology cost threshold. The commenter noted that such an analysis might provide useful insights as to whether a more flexible cost criterion is needed.

Response: We will take this suggestion under consideration.

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

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

utilization of the technology due to the absence of the add-on payment.

Therefore, for FY 2004, we will continue to make add-on payments for cases involving the administration of Xigris® as identified by the presence of code 00.11. Based on preliminary analysis of the incidence of Xigris® in the first quarter FY 2003 MedPAR file, in the May 19, 2003 proposed rule, we proposed to revise downward our estimate of total add-on payments for Xigris®. For FY 2003, we estimated that total add-on payments would be approximately $74.8 million (22,000 Medicare patients who would be eligible for a $3,400 add-on payment). For FY 2004, we estimated in the proposed rule the total add-on payments would be approximately $50 million (based on 14,000 Medicare patients who would be eligible for a $3,400 add-on payment). We indicated that this proposed additional payment would be included in the DRG reclassification and recalibration budget neutrality factor, which is applied to the standardized amounts and the hospital-specific amounts. However, we indicated that, before the publication of the FY 2004 IPPS final rule, we would reevaluate our assumptions regarding this estimate based on preliminary claims data from the FY 2003 MedPAR file.

We have analyzed the claims from the March 2003 update to the FY 2003 MedPAR file. We identified claims that had received Xigris® based on the inclusion of procedure code 00.11. We identified only 1,500 claims from this file. Although the March 2003 update of the FY 2003 MedPAR probably only realistically includes about 5 months' worth of claims, it appears that a lower than expected number of cases are receiving this new technology at the present time.

Therefore, in this final rule for FY 2004, we are lowering the total payments in proportion to the cases that have actually received this drug. We are doubling the number of cases in our March 2003 MedPAR update to an estimated 3,000 cases that will receive Xigris® in FY 2003. We recognize there may actually be more cases than this by the end of the year, as only about 5 months of data are accounted for in our analysis. Also, this estimate does not account for future increased use of the drug. However, these potential underestimates are offset by the fact that we are assuming all cases will qualify for the full $3,400 add-on payment. We believe these effects will largely offset one another. Therefore, the final projected costs for add-on payments are estimated to be $10 million. We will use this estimate in our budget neutrality calculations.

Comment: One commenter supported our decision to continue paying add on payments for Xigris®, but disagreed with the proposed estimated decline in add-on payments in FY 2004 from $74.8 million to $50 million. The commenter explained that this conclusion was made using only first quarter FY 2003 MedPAR data and, since this technology is still in its infancy, the commenter believed FY 2003 MedPAR data will reflect an upward trend in its use and overall availability.

Some commenters were concerned that first year utilization of any new technology is an inappropriate measure for CMS to rely on in determining the full extent of use of a new technology. They asserted that the gradual adoption of new technology and the time required for hospitals to adapt their coding and charge structures to new technologies make it difficult to base projections of the ultimate utilization and costs of new technology immediately following its introduction. In addition, one commenter explained that CMS' system delays in processing claims have led to a negative impact on both uptake of the technology and the data collection associated with its use.

Also, the commenter explained that Congress required data relating to the cost of the technology be collected for not less than 2 years and not more than 3 years after an appropriate inpatient hospital service code is established. The commenter added that, because CMS publishes its proposed and final rules before the completion of a fiscal year, CMS would make its decision for FY 2005 with less than 2 full year's worth of data. As a result, the commenters recommended that CMS make additional payments for the full 3 years so when it moves a new technology into a DRG, it does so based on accurate and reliable information about its cost and clinical use.

Response: Before each fiscal year, we use the latest available data to determine if we should continue to pay add-on payments for approved new technologies. As stated above, we are continuing to pay for Xigris® for FY 2004 because FY 2002 discharges may not reflect full utilization of the technology. Based on the March update of the FY 2003 MedPAR file, we lowered our cost estimates from the proposed rule because a lower than projected number of cases is receiving this technology at the present time. Before FY 2005, we will again use the latest available data to determine whether we would propose to continue to make add-on payments for Xigris® for FY 2005.

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

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

a. Bone Morphogenetic Proteins (BMPs) for Spinal Fusions

An application was submitted for the InFUSE™ Bone Graft/LT–CAGE™ Lumbar Tapered Fusion Device (InFUSE™) for approval as a new technology eligible for add-on payments. A similar application was submitted last year. However, we denied it because, based on the available data, the technology did not exceed the 1 standard deviation threshold above the average charges for the DRGs to which the technology is assigned.

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

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

add-on payments for FY 2003. For similar reasons, we did not consider data on the charges for multilevel fusions in our analysis of whether this technology meets the cost threshold for FY 2004.

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

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

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

The applicant also submitted data from actual cases involving the InFUSE™ with single level fusions only. The data submitted included 31 claims from 4 hospitals (only one Medicare patient was included in the sample). All 31 cases were from DRG 498. The average standardized charge for these cases was $47,172. Based on these data, the average standardized charge exceeds the threshold for DRG 498. However, we note that this limited sample excludes any cases from DRG 497.

For discharges occurring on or after October 1, 2002, ICD–9–CM codes 84.51 (Insertion of interbody spinal fusion device) and 84.52 (Insertion of recombinant bone morphogenetic protein) are effective to identify cases involving this technology. Therefore, in an effort to resolve the difficulties in obtaining sufficient data upon which to determine whether this technology exceeds the applicable threshold in the May 19, 2003 proposed rule, we stated our intention to review available MedPAR data for the first several months of FY 2003 to identify these cases and calculate their average standardized charges to compare with the thresholds. We noted that some of these cases would involve multilevel spinal fusions, and that it would be necessary to adjust for those cases in order to remove them from the calculation of the average charges.

We have analyzed data from the March update of FY 2003 MedPAR, containing claims data for the first 6 months of FY 2003. As discussed above, accounting for a lag time in claims processing, we are assuming that this data accounts for approximately 5 months of FY 2003 discharges. We identified InFUSE™ cases by the presence of the two new ICD–9–CM codes 84.51 and 84.52, used in combination with each other. We identified 117 and 88 cases in the March 2003 MedPAR data for DRGs 497 and 498, respectively.

We standardized the charges 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, and calculated an average standardized charge of $64,931 for the 117 cases in DRG 497. For DRG 498, the average standardized charge was $58,266 for the 88 cases in our data. The average standardized charge across both DRGs was $62,752. As we noted in the proposed rule, we anticipate that some of these cases will involve multilevel spinal fusions. Based on the applicant's analysis of FY 2001 Standard Analytical File data in which they were able to distinguish between one, two, and three or more levels fused by using CPT codes on the physician claims, we determined that the average charges of single level fusions were about 78 percent of the average charges across all spinal fusions in the analysis. (It was not possible to independently match records from the Standard Analytical File in the time available after we attained the March 2003 MedPAR data.) However, as noted above, these data are from FY 2001 and did not include any cases involving InFUSE™. Therefore, we anticipate more of the cases in our data will be single-fusion cases, consistent with the FDA approval, and that the total charges in our data for single-level fusion cases will be higher than 78 percent of the average for all InFUSE™ cases in our data. Given the relatively recent approval by the FDA of this product, we anticipate the majority of uses are in accordance with the FDA's approval criteria. Therefore, to estimate the average standardized charges of the single-level spinal fusion cases in our data, we estimated 90 percent of the average standardized charges of all the InFUSE™ cases in our data would approximate the charges for single-level cases.

Finally, because these were FY 2003 cases compared to FY 2002 thresholds (based on FY 2001 cases), we adjusted the average charges (by the market basket) to be consistent with the FY 2002 thresholds. The resulting average standardized charge for the cases from our FY 2003 MedPAR data for all InFUSE™ cases across both DRGs 497 and 498 was $53,376.

We then calculated the case-weighted threshold amount across DRGs 497 and 498 based on the proportion of cases in our data in each DRG. Since 57 percent of the cases we identified in our database were in DRG 497, we applied this percentage to the threshold amount for DRG 497 of $58,040. We then added this amount to 43 percent of the threshold amount for DRG 498, for a combined threshold amount of $51,121. Because our data indicates that the average standardized charge for single-level InFUSE™ cases exceeds this threshold amount, this technology has met the cost criteria to qualify for new technology add-on payments.

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

''InFUSE™ Bone Graft is more appropriate to use and has been proven

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

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

As indicated in the May 19, 2003 proposed rule, among the issues we planned to consider were: does avoiding the complications associated with the iliac crest bone harvesting procedure constitute a substantial clinical improvement; and, with the increased rate of osteoarthritis and osteoporosis in the Medicare population, is there evidence that the technology represents a substantial clinical improvement in spinal fusions among this population? In the May 19, 2003 proposed rule, we indicated we were particularly interested in data on the results of aged Medicare patients who have been treated with BMP, and any basic biology bench data on the results of using BMP in osteoporotic bones.

Since the May 19, 2003 proposed rule, we received from the sponsor of this application an analysis, prepared by an orthopedic surgeon, that showed limited evidence of results in a series of patients older than 65, all with good or better fusion results than the younger age group. That analysis presented evidence that older patients typically have better results than younger patients in the standard iliac crest bone harvesting fusion procedure. Finally, it included the results of bench testing of mesenchymal and osteoblastic cells that demonstrated response to rhBMP–2, including cells from elderly patients.

The sum of this evidence does not preclude generalizing the results of InFUSE™ trials to Medicare aged beneficiaries. In addition, the small series of Medicare-aged patients treated with InFUSE™ technology, as well as the bench science on the response of elderly mesenchymal cells to rhBMP–2, do provide some positive, though limited, evidence for generalizability. These results, combined with the benefits of the elimination of the need to harvest bone from the iliac crest (and the associated complications), lead us to conclude that InFUSE™ does meet the substantial improvement criteria. Therefore, we are approving InFUSE™ for add-on payments under § 412.88, to be effective for FY 2004.

This approval is on the basis of using InFUSE™ for a single-level, lumbar spinal fusions, consistent with the FDA's approval and the data presented to us by the applicant. Therefore, we intend to limit the add-on payment to cases using this technology for anterior lumbar fusions in DRGs 497 and 498. Cases involving InFUSE™ that are eligible for the new technology add-on payment will be identified by assignment to DRGs 497 or 498 as a lumbar spinal fusion, with the combination of ICD–9–CM procedure codes 84.51 and 84.52.

As explained above, we are limiting our approval of this technology to uses consistent with our substantial clinical improvement decision. Therefore, add-on payments are only available for use of the technology at a single-level. The average cost of the InFUSE™ is reported to be $8,900, and a single level fusion requires two of the products. Therefore, the total cost for the InFUSE™ for a single-level fusion is expected to be $17,800. Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device 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 InFUSE™ is $8,900.

For purposes of budget neutrality, it is necessary to estimate the additional payments that would be made under this provision during FY 2004. We identified 205 cases in DRGs 497 and 498 in the March 2003 update of the FY 2003 MedPAR data. For our FY 2004 budget neutrality estimate, we are projecting this number will grow to 500. Given this estimate and the maximum add-on payment of $8,900, we estimate the total amount of the add-on payments for the InFUSE™ for FY 2004 will be $4.4 million dollars.

Comment: One commenter asked that CMS reconsider the decision to exclude multilevel fusions with InFUSE™ from the cost threshold calculation. The commenter noted that excluding multilevel fusions with InFUSE™ is inconsistent with FDA guidance, clinical practice and other CMS payment decisions for new technologies (notably the creation of DRGs for drug-eluting stents based on the presence of a condition not indicated on the product label, that is, acute myocardial infarction).

Response: As stated previously, because the FDA has not approved this technology for multilevel fusions and the applicant has not submitted data to demonstrate this technology is a substantial clinical improvement for multilevel fusions, we cannot issue a substantial clinical improvement for multilevel fusions. In the September 7, 2001 final rule implementing this provision (66 FR 46913), we stated our position that the special payments under this provision should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries. Where such an improvement is not demonstrated, we continue to believe the incentives of the DRG system provide a useful balance to the introduction of new technologies, and no new technology add-on payment is necessary.

Comment: In the proposed rule, we stated that, if InFUSE™ meet the cost threshold, we would evaluate whether it qualifies as a substantial clinical improvement. One commenter noted that, assuming InFUSE™ does meet the cost threshold, CMS would make a determination on whether the technology meets the substantial clinical improvement criterion without public input or the opportunity to address concerns that CMS may have. The commenter noted that these actions are inconsistent with the Administrative Procedure Act and CMS's pledge to be more open in its policy making.

Response: Because of the many questions that remained at the time of the proposed rule, we were unable to determine if InFUSE™ qualified as a substantial clinical improvement. However, in order to receive comments on this determination, we indicated certain issues we would consider when determining if InFUSE™ qualifies as a substantial clinical improvement. As noted above, we received additional information that enabled us to approve this technology as a substantial clinical improvement. Therefore, we believe interested parties had sufficient information to provide informed comments.

Comment: One commenter, a designer, manufacturer, and supplier of orthopedic devices and supplies, explained that the applicant's analysis probably includes cases for both posterior approaches or posterior instrumentation, or both, which are considered off-label uses from the indications approved by the FDA. Therefore, the commenter requested that cases that do not meet FDA approved indications, once identified, be eliminated from the analysis.

The commenter also noted that once claims of InFUSE™ can be identified

with MedPAR data, DRG weights become eligible for recalibration in order to reflect the appropriate payment within the assigned DRG. Once the weights of a DRG can be evaluated, a technology should no longer be classified as new. Also, the commenter stated that clinical trial results counter the claim of significant improvement, because information presented at the FDA Orthopedics and Rehabilitation Devices Panel public meeting on January 20, 2002, indicated that the InFUSE™ product resulted in an equivalency to that of traditional bone grafting techniques. Although there was a decrease in donor site pain in a small number of subjects in the BMP group, compared with the control group, the commenter questioned whether this factor meets the criteria of substantial clinical improvement. The commenter also questioned the results of a published article on this technology.

Response: One of the criteria for a substantial clinical improvement classification is avoidance of surgery. CMS determined that InFUSE™ should be classified as a substantial improvement if the results of the clinical trials demonstrated outcomes at least equivalent to bone grafting, and the bone harvesting procedure was avoided. CMS clinical staff reviewed the literature and concluded that the current evidence did support grafting equivalence for the FDA approved indications and, therefore, InFUSE™ met the substantial improvement standard. As described above, we did not rely on the applicant's analysis to determine the technology met the high-cost threshold, but conducted direct analysis of available FY 2003 MedPAR data.

b. GLIADEL® Wafer

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

The FDA approved GLIADEL® Wafer on September 23, 1996, for use as an adjunct to surgery to prolong survival in patients with recurrent GBM for whom surgical resection is indicated. In announcing its approval, the FDA indicated that GLIADEL® was approved:

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

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

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

As mentioned in section II.B.3.a of the May 19, 2003 proposed rule and above in this final rule, we examined the definitions of DRGs 1 and 2 to determine whether they could be improved. As proposed, we are creating a new DRG for patients with an intracranial vascular procedure and an intracranial hemorrhage and two new DRGs for patients with only a vascular shunt procedure (splitting on the presence or absence of a CC). We also compared the data submitted in the application for add-payments regarding the charges for GLIADEL® cases with the charges of other procedures in DRGs 1 and 2. We found that, although the $33,002 average standardized charge reported is just below the qualifying threshold in DRG 2, it is actually well below the mean average standardized charge for DRG 1 ($42,092). As noted previously, as many as 60 percent of current GLIADEL® cases may be assigned to DRG 1 based on the presence of CCs. Therefore, we do not believe that any change to the DRG assignment of cases receiving GLIADEL® is warranted at this time. However, we will continue to monitor our data to determine whether a change is warranted in the future.

Comment: One commenter supported CMS' determination that this technology is currently reflected within the DRG weights and does not meet the criteria of being called ''new.'' Another commenter commented that CMS' interpretation of whether a technology is ''new'' is inconsistent with the current statute. The commenter explained that section 1886 (d)(5)(K)(ii)(II) of Act states that CMS should collect data on new technologies ''for a period of not less than 2 years and not more than 3 years beginning on the date on which an inpatient hospital code is issued for the technology.'' Accordingly, the commenter believed it is inconsistent with the intent of Congress to deny new technology status to a product that has been on the market but for which there is no unique ICD–9 code that allows CMS to track the costs of cases in which it is utilized. The commenter urged CMS to reconsider its interpretation of the statute and approve GLIADEL® as a new technology, making clear that a technology will be considered new for 2 to 3 years from the date that an ICD–9–CM code, specific to the technology, becomes available.

Response: As stated above, we discussed our position on this issue in detail in the September 7, 2001 final rule (66 FR 46905). Our rationale for this policy has not changed since we discussed it in that final rule, and we did not propose changes to this policy in the May 19, 2003 proposed rule. Therefore, we are denying this application for add-on payments for FY 2004.

4. Review of the High-Cost Threshold

The current cost threshold for a new technology to qualify for add-on payments is that the average standardized charges of cases involving the new technology must be demonstrated to exceed 1 standard deviation beyond the geometric mean of the standardized charges of the DRG to which the new technology will be assigned. If the new technology is assigned to more than one DRG, the qualifying threshold is equal to the case-weighted (based on the proportion of cases involving the new technology estimated to be assigned to each DRG) average threshold across all relevant DRGs. When we established this threshold in the September 7, 2001 final rule, we expressed our belief that it is important to establish a threshold that recognizes the variability in costs per case within DRGs and maintains the fundamental financial incentives of the IPPS (66 FR 46917).

In commenting on this approach, MedPAC and some hospital associations supported the 1 standard deviation threshold. However, others, particularly representatives of the manufacturers of new technology, have argued this threshold is too high, and that virtually no new technology would qualify for the special payment provision.

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

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

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

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

At the same time, we recognize that the very limited number of applications that have been submitted the past 2 years (five for FY 2003; two for FY 2004) may indicate that only a very small number of the new technologies that come onto the market every year are costly enough even to apply for new technology add-on payments. Therefore, for FY 2005 and subsequent fiscal years, in the May 19, 2003 proposed rule, we proposed to reduce the threshold to 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the DRG to which the new medical service or technology is assigned (§ 412.87(b)(3)).

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

Comment: Some commenters were concerned that the revised threshold of 75 percent of the standard deviation remains too high. The commenters noted that even with the revised cost threshold, few technologies would qualify for add-on payments.

On the assumption that the vast majority of technologies that would qualify for add-on payments would be identified by a new ICD–9–CM procedure code, one commenter identified a total of 26 ICD–9–CM procedure codes issued between the years of 1998 and 2001. The commenter then analyzed 2001 MedPAR data and found that only 2 of the 26 procedures will exceed either the current 1 standard deviation threshold, and 4 would exceed the a threshold at 75 percent of 1 standard deviation. The commenter also explained that the proposed reduction of the threshold is only an 8-percent reduction, and continues to block eligibility for add-on-payments for important new technologies, even where costs increase by 70 percent. The commenter recommended that CMS use a threshold based upon 75 percent of the standardized amount inflated to charges, plus the geometric mean charges for the DRG. The commenter identified 13 of the 26 procedures that would qualify using this threshold.

Another commenter asked that CMS consider adopting separate criteria for biologics and devices, because they have different price levels and pricing patterns relative to drugs and relative to DRG standardized amounts. Other commenters recommended a threshold where the cost of the technology must exceed the cost of existing technologies by at least 50 percent of the DRG standardized amount, multiplied by the DRG weight, but not to exceed $7,500.

One commenter was concerned that, because of budget neutrality, any reduction to the threshold for new technologies would allow more technologies to qualify for add-on payments and would therefore reduce payments for all other hospital inpatient services. The commenter explained that shifting money within the IPPS leaves some hospitals without additional money they need to ensure beneficiaries have access to the newest medical tests and treatments. Therefore, the commenter recommended that add-on payments continue to be limited to new, cutting-edge, breakthrough technologies with significant cost implications.

Response: As stated in the August 1, 2002 final rule (67 FR 50011), it is our intention to implement this provision without fundamentally disrupting the

IPPS. A substantial number of cases receiving extra cost-based payments (or substantial disaggregation of the DRGs into smaller units of payment) would undermine the efficiency incentives of the DRG payment system. Also, we continue to believe a threshold based on the standard deviation is appropriate for this purpose. (For further reading on this, see the September 7, 2001 final rule (66 FR 46917).)

The DRG system is an average-based system under which hospitals expect to finance costly cases through less costly cases. We believe the add-on policy envisioned by some commenter, that would reduce the maximum threshold across all DRGs to 75 percent of the standardized amount (approximately $3,300) adjusted to charges, would significantly disrupt the averaging principles of the IPPS. By assuming only 26 new technologies over a 4-year span, the analysis presented by the commenter dramatically underestimates the annual volume of new technologies that would be likely to meet such a reduced threshold. Industry sources cite over 1,000 companies producing medical devices, diagnostic products, and medical information systems in the U.S., producing over $70 billion worth of products annually. A very limited number of these products receive specific ICD–9–CM procedure codes, particularly in years prior to the establishment of the IPPS new technology add-on policy. A more accurate estimate of the number of technologies likely to be approved under this revised threshold could be attained by listing the technologies approved during that period with the average wholesale price.

As stated above, we recognize the limited number of applications for add-on payments that have been submitted in the past 2 years and, therefore, we are lowering the threshold. We believe this new threshold is a fair balance that maintains the averaging principles of the IPPS while easing the qualifying requirement. Therefore, for FY 2005 and subsequent fiscal years, we are reducing the threshold to 75 percent of 1 standard deviation (based on the logarithmic values of the charges) beyond the geometric mean standardized charges for all cases in the DRG to which the new medical service or technology is assigned, transformed back to charges.

We disagree with the commenter's suggestion that we establish separate thresholds for biologics and devices. We believe the IPPS is intended to pay hospitals for their costs to treat patients, and physicians select from a range of options based on the medical needs of the patients. The payment system should be neutral with respect to those options. We are concerned that establishing separate thresholds for biologics and devices would indicate an inappropriate payment preference for one or the other option.

Comment: Other commenters representing hospitals approved of the threshold proposed by CMS. One commenter explained that a threshold that limits the number of new technologies is necessary, as the administrative burden for hospitals and the program is significant for each additional item qualifying. Given the finite pool of funds, an abundance of qualifying technologies could result in prorata reductions, such as those that were experienced under the outpatient prospective payment system. With that in mind, the commenter asked that CMS look at other approval mechanisms that would direct the funds to be focused on significantly expensive new technologies that also have significant volumes nationally. For example, national expenditures projected by CMS for each technology seeking approval should exceed $30 million. Assuming national total expenditures of $75 billion with a 1 percent set aside at $750 million, and a marginal cost at 50 percent, 25 technologies could be approved by CMS.

As an alternative, the commenter recommended that CMS incorporate new technologies into the appropriate DRG without having to specifically code the new technology. The DRG weights would then be adjusted to reflect the increased costs associated with such new technologies rather than making a separate add-on payment. The commenter believed this would be a reasonable compromise between the need to incorporate new technologies into the DRGs, while avoiding an unduly burdensome coding and billing process.

Response: We believe the incremental costs to hospitals associated with this provision should be minimal. Specifically, the additional payments are triggered by the presence of an ICD–9–CM code on the bill, information already required to process the claim for normal DRG payments. Accordingly, there should be little need for training or other operational changes in response to the approval of a new technology for add-on payments.

Also, adding further criteria as suggested by the commenter would make it even more difficult for new technologies to qualify for add-on payments. In this final rule, it is our intention to lower the threshold in order to increase the number of applications we receive each year for add-on payments. With respect to the commenter's suggestion to incorporate a new technology in a DRG and raise the weight of the DRG based on the increased cost of the new technology, we are concerned that this suggestion would have the potential to create possibly large imbalances in the DRG weights if the predicted volume of a particular technology turns out to be inaccurate. We believe an add-on payment is the most appropriate methodology to provide additional payments for qualifying high cost new technologies, while still maintaining the overall integrity of the DRG system.

5. Technical Changes

Subpart H of part 412 describes payments to hospitals under IPPS. We have become aware of references to the calculation of IPPS payments in this subpart that inadvertently omit references to new technology add-on payments. For example, § 412.112(c) describes the basis for per case payments. This section refers to outlier payments under subpart F, but was not revised to reflect the implementation of the new technology add-on payments. Therefore, in the May 19, 2003 proposed rule, we proposed to amend § 412.112(c) to add a new paragraph (d) to include a reference to additional payments for new medical services or technologies under subpart F.

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

Section 412.116(e) currently states that payments for outlier cases are not made on an interim basis. That is, for hospitals receiving payments under a biweekly, lump-sum payment methodology, outlier payments are not included in the calculation of the lump-sum payment amounts. Rather, outlier payments are calculated on a case-by-case basis. Similarly, due to the unique nature of the new technology add-on payments, in the May 19, 2003 proposed rule, we proposed that they would also be calculated on a case-by-case basis rather than included in the calculation of interim payment amounts. Therefore, we proposed to revise § 412.116(e) to include this policy.

We did not receive any comments on this proposal. Therefore, in this final rule, we are adopting the proposal as final without modification.

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 Metropolitan Statistical Areas (MSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs) issued by the Office of Management and Budget (OMB). OMB also designates Consolidated MSAs (CMSAs). A CMSA is a metropolitan area with a population of one million or more, comprising two or more PMSAs (identified by their separate economic and social character). For purposes of the hospital wage index, we use the PMSAs rather than CMSAs because they allow a more precise breakdown of labor costs. If a metropolitan area is not designated as part of a PMSA, we use the applicable MSA. For purposes of the IPPS wage index, rural areas are counties outside a designated MSA, PMSA, or NECMA. For purposes of the wage index, we combine all of the rural counties in a State to calculate a rural wage index for that State.

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

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

On June 6, 2003, the Office of Management and Budget (OMB) issued OMB Bulletin No. 03–04, announcing revised definitions of Metropolitan Statistical Areas and new definitions of Micropolitan Statistical Areas and Combined Statistical Areas. A copy of the bulletin may be obtained at the following Internet address: *http://www.whitehouse.gov/omb/bulletins/b03–04.html.* According to OMB, ''(t)his bulletin provides the definitions of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on December 27, 2000, in the **Federal Register** (65 FR 82228–82238) and Census 2000 data.''

In the proposed rule, we stated that we would evaluate the new area designations and their possible effects on the Medicare hospital wage index. In addition, we proposed that the earliest usage of these new definitions would be the FY 2005 wage index.

The new definitions recognize 49 new Metropolitan Statistical Areas and 565 new Micropolitan Statistical Areas, as well as extensively revising the construct of many of the existing Metropolitan Areas. For example, according to OMB's previous definition of the Asheville, NC MSA, this Metropolitan Statistical Area was comprised of Buncombe and Madison counties. When we apply the new definitions, Asheville's Metropolitan Statistical Area includes both Buncombe and Madison counties, as well as Henderson and Haywood counties. An example of a Micropolitan Statistical Area is that of Elizabeth City, NC which includes Camden, Pasquotank, and Perquimans counties. These were non-Metropolitan Statistical Area counties in previous OMB definitions.

In order to implement these changes for the IPPS, it is necessary to identify the new area designation for each county and hospital in the country. Because this process will have to be extensively reviewed and verified, we are unable to undertake it before publication of this final rule. In addition, because we wish to engage in notice and comment rulemaking, prior to adopting these changes, it would be impractical to have done so prior to this final rule. (We note that the OMB Bulletin was issued during the comment period and we did not receive any comments regarding whether the new definitions should be applied to the FY 2004 wage index or objecting to our proposed policy of implementing the changes in FY 2005 at the earliest.)

Finally, geographic reclassification decisions for FY 2004 have already been made based on the previous Metropolitan Statistical Area definitions. These decisions would have to be individually reevaluated if we were to adopt the new OMB definitions for FY 2004. This would not be possible to accomplish while complying with the requirement of section 1886(d)(6) of the Act to publish this annual IPPS update final rule by August 1. For these reasons, at this time, we are not applying these new definitions to the FY 2004 wage index.

Comment: Several commenters recommended that when CMS does implement OMB's new definitions, it should adopt the new 49 MSAs as outlined in the OMB Bulletin. However, the commenters mentioned that the adoption of the MSAs for FY 2004 would be premature, given the magnitude of the policy change. One commenter encouraged CMS to issue a rule or to elaborate on plans for the new Metropolitan and Micropolitan Statistical Area definition changes as soon as possible to allow time for impact analysis, as well as public comments and input. One commenter raised concerns with respect to the criteria that OMB used to define the new MSAs.

Response: We indicated in the proposed IPPS rule that we would need to assess these new definitions before adopting them. In order to implement such a change, it will be necessary to identify the new area designation for each county and hospital in the country, requiring extensive review and verification. We will undertake this analysis as soon as possible. We intend to move very deliberately and expeditiously regarding these potentially vast changes. Any changes would be made through notice and comment rulemaking. Therefore, we are not addressing technical comments relating to the new MSAs in this document.

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. This adjustment is discussed in section II.4.a. of the Addendum to this final rule.

As discussed below in section III.F. of this preamble, we also take into account the geographic reclassification of