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Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412 et al.

**Medicare Program; Changes to the
Hospital Inpatient Prospective Payment
Systems and Fiscal Year 2003 Rates;
Proposed Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, 482, 485, and 489

[CMS-1203-P]

RIN 0938-AL23

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2003 Rates

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

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare acute care hospital inpatient prospective payment systems for operating and capital costs to implement changes arising from our continuing experience with these systems. In addition, in the Addendum to this proposed rule, we describe the proposed changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes would be applicable to discharges occurring on or after October 1, 2002. We also are setting forth proposed rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the acute care hospital inpatient prospective payment systems.

In addition, we are proposing changes to other hospital payment policies, which include policies governing: payments to hospitals for the direct and indirect costs of graduate medical education; pass-through payments for the services of nonphysician anesthetists in some rural hospitals; clinical requirements for swing-bed services in critical access hospitals (CAHs); payments to provider-based entities; and implementation of the Emergency Medical Treatment and Active Labor Act (EMTALA).

DATES: Comments will be considered if received at the appropriate address, as provided below, no later than 5 p.m. on July 8, 2002.

ADDRESSES: Mail written comments (an original and three copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1203-P, P.O. Box 8010, Baltimore, MD 21244-1850.

If you prefer, you may deliver, by hand or courier, your written comments

(an original and three copies) to one of the following addresses:

Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, or Room C5-14-03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

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

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

Centers for Medicare & Medicaid Services, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Attn: John Burke, CMS-1203-P; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, CMS Desk Officer.

FOR FURTHER INFORMATION CONTACT: Stephen Phillips, (410) 786-4548, Operating Prospective Payments, Diagnosis-Related Groups (DRGs), Wage Index, New Medical Services and Technology, Hospital Geographic Reclassifications, and Postacute Transfer Issues. Tzvi Hefter, (410) 786-4487, Capital Prospective Payment, Excluded Hospitals, Graduate Medical Education, Provider-Based Entities, Critical Access Hospital (CAH), EMTALA Issues. Stephen Heffler, (410) 786-1211, Hospital Market Basket Rebasing. Jeannie Miller, (410) 786-3164, Clinical Standards for CAHs. Tom Hutchinson, (410) 786-8953, Hospital Communication with Medicare+Choice Organizations.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments

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

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I. Background

A. Summary

1. Acute Care Hospital Inpatient Prospective Payment System

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. Under these prospective payment systems, 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 share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital is recognized as serving a disproportionate share of low-income patients, it receives a percentage add-on payment for each case paid through the acute care hospital inpatient prospective payment system. This percentage varies, depending on several factors which include the percentage of low-income patients served. It is applied to the DRG-adjusted base payment rate, plus any outlier payments received.

If the hospital is an approved teaching hospital, it receives a percentage add-on payment for each case paid through the acute care hospital inpatient prospective payment system. This percentage varies, depending on the ratio of residents to beds.

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.

Although payments to most hospitals under the acute care hospital inpatient prospective payment system 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 Federal fiscal year (FY) 1982, FY 1987, or FY 1996) or the prospective payment system 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 prospective payment system rate and their hospital-specific rates, if the hospital-specific rate is higher than the prospective payment system rate).

The existing regulations governing payments to hospitals under the acute care hospital inpatient prospective payment system are located in 42 CFR part 412, Subparts A through M.

2. Hospitals and Hospital Units Excluded From the Acute Care Hospital Inpatient Prospective Payment System

Under section 1886(d)(1)(B) of the Act, as amended, certain specialty hospitals and hospital units are excluded from the acute care hospital inpatient prospective payment system. These hospitals and units are: psychiatric hospitals and units; rehabilitation hospitals and units; long-term care hospitals; children's hospitals; and cancer hospitals. Various sections of the Balanced Budget Act of 1997 (Public Law 105-33), the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (Public Law 106-113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106-554) provide for the implementation of prospective payment systems for rehabilitation hospitals and units, psychiatric hospitals and units, and long-term care hospitals, as discussed below. Children's hospitals and cancer hospitals will continue to be paid on a cost-based reimbursement basis.

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

Under section 1886(j) of the Act, as amended, rehabilitation hospitals and units are being transitioned from a blend of reasonable cost-based reimbursement subject to a hospital-specific annual limit under section 1886(b) of the Act and Federal prospective payments for cost reporting periods beginning January 1, 2002 through September 30, 2002, to payment on a fully Federal prospective rate effective for cost reporting periods beginning on or after October 1, 2002 (66 FR 41316, August 7, 2001). The statute also provides that IRFs may elect to receive the full prospective payment instead of a blended payment. The existing regulations governing payment under the inpatient rehabilitation facility prospective payment system (for

rehabilitation hospitals and units) are located in 42 CFR part 412, subpart P.

Under the broad authority conferred to the Secretary by section 123 of Public Law 106-113 and section 307(b) of Public Law 106-554, we are proposing to transition long-term care hospitals from payments based on reasonable cost-based reimbursement under section 1886(b) of the Act to fully Federal prospective rates during a 5-year period. For cost reporting periods beginning on or after October 1, 2006, we are proposing to pay long-term care hospitals under the fully Federal prospective payment rate. (See the proposed rule issued in the **Federal Register** on March 22, 2002 (67 FR 13416).) Under the proposed rule, long-term care hospitals would also be permitted to elect to be paid based on full Federal prospective rates. The proposed regulations governing payments under the long-term care hospital prospective payment system would be located in 42 CFR part 412, subpart O.

Sections 124(a) and (c) of Public Law 106-113 provide for the development of a per diem prospective payment system for payment for inpatient hospital services furnished by 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 must maintain budget neutrality. We are in the process of developing a proposed rule, to be followed by a final rule, to implement the prospective payment system for psychiatric hospitals and units.

3. Critical Access Hospitals

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

4. Payments for Graduate Medical Education

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act; the

amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year.

The existing regulations governing GME payments are located in 42 CFR part 413.

B. Major Contents of This Proposed Rule

In this proposed rule, we are setting forth proposed changes to the Medicare hospital inpatient prospective payment systems for operating costs and for capital-related costs in FY 2003. We also are proposing changes relating to payments for GME costs; payments to excluded hospitals and units; policies implementing EMTALA; clinical requirements for swing beds in CAHs; and other hospital payment policy changes. The proposed changes would be effective for discharges occurring on or after October 1, 2002.

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

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

As required by section 1886(d)(4)(C) of the Act, we adjust the DRG classifications and relative weights annually. Based on analyses of Medicare claims data, we are proposing to establish a number of new DRGs and to make changes to the designation of diagnosis and procedure codes under other existing DRGs. Our proposed changes for FY 2003 are set forth in section II. of this preamble.

Among the proposed changes discussed are:

- Revisions of DRG 1 (Craniotomy Age >17 Except for Trauma) and DRG 2 (Craniotomy for Trauma Age >17) to reflect the current assignment of cases involving head trauma patients with other significant injuries to MDC 24;
- Reconfiguration of DRG 14 (Specific Cerebrovascular Disorders Except Transient Ischemic Attack) and DRG 15 (Transient Ischemic Attack and Precerebral Occlusions) and creation of a new DRG 524 (Transient Ischemia);
- Creation of a new DRG for heart assist devices;
- Reassignment of the diagnosis code for rheumatic heart failure with cardiac catheterization;
- Assignment of new, and reassignment of existing, cystic fibrosis principal diagnosis codes;
- Designation of a code for insertion of totally implantable vascular access device (VAD);

- Changes in the DRG assignment for the bladder reconstruction procedure code.
- Changes in DRG and MDC assignments for numerous newborn and neonate diagnosis codes; and
- Changes in DRG assignment for cases of tracheostomy and continuous mechanical ventilation greater than 96 hours.

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

2. Proposed Changes to the Hospital Wage Index

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

- The FY 2003 wage index update, using FY 1999 wage data.
- Exclusion from the wage index of Part A physician wage costs that are teaching-related, as well as resident and Part A certified registered nurse anesthetist (CRNA) costs.
- Collection of data for contracted administrative and general, housekeeping, and dietary services.
- Revisions to the wage index based on hospital redesignations and reclassifications by the Medicare Geographic Classification Review Board (MGRB).
- Requests for wage data corrections, including clarification of our policies on mid-year corrections.

3. Revision and Rebasings of the Hospital Market Basket

In section IV. of this preamble, we discuss issues relating to our proposed rebasing and revision of the hospital market basket in developing the recommended FY 2003 update factor for the operating prospective payment rates and the excluded hospital rate-of-increase limits. We also set forth the data sources used to determine the proposed revised market basket relative weights and choice of price proxies.

4. Other Decisions and Proposed Changes to the Prospective Payment System for Inpatient Operating and Graduate Medical Education Costs

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

- Options for expanding the postacute care transfer policy.
- Refinement of the application of a hospital bed-count policy that would more accurately reflect the size of a hospital's operations.

• Clarification of the application of the statutory provisions on the calculation of hospital-specific rates for SCHs.

- Technical change regarding additional payments for outlier cases.
- Rural referral centers proposed case-mix index values for FY 2003.
- Changes relating to the IME adjustment, including resident-to-bed ratio caps and counting beds for IME and DSH adjustments.
- Clarification and codification of classification requirements for MDHs and intermediary evaluations of cost reports for these hospitals.
- Changes to policies on pass-through payments for the costs of nonphysician anesthetists in some rural hospitals.
- Clarification of policies relating to implementing 3-year reclassifications of hospitals and other policies related to hospital reclassifications decisions made by the MGRB.
- Changes relating to payment for the direct costs of GME.
- Changes related to emergency medical conditions in hospital emergency department under the EMTALA provisions.
- Criteria for and payments to provider-based entities.
- CMS-directed reopening of intermediary determinations and hearing decisions on provider reimbursements.

5. Prospective Payment System for Capital-Related Costs

In section VI. of this preamble, we specify the proposed payment requirements for capital-related costs which include:

- Capital-related costs for new hospitals.
- Additional payments for extraordinary circumstances.
- Restoration of the 2.1 percent reduction to the standard Federal capital prospective payment system rate.
- Clarification of the special exceptions payment policy.

6. Proposed Changes for Hospitals and Hospital Units Excluded From the Prospective Payment Systems

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

- Payments for existing excluded hospitals and hospital units for FY 2003.
- Updated caps for new excluded hospitals and hospital units.
- Revision of criteria for exclusion of satellite facilities from the acute care hospital inpatient prospective payment system.

- The prospective payment systems for inpatient rehabilitation hospitals and units and long-term care hospitals.

- Changes in the advance notification period for CAHs electing the optional payment methodology.

- Removal of the requirement on CAHs to use a State resident assessment instrument (RAI) for patient assessments for swing-bed patients.

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

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the FY 2003 prospective payment rates for operating costs and capital-related costs. We also establish the proposed threshold amounts for outlier cases. In addition, we address update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2003 for hospitals and hospital units excluded from the acute care hospital inpatient prospective payment system.

8. Impact Analysis

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

9. Report to Congress on the Update Factor for Hospitals Under the Prospective Payment System and Hospitals and Units Excluded From the Prospective Payment System

Section 1886(e)(3) of the Act requires the Secretary to report to Congress on our initial estimate of a recommended update factor for FY 2003 for payments to hospitals included in the acute care hospital inpatient prospective payment system, and hospitals excluded from this prospective payment system. This report is included as Appendix B to this proposed rule.

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

As required by sections 1886(e)(4) and (e)(5) of the Act, appendix C provides our recommendation of the appropriate percentage change for FY 2003 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 prospective payment system 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

acute care hospital inpatient prospective payment system.

11. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, the Medicare Payment Advisory Commission (MedPAC) is required to submit a report to Congress, not later than March 1 of each year, that reviews and makes recommendations on Medicare payment policies. This annual report makes recommendations concerning hospital inpatient payment policies. In section VIII. of this preamble, we discuss the MedPAC recommendations and any actions we are proposing to take with regard to them (when an action is recommended). For further information relating specifically to the MedPAC March 1 report or to obtain a copy of the report, contact MedPAC at (202) 653-7220 or visit MedPAC's website at: www.medpac.gov.

II. Proposed Changes to DRG Classifications and Relative Weights

A. Background

Under the acute care hospital inpatient prospective payment system, we pay for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG relative to the average resources used to treat cases in all DRGs.

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The proposed changes to the DRG classification system and the proposed recalibration of the DRG weights for discharges occurring on or after October 1, 2002 are discussed below.

B. DRG Reclassification

1. General

Cases are classified into DRGs for payment under the acute care hospital inpatient prospective payment system

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 International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM).

For FY 2002, cases are assigned to one of 506 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. However, some MDCs are not constructed on this basis because they involve multiple organ systems (for example, MDC 22 (Burns)).

In general, cases are assigned to an MDC based on the patients' principal diagnosis before assignment to a DRG. However, for FY 2002, there are eight DRGs to which cases are directly assigned on the basis of ICD-9-CM procedure codes. These are the DRGs for heart, liver, bone marrow, lung transplants, simultaneous pancreas/kidney, and pancreas transplants (DRGs 103, 480, 481, 495, 512, and 513, respectively) and the two DRGs for tracheostomies (DRGs 482 and 483). Cases are assigned to these DRGs before classification to an MDC.

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

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

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

After screening through the MCE and any further development of the claims, cases are classified into the appropriate

DRG by the Medicare GROUPER software program. The GROUPER program was developed as a means of classifying each case into a DRG on the basis of the diagnosis and procedure codes and, for a limited number of DRGs, demographic information (that is, sex, age, and discharge status). The GROUPER is used both to classify current cases for purposes of determining payment and to classify past cases in order to measure relative hospital resource consumption to establish the DRG weights.

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 final rule (64 FR 41500), we discussed a process for considering non-MedPAR data in the recalibration process. In order for the use of particular data to be feasible, we must have sufficient time to evaluate and test the data. The time necessary to do so depends upon the nature and quality of the data submitted. Generally, however, a significant sample of the data should be submitted by mid-October, so that we can test the data and make a preliminary assessment as to the feasibility of using the data. Subsequently, a complete database should be submitted no later than December 1 for consideration in conjunction with next year's proposed rule.

The major changes we are proposing to the DRG classification system for FY 2003 GROUPER version 20.0 and to the methodology to recalibrate the DRG weights are set forth below. Unless otherwise noted, our DRG analysis is based on data from 100 percent of the FY 2001 MedPAR file, which contains hospital bills received through May 31, 2001, for discharges in FY 2001.

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

a. Proposed Revisions of DRGs 1 and 2

Currently, adult craniotomy patients are assigned to either DRG 1 (Craniotomy Age >17 Except for Trauma) or DRG 2 (Craniotomy for Trauma Age >17). The trauma distinction recognizes that head trauma

patients requiring a craniotomy often have multiple injuries affecting other body parts. However, we note that the structure of these DRGs predates the creation in FY 1991 of MDC 24 (Multiple Significant Trauma). The creation of MDC 24 resulted in head trauma patients with other significant injuries being assigned to MDC 24 and removed from DRG 2. In FY 1990, there was a 16-percent difference in the DRG weights for DRG 1 and DRG 2. In FY 1992, after the creation of MDC 24, the percentage difference in the DRG weights for DRG 1 and DRG 2 had declined to 1.2 percent. The FY 2002 payment weight for DRG 1 is 3.2713 and for DRG 2 is 3.3874, a 3.5 percent difference.

For FY 2003, we reevaluated the GROUPER logic for DRGs 1 and 2 by combining the patients assigned to these DRGs and examining the impact of other patient attributes on patient charges. The presence or absence of a CC was found to have a substantial impact on patient charges.

Cases in DRGs 1 and 2	Number of patients	Average charges
With CC	19,012	\$49,659
Without CC	9,618	26,824

Thus, there is an 85.1 percent difference in average charges for the groups with and without CC for the combined DRGs 1 and 2. On this basis, we are proposing to redefine and retitile DRGs 1 and 2 as follows: DRG 1 (Craniotomy Age >17 with CC); and DRG 2 (Craniotomy Age >17 without CC).

b. Proposed Revisions of DRGs 14 and 15

To assess the appropriate classification of patients with stroke symptoms, we evaluated the assignment of cases to DRGs 14 (Specific Cerebrovascular Disorders Except Transient Ischemic Attack (TIA) and DRG 15 (Transient Ischemic Attack and Precerebral Occlusions). Our data review indicated that the cases in DRGs 14 and 15 fell into three discrete groups. The first group included cases in which the patients were very sick, with severe intracranial lesions or subarachnoid

hemorrhage and severe consequences. The second group included cases in which patients had not suffered a debilitating stroke but instead may have experienced a transient ischemic attack. The patients in the second group had one half of the average length of stay in the hospital as the first group. The third group of cases included patients who appeared to suffer strokes with minor consequences, as well as those having occluded vessels without having a full-blown stroke.

We found that patients who have intracranial hemorrhage and patients who have infarction are similar in severity. These cases are more frequent in occurrence than cases with patients who have subarachnoid hemorrhage. Therefore, we are proposing to continue to group patients with intracranial hemorrhage and infarction together. These types of cases are different from patients with, for example, an occlusive carotid artery without infarction. In this common group of cases, patients are not as severely ill because they typically have lesser degrees of functional status deficits.

Our analysis indicates that we can improve the clinical and resource cohesiveness of DRGs 14 and 15 by reassigning several specific ICD-9-CM codes. For example, code 436 (Acute, but ill-defined, cerebrovascular disease) is not a specific code and contains patients with a wide range of deficits and anatomic problems. Our data show that these cases consume fewer resources and have shorter lengths of stay than other cases in DRG 14. Therefore, we are proposing to remove code 436 from DRG 14 and reassign it to DRG 15. We also are proposing to create a third new DRG to further identify these cases. The proposed revised or new DRG titles are as follows: DRG 14 (Intracranial Hemorrhage and Stroke with Infarction); DRG 15 (Nonspecific Cerebrovascular and Precerebral Occlusion without Infarction); and DRG 524 (Transient Ischemia).

The following table represents a proposed reconfiguration of DRGs 14 and 15 and the creation of a new DRG 524 reflecting these three categorizations:

Proposed DRG and title	Number of cases	Average length of stay (days)	Average charge
Revised DRG 14 (Intracranial Hemorrhage and Stroke with Infarction)	164,786	6.1	\$15,643
Revised DRG 15 (Nonspecific Cerebrovascular and Precerebral Occlusion without Infarction)	70,866	4.9	11,595
New DRG 524 (Transient Ischemia)	92,835	3.3	8,633

The proposed reconfiguration of DRGs 14 and 15 would result in the following codes being designated as principal diagnosis codes in proposed revised DRG 14:

- 430, Subarachnoid hemorrhage
- 431, Intracerebral hemorrhage
- 432.0, Nontraumatic extradural hemorrhage
- 432.1, Subdural hemorrhage
- 432.9, Unspecified intracranial hemorrhage
- 433.01, Occlusion and stenosis of basilar artery, with cerebral infarction
- 433.11, Occlusion and stenosis of carotid artery, with cerebral infarction
- 433.21, Occlusion and stenosis of vertebral artery, with cerebral infarction
- 433.31, Occlusion and stenosis of multiple and bilateral arteries, with cerebral infarction
- 433.81, Occlusion and stenosis of other specified precerebral artery, with cerebral infarction
- 433.91, Occlusion and stenosis of unspecified precerebral artery, with cerebral infarction
- 434.01, Cerebral thrombosis with cerebral infarction
- 434.11, Cerebral embolism with cerebral infarction
- 434.91, Cerebral artery occlusion, unspecified, with cerebral infarction

In addition, we are proposing that the following two codes be moved from DRG 14 to DRG 34 (Other Disorders of Nervous System with CC) and DRG 35 (Other Disorders of Nervous System without CC): Code 437.3 (Cerebral aneurysm, nonruptured) and Code 784.3 (Aphasia). These codes do not represent acute conditions. Aphasia, for example, could result from a cerebral infarction, but if it does, the infarction should be correctly coded as the principal diagnosis.

The proposed redefined DRG 15 would contain the following principal diagnosis codes:

- 433.00, Occlusion and stenosis of basilar artery, without mention of cerebral infarction
- 433.10, Occlusion and stenosis of carotid artery, without mention of cerebral infarction
- 433.20, Occlusion and stenosis of vertebral artery, without mention of cerebral infarction
- 433.30, Occlusion and stenosis of multiple and bilateral arteries, without mention of cerebral infarction
- 433.80, Occlusion and stenosis of other specified precerebral artery, without mention of cerebral infarction
- 433.90, Occlusion and stenosis of unspecified precerebral artery, without mention of cerebral infarction

- 434.00, Cerebral thrombosis without mention of cerebral infarction
- 434.10, Cerebral embolism without mention of cerebral infarction
- 434.90, Cerebral artery occlusion, unspecified, without mention of cerebral infarction
- 436, Acute, but ill-defined, cerebrovascular disease

In addition, we are proposing to remove the following codes from the existing DRG 15 and place them in the proposed newly created DRG 524:

- 435.0, Basilar artery syndrome
- 435.1, Vertebral artery syndrome
- 435.2, Subclavian steal syndrome
- 435.3, Vertebrobasilar artery syndrome
- 435.8, Other specified transient cerebral ischemias
- 435.9, Unspecified transient cerebral ischemia

We are proposing to move code 437.1 (Other generalized ischemic cerebrovascular disease) from DRG 16 (Nonspecific Cerebrovascular Disorders with CC) and DRG 17 (Nonspecific Cerebrovascular Disorders without CC) and add it to the proposed new DRG 524. This proposed change represents a modification to improve clinical coherence and seems to be a logical change for the construction of the proposed new DRG 524.

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

a. Heart Assist Systems

Heart failure is typically caused by persistent high blood pressure (hypertension), heart attack, valve disease, other forms of heart disease, or birth defects. It is a chronic condition in which the lower chambers of the heart (ventricles) cannot pump sufficient amounts of blood to the body. This causes the organs of the body to progressively fail, resulting in numerous medical complications and frequently death. DRG 127 (Heart Failure and Shock), to which heart failure cases are assigned, is the single most common DRG in the Medicare population, and represents the medical, not surgical, treatment options for this group of patients.

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

Studies are currently underway to evaluate LVADs as permanent support for end-stage heart failure patients.

We have reviewed the payment and DRG assignment of this type of device in the past. Originally, these cases were assigned to DRG 110 (Major Cardiovascular Procedures with CC) and DRG 111 (Major Cardiovascular Procedures without CC) in the September 1, 1994 final rule (59 FR 45345). A more specific procedure code, 37.66 (Implant of an implantable, pulsatile heart assist system) was made effective for use with hospital discharges occurring on or after October 1, 1995. In the August 29, 1997 final rule (62 FR 45973), we reassigned these cases to DRG 108 (Other Cardiothoracic Procedures), because it was the most clinically similar DRG with the best match in resource consumption according to our data. In the July 31, 1998 final rule (63 FR 40956), we again reviewed our data and discovered that the charges for implantation of an LVAD were increasing at a greater rate than the average charges for DRG 108. The length of stay for cases with code 37.66 was approximately 32 days, or three times as long as all other DRG 108 cases. Therefore, we decided to move LVAD cases from DRG 108 to DRG 104 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization) and DRG 105 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization). We continued to review our data and discuss this topic in the FY 1999 and FY 2000 annual final rules: July 30, 1999 (64 FR 41498) and August 1, 2000 (65 FR 47058).

In the August 1, 2001 final rule (66 FR 39838), we remodeled MDC 5 to add five new DRGs. We also added procedure codes 37.62 (Implant of other heart assist system), 37.63 (Replacement and repair of heart assist system), and 37.65 (Implant of an external, pulsatile heart assist system) to DRGs 104 and 105. We removed defibrillator cases from DRGs 104 and 105 and assigned them to DRG 514 (Cardiac Defibrillator Implant with Cardiac Catheterization) and DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheterization) to make these DRGs more clinically coherent. This also increased the relative weights for DRGs 104 and 105, as the defibrillator cases had lower average charges than other cases in those two DRGs.

In the FY 2001 MedPAR data file, we found 185 LVAD cases in DRG 104 and 90 cases in DRG 105, for a total of 275 cases. These cases represent 1.3 percent of the total cases in DRG 104, and approximately 0.5 percent of the total

cases in DRG 105. However, the average charges for these cases are approximately \$36,000 and \$85,000 higher than the average charges for cases in DRGs 104 and 105, respectively.

This situation presents a dilemma, in that the technology has been available since 1995 and is gradually increasing in utilization, while LVAD cases involving the technology remain a small part of the total cases in these two DRGs. In fact, removing LVAD cases from the calculation of the average charge changes the average by only -0.4 percent and -0.5 percent for DRGs 104 and 105, respectively. Therefore, despite the dramatically higher average charges for LVADs compared to the DRG averages, the relative volume is insufficient to affect the average to any great degree.

Therefore, we are proposing to create a new DRG 525 (Heart Assist System Implant), which would contain these cases. The proposed FY 2003 relative weight for proposed new DRG 525 is 11.3787.

The new DRG would consist of any principal diagnosis in MDC 5, plus one of the following surgical procedures:

- 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

Cases in which a subsequent heart transplant occurs during the hospitalization episode would continue to be assigned to DRG 103 (Heart Transplant) because cases involving procedure codes 336 (Combined heart/lung transplant) and 375 (Heart transplant) are assigned to DRG 103, regardless of other codes included on the bill.

We reiterate a discussion we included in the August 1, 2000 final rule (65 FR 47058) regarding placement of code 37.66 in the MCE screening software as a noncovered procedure. The default designation for that code will continue to be "noncovered" because of the stringent conditions that must be met by hospitals in order to receive payment for implantation of the device.

Section 65-15 of the Medicare Coverage Issues Manual (Artificial Hearts and Relative Devices) provides the national coverage determination regarding Medicare coverage of these devices. This section may be accessed online at www.hcfa.gov/pubforms/06_cim/ci00.htm.

b. Moving Diagnosis Code 398.91 (Rheumatic Heart Failure) From DRG 125 to DRG 124

DRG 124 (Circulatory Disorders Except Acute Myocardial Infarction (AMI), with Cardiac Catheterization and Complex Diagnosis) and DRG 125 (Circulatory Disorders Except Acute Myocardial Infarction (AMI) with Cardiac Catheterization without Complex Diagnosis) have a somewhat complex DRG logic. In order to be assigned to DRG 124 or 125, the patient must first have a circulatory disorder, which would be one of the diagnoses included in MDC 5. However, these DRGs exclude acute myocardial infarctions. Therefore, these DRGs are comprised of cases with a diagnosis from MDC 5, excluding acute myocardial infarction, but also with a cardiac catheterization during the stay.

DRGs 124 and 125 are then further defined by whether or not the patient had a complex diagnosis. If the patient had a complex diagnosis, the case is assigned to DRG 124. If the patient does not have a complex diagnosis, the case is assigned to DRG 125. A list of diagnoses that comprise complex diagnoses is identified within DRG 124. These diagnoses can be listed as either a principal or secondary diagnosis.

We have received correspondence regarding the current assignment of diagnosis code 398.91 (Rheumatic heart failure). The correspondent pointed out that, while other forms of heart failure are listed as complex diagnoses under DRG 124, rheumatic heart failure is not included as a complex diagnosis within that DRG. Currently, if a patient with rheumatic heart failure receives a cardiac catheterization, the case is assigned to DRG 125.

The correspondent had conducted a study and found that patients with rheumatic heart failure who receive a cardiac catheterization have lengths of stay that are significantly longer than patients with other forms of heart failure who receive a cardiac catheterization and who are assigned to DRG 125. The correspondent found that these patients have lengths of stay more similar to those cases assigned to DRG 124 (which have other forms of heart failure), and recommended that diagnosis code 398.91 be added to the list of complex diagnoses within DRG 124.

Within our claims data, we found 439 cases of patients in DRG 125 with rheumatic heart failure who received a cardiac catheterization. The average charges for these rheumatic heart failure cases were almost twice as much as for other cardiac patients in DRG 125 who received a cardiac catheterization and

who did not have a diagnosis of rheumatic heart failure. We also conferred with our medical consultants and they agree that rheumatic heart failure with cardiac catheterization is a complex diagnosis and should be assigned to DRG 124 along with the other complex forms of heart failure cases involving cardiac catheterization.

We are proposing to add code 398.91 to DRG 124 as a complex diagnosis. As a result, catheterization cases with rheumatic heart disease would no longer be assigned to DRG 125.

c. Radioactive Element Implant

In the August 1, 2001 final rule, we created DRG 517 (Percutaneous Cardiovascular Procedure without Acute Myocardial Infarction (AMI) with Coronary Artery Stent Implant) as a result of the overall DRG splits based on the presence of AMI (66 FR 39839). We assigned code 92.27 (Implantation or insertion of radioactive elements) to DRG 517 because we believed that code 92.27 would always accompany cases involving a percutaneous cardiovascular procedure and intravascular radiation treatment. We have since determined that code 92.27 can also be present as a stand-alone code in other types of cases. When cases with code 92.27 do not meet the criteria for DRG 517, they are currently directed into DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis). Because DRG 468 is for cases in which the O.R. procedure is unrelated to the principal diagnosis, rather than assign cases with code 92.27 that would otherwise be assigned to MDC 5 to DRG 468 because they do not meet the criteria for assignment to DRG 517, we are proposing to assign these cases to DRG 120 (Other Circulatory System O.R. Procedures).

4. MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders)

Currently, when ICD-9-CM code 277.00 (Cystic Fibrosis without mention of meconium ileus) is reported as the principal diagnosis, it is assigned to the following DRG series in MDC 10: DRG 296 (Nutritional and Metabolic Disease, Age >17 with CC); DRG 297 (Nutritional and Metabolic Disease, Age >17 without CC); and DRG 298 (Nutritional and Metabolic Disease, Age 0-17).

As part of our annual review of DRG assignments and based on correspondence that we have received, we examined claims relating to cases involving code 277.00 as a principal diagnosis in DRGs 296, 297, and 298. Our analysis of the average charges for cases in which code 277.00 was the principal diagnosis in DRGs 296, 297, and 298 indicates that resource

utilization for these cases is quite different from resource utilization for other cases in the three DRGs. We believe that this difference in resource utilization is due to the fact it is not

uncommon for cystic fibrosis patients to be admitted with pulmonary complications. Our findings on the number of cases and the average charges in the three DRGs when code 277.00 is

assigned as the principal diagnosis, and our findings for all cases in the three DRGs, are indicated in the charts below.

CASES IN DRG 296, 297, AND 298 WITH CODE 277.00 AS THE PRINCIPAL DIAGNOSIS

DRG and description	Number of cases	Average charges
DRG 296 (Nutritional & Metabolic Disease Age >17 with CC)	271	\$34,111
DRG 297 (Nutritional & Metabolic Disease Age >17 with CC)	133	21,998
DRG 298 (Nutritional & Metabolic Disease Age 0-17)	0

ALL CASES IN DRG 296, 297, 298

DRG and description	Number of cases	Average charges
DRG 296 (Nutritional & Metabolic Disease Age >17 with CC)	169,768	\$10,480
DRG 297 (Nutritional & Metabolic Disease Age >17 without CC)	31,560	6,190
DRG 298 (Nutritional & Metabolic Disease Age 0-17)	17	8,603

Based on the results of our analysis, we are proposing that three new cystic fibrosis principal diagnosis codes be assigned to specific DRGs and MDCs, and that other changes be made to DRG and MDC assignments of existing cystic fibrosis codes, as discussed below.

We are proposing to create the following three new principal diagnosis codes:

- 277.02 (Cystic fibrosis with pulmonary manifestations)
- 277.03 (Cystic fibrosis with gastrointestinal manifestations)
- 277.09 (Cystic fibrosis with other manifestations)

We are proposing that existing code 277.01 (Cystic fibrosis with mention of meconium ileus) would continue to be assigned to DRG 387 (Prematurity with Major Problems) and DRG 389 (Full

Term Neonate with Major Problems) in MDC 15 (Newborns and Other Neonates with Conditions Originating in the Perinatal Period), since it is a newborn diagnosis code.

Because proposed new code 277.02 would identify those patients with cystic fibrosis who have pulmonary manifestations, we are proposing to assign cases in which the principal diagnosis is the proposed new code 277.02 to DRG 79 (Respiratory Infection and Inflammations Age >17 with CC), DRG 80 (Respiratory Infections and Inflammations Age >17 without CC), or DRG 81 (Respiratory Infections and Inflammations Age 0-17) in MDC 4 (Diseases and Disorders of the Respiratory System).

We are proposing that proposed new code 277.03 would be assigned to DRG

188 (Other Digestive System Diagnoses Age >17 with CC), DRG 189 (Other Digestive System Diagnoses Age >17 without CC), and DRG 190 (Other Digestive System Diagnoses Age 0-17) in MDC 6 (Diseases and Disorders of the Digestive System), because of its specific relationship to the digestive system.

Since proposed new code 277.09 could involve a number of manifestations (excluding pulmonary and gastrointestinal), we are proposing to assign this proposed new code to DRGs 296, 297, and 298 in MDC 10, where we are retaining the current assignment of existing code 277.00.

The following chart summarizes our proposed DRG and MDC assignments for new and existing cystic fibrosis principal diagnosis codes:

Principal diagnosis code and description	Proposed MDC assignment	Proposed DRG assignments
Existing 277.00 (Cystic fibrosis without mention of meconium ileus)	10	296, 297, 298
Existing 277.01 (Cystic fibrosis with mention of meconium ileus)	15	387, 389
Proposed new 277.02 (Cystic fibrosis with pulmonary manifestations)	4	79, 80, 81
Proposed new 277.03 (Cystic fibrosis with gastrointestinal manifestations)	6	188, 189, 190
Proposed new 277.09 (Cystic fibrosis with other manifestations)	10	296, 297, 298

5. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)

a. Insertion of Totally Implantable Vascular Access Device (VAD)

In the August 1, 2001 final rule (66 FR 39844), we discussed our review of the DRG assignment of code 86.07 (Insertion of totally implantable vascular access device (VAD)). Code 86.07 is considered a nonoperative procedure when it occurs in MDC 11. Therefore, patients in

renal (kidney) failure requiring implantation of this device for dialysis are grouped to medical DRG 316 (Renal Failure). We examined whether implantation of this device should be removed from DRG 316 and placed into surgical DRG 315 (Other Kidney and Urinary Tract O.R. Procedures).

Implantation of a VAD into the chest wall and blood vessels of a patient's upper body allows access to a patient's vessels via an implanted valve and

cannula. Two devices are implanted during one operative session. One system is implanted arterially (the "draw"), while the other is implanted venously (the "return"). Typically, the VAD allows access to the patient's blood for hemodialysis purposes when other sites in the body have been exhausted. The device is usually inserted in the outpatient setting. Operative time is approximately 1 to 1.5 hours.

In the FY 2002 final rule (66 FR 39844–39845), we pointed out that cases where the VAD was inserted as an inpatient procedure also involved other complications, leading to higher average charges. Therefore, we indicated that we were not assigning code 86.07 to DRG 315 at that time, but we would consider other alternative adjustments to DRGs 315 and 316.

For FY 2003, we explored whether DRG 315 should be split based on existence or nonexistence of CCs. However, during our consideration of this alternative, we discovered that DRG 315 does not lend itself to a CC split due to the high occurrence of cases in this DRG that already have complications identified on the CC list. Therefore, we reexamined cases in DRGs 315 and 316 in the FY 2001 MedPAR file. The results are reflected in the chart below:

	With Code 86.07	Without Code 86.07
DRG 315 (surgical):		
Number of Cases	354	21,089.
Average Length of Stay	12.6 days	6.7 days.
Average Charges ..	\$47,251 ...	\$25,622.
DRG 316 (Medical):		
Number of Cases	887	76,676.
Average Length of Stay	10.3	6.6 days.
Average Charges ..	\$31,904 ...	\$16,934.

These results are similar to the findings included in the FY 2002 final rule that were based on data from the FY 2000 MedPAR file (66 FR 39845).

We found that the average length of stay in DRG 315 for patients not receiving the VAD is 6.7 days, while those patients who received the VAD had an average length of stay of 12.6 days. We found the average charges in DRG 315 for patients not receiving the VAD were approximately \$25,622, while the average charges for those

patients who received the VAD were \$47,251.

We found that the cases receiving the VAD as an inpatient procedure are significantly more costly than other cases in DRG 316. Therefore, we are proposing to designate code 86.07 as an O.R. procedure under MDC 11. Specifically, code 86.07 would be recognized as an O.R. procedure code in MDC 11 and assigned to DRG 315 when combined with the following principal diagnosis codes from DRG 316:

- 403.01, Malignant hypertensive renal disease with renal failure
- 403.11, Benign hypertensive renal disease with renal failure
- 403.91, Unspecified hypertensive renal disease with renal failure
- 404.02, Malignant hypertensive heart and renal disease with renal failure
- 404.12, Malignant hypertensive heart and renal disease with renal failure
- 404.92, Unspecified hypertensive heart and renal disease with renal failure
- 584.5, Acute renal failure with lesion of tubular necrosis
- 584.6, Acute renal failure with lesion of renal cortical necrosis
- 584.7, Acute renal failure with lesion of renal medullary (papillary) necrosis
- 584.8, Acute renal failure with other specified pathological lesion in kidney
- 584.9, Acute renal failure, unspecified
- 585, Chronic renal failure
- 586, Renal failure, unspecified
- 788.5, Oliguria and anuria
- 958.5, Traumatic anuria

b. Bladder Reconstruction

We received correspondence regarding the current classification of procedure code 57.87 (Reconstruction of urinary bladder) as a minor bladder procedure and the assignment of the code under DRG 308 (Minor Bladder Procedures with CC) and DRG 309 (Minor Bladder Procedures without CC).

The correspondent believed that bladder reconstruction is not a minor procedure, submitted individual hospital charges to support this contention, and recommended that the code be classified as a major procedure and assigned to a higher weighted DRG.

Our clinical advisors indicated that reconstruction of the bladder is a more extensive procedure than the other minor bladder procedures in DRGs 308 and 309. They agree that the bladder reconstruction procedure is as complex as the procedures under code 57.79 (Total cystectomy) and the other major bladder procedures in DRGs 303 through 305.

As indicated in the chart below, we found that the average charges for bladder reconstruction are significantly higher than the average charges for other minor procedures within DRGs 308 and 309:

	With Code 57.87	Without Code 57.87
DRG 308 (minor bladder procedure with CC):		
Number of Cases	64	5,066
Average Charges	\$36,560	\$19,923
DRG 309 (minor bladder procedures without CC):		
Number of Cases	25	3,021
Average Charges	\$23,390	\$11,200

We found that procedure code 57.87 may be more appropriately placed in DRG 303 (Kidney, Ureter and Major Bladder Procedures for Neoplasm), 304 (Kidney, Ureter and Major Bladder Procedures for Nonneoplasm with CC), and DRG 305 (Kidney, Ureter and Major Bladder Procedures for Nonneoplasm without CC), based on average charges for procedures in these three DRGs as indicated in the following chart:

DRG	Number of cases	Average charges
303 (Kidney, Ureter and Major Bladder Procedures for Neoplasm)	14,116	\$30,691
304 (Kidney, Ureter and Major Bladder Procedures for Nonneoplasm with CC)	8,060	30,577
305 (Kidney, Ureter and Major Bladder Procedures for Nonneoplasm without CC)	2,029	15,492

Based on the results of our analysis and the advice of our medical consultants discussed above, we are proposing to classify code 57.87 as a major bladder procedure and to assign it to DRGs 303, 304, and 305.

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

The primary focus of updates to the Medicare DRG classification system is for changes relating to the Medicare patient population, not the pediatric or neonatal patient populations. However, the Medicare DRGs are sometimes used to classify other patient populations.

Over the years, we have received comments about aspects of the Medicare newborn DRGs that appear problematic, and we have responded to these on an individual basis. Some correspondents have requested that we take a closer

overall look at the DRGs within MDC 15.

To respond to this request relating to review of MDC 15, we contacted the National Association of Children's Hospitals and Related Institutions (NACHRI), along with our own medical advisors, to obtain proposals for possible revisions of the existing DRG categories in MDC 15. The focus of the requested proposals was to refine category definitions within the framework of the existing seven broadly defined neonatal DRGs. The proposals also were to take advantage of the new, more specific neonatal diagnosis codes to be adopted, effective October 1, 2002, to assist with refinements to the existing DRG category definitions.

In preparing these proposed changes to MDC 15, we have considered comments and suggestions previously received, including suggestions from NACHRI on how to make improvements

within the existing framework of seven very broadly defined neonatal DRGs. In the future, we may consider broader changes to MDC 15.

a. Definition of MDC 15

The existing diagnosis definitions for MDC 15 include certain diagnoses that may be present at the time of birth but may also continue beyond the perinatal period.

These diagnoses are basically congenital anomalies, and even though they may continue beyond the perinatal period, they are assigned to MDC 15 which is specific to newborns and neonates.

The diagnosis codes assigned to the DRGs under MDC 15 have been a source of confusion because older children and adults can be admitted with these principal diagnoses and assigned to newborn or neonate DRGs in MDC 15 as if they were newborns.

Our medical consultants and NACHRI have reviewed the listing of diagnosis codes and identified those that should not be routinely classified under MDC 15. As a result of this review, we are proposing that the following list of diagnosis codes be removed from MDC 15:

- 758.9, Conditions due to anomaly of unspecified chromosome
- 759.4, Conjoined twins
- 759.7, Multiple congenital anomalies, so described
- 759.81, Prader-Willi Syndrome
- 759.83, Fragile X Syndrome
- 759.89, Other specified anomalies
- 759.9, Congenital anomaly, unspecified
- 779.7, Periventricular leukomalacia
- 795.2, Nonspecific abnormal findings on chromosomal analysis

We are proposing to assign the nine diagnosis codes listed above to the following MDCs and DRGs (if medical):

Diagnosis code	Title	Proposed MDC assignment	Proposed DRG assignment
758.9	Conditions due to anomaly of unspecified chromosome.	23	467 (Other Factors Influencing Health Status).
759.4	Conjoined twins	6	188, 189, 190 (Other Digestive System Diagnoses, age >17 with CC, Age >17 without CC, and Age 0–17, respectively).
759.7	Multiple congenital anomalies, so described	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	Other specified anomalies	8	256 (Other Musculoskeletal System and Connective Tissue Diagnoses).
759.9	Congenital anomaly, unspecified	23	467 (Other Factors Influencing Health Status).
779.7	Periventricular leukomalacia	1	34, 35 (Other Disorders of the Nervous System with CC and without CC, respectively).
795.2	Nonspecific abnormal findings on chromosomal analysis.	23	467 (Other Factors Influencing Health Status).

The following three specific 4-digit diagnosis codes have been determined invalid by the ICD–9–CM Coordination and Maintenance Committee, effective October 1, 2002, and we are proposing to remove them from MDC 15.

- 770.8, Other newborn respiratory problems
- 771.8, Other infection specific to the perinatal period
- 779.8, Other specified conditions originating in the perinatal period

The above three codes are being replaced by 5-digit codes to capture more detail. These new 5-digit codes are assigned to DRGs within MDC 15 and are listed among the codes in Table 6A—New Diagnosis Codes in the Addendum of this proposed rule.

In addition, the ICD–9–CM Coordination and Maintenance Committee created a number of new

codes, effective October 1, 2002, to capture newborn and neonatal conditions. Therefore, we are proposing to add the following new 23 diagnosis codes to MDC 15:

- 747.83, Persistent fetal circulation
- 765.20, Unspecified weeks of gestation
- 765.21, Less than 24 completed weeks of gestation
- 765.22, 24 completed weeks of gestation
- 765.23, 25–26 completed weeks of gestation
- 765.24, 27–28 completed weeks of gestation
- 765.25, 29–30 completed weeks of gestation
- 765.26, 31–32 completed weeks of gestation
- 765.27, 33–34 completed weeks of gestation

- 765.28, 35–36 completed weeks of gestation
- 765.29, 37 or more completed weeks of gestation
- 770.81, Primary apnea of newborn
- 770.82, Other apnea of newborn
- 770.83, Cyanotic attacks of newborn
- 770.84, Respiratory failure of newborn
- 770.89, Other respiratory problems after birth
- 771.81, Septicemia [sepsis] of newborn
- 771.82, Urinary tract infection of newborn
- 771.83, Bacteremia of newborn
- 771.89, Other infections specific to the perinatal period
- 779.81, Neonatal bradycardia
- 779.82, Neonatal tachycardia
- 779.89, Other specified conditions originating in perinatal period

b. DRG 386 (Extreme Immaturity or Respiratory Distress Syndrome, Neonate)

The existing DRG 386 is defined by the presence of one of the ICD-9-CM extreme prematurity codes (765.01 through 765.05) with the fifth digit indicating birthweight less than 1,500 grams (3.3 pounds). NACHRI has identified two weaknesses in the use of the fifth digit to define prematurity.

One weakness relates to determining extreme immaturity, which, in part, is limited by the existing ICD-9-CM diagnosis codes. The existing ICD-9-CM definition for the extreme immaturity codes "usually implies birthweight less than 1,000 grams (2.2 pounds) or gestational age less than 28 completed weeks," or both. The fifth digit provides range values for birthweight but gives no information on gestational age. A specific and distinct set of ICD-9-CM diagnosis codes for gestational age is to be introduced effective October 1, 2002. These new codes will provide a clearer basis for differentiating extreme immaturity or gestational age, or both.

The second weakness is that diagnosis code 769 (Respiratory distress syndrome in newborn) is currently only associated with DRG 386, which requires extreme prematurity, but respiratory distress syndrome in newborns can occur with all levels of prematurity. Therefore, we believe that code 769 should not be used to classify a diagnosis under DRG 386.

The proposed revision to DRG 386 would reflect the upcoming new ICD-9-CM diagnosis codes. We are proposing to redefine DRG 386 to include those newborns whose preterm birthweight is less than 1,000 grams or gestational age is less than 27-28 completed weeks, or both. Therefore, we would remove diagnosis code 769 from DRG 386, as this code is associated with all levels of prematurity, not just extreme immaturity. In addition, we are proposing to revise the title of DRG 386 to read "Extreme Immaturity".

Because birthweight for neonates varies at all gestational ages, some neonates will meet the DRG 386 criteria for preterm extremely low birthweight (less than 1,000 grams) but not the DRG 386 criteria for extremely short gestation age (less than 27-28 completed weeks). The reverse may also occur, where a neonate meets the DRG 386 criteria for extremely short gestational age (less than 27-28 completed weeks) but not for preterm extremely low birthweight (less than 1,000 grams). In either situation, the neonate would be

assigned to the proposed retitled DRG 386 (Extreme Immaturity).

NACHRI provided the following information on the measurement of gestational age and its use in the definition of Medicare neonatal DRGs. First, they noted that gestational age can be as powerful a predictor of a newborn's hospitalization course as birthweight and corresponds more directly to organ system immaturity. Second, while gestational age can be identified with a reasonable level of accuracy, it cannot be measured as precisely as birthweight. These two considerations led NACHRI to recommend the inclusion of gestational age in the definition of the Medicare neonatal DRGs, but in a conservative manner. Specifically, extremely short gestational age, as identified earlier, usually implies gestational age less than 28 weeks. The proposed new definition of DRG 386 includes only the gestational age codes for less than 27 to 28 completed weeks. Thus, there is a 1-week conservative bias in the use of the new gestational age codes for DRG 386. It is also important to note that the existing DRG 386 definition includes existing codes 765.01 through 765.05, which include extreme immaturity without a specific identification of gestational age and birthweight up to 1,499 grams (3.3 pounds). Thus, the proposed revised definition of DRG 386 is actually somewhat more stringent as well as more specific.

To implement these changes, we are proposing to remove the following diagnosis codes from the list of "principal or secondary diagnosis" under DRG 386:

- 765.04, Extreme immaturity, 1,000-1,249 grams
- 765.05, Extreme immaturity, 1,250-1,499 grams
- 769, Respiratory distress syndrome in newborn

Note, as explained above, while we are proposing to remove diagnosis codes 765.04, 765.05, and 769 from the list of principal or secondary diagnosis under DRG 386, a neonate would still be assigned to DRG 386 if there is a diagnosis of gestational age less than 27 to 28 completed weeks reported (765.21 through 765.23).

We are proposing to add the following diagnosis codes to the list of "principal or secondary diagnosis" under DRG 386:

- 765.11, Other preterm infants, less than 500 grams
- 765.12, Other preterm infants, 500-749 grams
- 765.13, Other preterm infants, 750-999 grams
- 765.21, Less than 24 completed weeks of gestation

- 765.22, 24 completed weeks of gestation
- 765.23, 25-26 completed weeks of gestation

c. DRG 387 (Prematurity With Major Problems)

The existing definition of DRG 387 has the following three components: (1) Principal or secondary diagnosis of prematurity; (2) Principal or secondary diagnosis of major problem (these are diagnoses that define MDC 15); or (3) secondary diagnosis of major problem (these are diagnoses that do not define MDC 15 so they can only be secondary diagnosis codes for patients assigned to MDC 15). We are proposing changes for each component of the definition for DRG 387.

We are proposing to revise the definition for the first component of DRG 387, "principal or secondary diagnosis of prematurity", to include all preterm low birthweight codes with fifth digit range code values indicating birthweight between 1,000 grams (2.2 pounds) and 2,499 grams (5.5 pounds), or gestational age between 27 to 28 and 35 to 36 completed weeks, or both. This would include all of the preterm low birthweight and gestational age codes except those assigned to the proposed revised DRG 386 and except for the following four preterm and gestational age codes: 765.10, 765.19, 765.20, and 765.29.

It is possible for a neonate to be premature and greater than 2,500 grams (5.5 pounds). In this instance, one of the new gestational age codes that specifically identifies the newborn to be less than 37 completed weeks of gestation would need to be present to meet the criteria for inclusion in DRG 387. This is not a conceptual change for DRG 387, in that diagnosis codes 765.10 and 765.19 should both refer to newborns less than 37 completed weeks of gestation. Therefore, we are proposing to take into consideration the new ICD-9-CM codes that require a more specific affirmation that the newborn is less than 37 completed weeks of gestation. Because DRG 387 is a broadly defined category (1,000-2,499 grams or 27-36 completed weeks of gestation), NACHRI recommends that it is important to require specific information for inclusion of patients at the high end of the birthweight/gestational age range.

We are proposing to remove the following diagnosis codes from the list of diagnoses defined as "principal or secondary diagnosis of prematurity" for DRG 387:

- 765.10, Other preterm infants, unspecified (weight)

- 765.11, Other preterm infants, less than 500 grams
- 765.12, Other preterm infants, 500–749 grams
- 765.13, Other preterm infants, 750–999 grams
- 765.19, Other preterm infants, 2,500+ grams

We are proposing to add the following diagnosis codes to the list of diagnoses defined as “principal or secondary diagnosis of prematurity” for DRG 387:

- 765.04, Extreme immaturity, 1000–1249 grams
- 765.05, Extreme immaturity, 1250–1499 grams
- 765.24, 27–28 completed weeks of gestation
- 765.25, 29–30 completed weeks of gestation
- 765.26, 31–32 completed weeks of gestation
- 765.27, 33–34 completed weeks of gestation
- 765.28, 35–36 completed weeks of gestation

We are proposing to revise the definition for the second component of DRG 387, “principal or secondary diagnosis of major problem”, to remove certain diagnosis codes and to add other diagnosis codes. We are proposing to remove three groups of diagnosis codes. The first group of diagnosis codes that we are proposing to remove includes the fetal malnutrition codes for the birthweight ranges less than 2500 grams. NACHRI indicates that these newborns are not necessarily more complicated than preterm infants of the same birthweight range. These newborns have fewer problems related to organ system immaturity and often demonstrate excellent catch-up growth after delivery. Some of the fetal malnutrition diagnosis neonates may have serious problems. Therefore, it is best for the classification system to look for other more specific, major problem diagnoses than to include all of these newborns in DRG 387. We are proposing to remove the following diagnosis codes from DRG 387.

- 764.11, “Light-for-dates” with signs of fetal malnutrition, less than 500 grams
- 764.12, “Light-for-dates” with signs of fetal malnutrition, 500–749 grams
- 764.13, “Light-for-dates” with signs of fetal malnutrition, 750–999 grams
- 764.14, “Light-for-dates” with signs of fetal malnutrition, 1,000–1,249 grams
- 764.15, “Light-for-dates” with signs of fetal malnutrition, 1,250–1,499 grams
- 764.16, “Light-for-dates” with signs of fetal malnutrition, 1,500–1,749 grams
- 764.17, “Light-for-dates” with signs of fetal malnutrition, 1,750–1,999 grams
- 764.18, “Light-for-dates” with signs of fetal malnutrition, 2,000–2,499 grams

- 764.21, Fetal malnutrition without mention of “light-for-dates”, less than 500 grams
- 764.22, Fetal malnutrition without mention of “light-for-dates”, 500–749 grams
- 764.23, Fetal malnutrition without mention of “light-for-dates”, 750–999 grams
- 764.24, Fetal malnutrition without mention of “light-for-dates”, 1,000–1,249 grams
- 764.25, Fetal malnutrition without mention of “light-for-dates”, 1,250–1,499 grams
- 764.26, Fetal malnutrition without mention of “light-for-dates”, 1,500–1,749 grams
- 764.27, Fetal malnutrition without mention of “light-for-dates”, 1,750–1,999 grams
- 764.28, Fetal malnutrition without mention of “light-for-dates”, 2,000–2,499 grams

The second group of codes we are proposing to remove from the list of “principal or secondary diagnosis of major problems” under DRG 387 consists of the following 13 diagnosis codes. The majority of these diagnosis codes do not represent a major problem for a newborn at or shortly after birth. NACHRI believes that costs associated with newborns with these conditions are similar to costs associated with neonates without a major problem.

- 763.4, Cesarean delivery affecting fetus or newborn
- 770.1, Meconium aspiration syndrome
- 770.8, Other newborn respiratory problems
- 771.8, Other infection specific to the perinatal period
- 772.0, Fetal blood loss
- 773.2, Hemolytic disease due to other and unspecified isoimmunization of fetus or newborn
- 773.5, Late anemia due to isoimmunization of fetus or newborn
- 775.5, Other transitory neonatal electrolyte disturbances
- 775.6, Neonatal hypoglycemia
- 776.0, Hemorrhagic disease of newborn
- 776.6, Anemia of prematurity
- 777.1, Meconium obstruction in fetus or newborn
- 777.2, Intestinal obstruction due to inspissated milk in newborn

We note that diagnosis code 770.8 (Other newborn respiratory problems) and diagnosis code 771.8 (Other infection specific to the perinatal period) are 4-digit codes that are being replaced by a series of more specific 5-digit codes, effective October 1, 2002. (See Table 6C in the Addendum of this

proposed rule.) The listing of the codes on the second group above includes some of these new 5-digit codes.

The third group of diagnosis codes that we are proposing to remove from the list of diagnosis defined as “principal or secondary diagnosis of major problem” under DRG 387 includes the following two diagnosis codes. These codes are no longer assigned to MDC 15 when they are the principal diagnosis.

- 759.4, Conjoined twins
- 779.7, Periventricular leukomalacia

We are proposing to add the following nine new and existing diagnosis codes to the list of “principal or secondary diagnosis of major problem” that defines DRG 387. These nine diagnosis codes generally represent major problems at the time of birth and have costs more similar to those of neonates with major problems than neonates without major problems. Many of these diagnosis codes are related to congenital anomaly conditions.

- 747.83, Persistent fetal circulation (new code)
- 769, Respiratory distress syndrome in newborn
- 770.84, Respiratory failure of newborn (new code)
- 771.3, Tetanus neonatorum
- 771.81, Septicemia of newborn (new code)
- 771.82, Neonatal urinary tract infection (new code)
- 771.83, Bacteremia of newborn (new code)
- 771.89, Other infections specific to perinatal period (new code)
- 776.7, Transient neonatal neutropenia

Of special note is the handling of diagnosis code 769 (Respiratory distress syndrome in newborn). Earlier in this preamble, we discussed the proposed removal of this diagnosis code from the definition of proposed retitled DRG 386 (Extreme Immaturity) because, even though it is usually associated with prematurity, it may occur with all levels of prematurity. We are proposing to add respiratory distress syndrome (which was previously assigned to existing DRG 386) to the list of diagnoses that define “principal or secondary diagnosis of major problem” for DRG 387. We are not proposing to add it to the list of diagnoses that define “principal or secondary diagnosis of prematurity” for DRG 387. The rationale for not adding code 769 as a prematurity diagnosis is that it occurs in only a small subset of neonates in the birthweight range of 1,000 to 2,499 grams (2.2 to 5.5 pounds), and the vast majority of occurrences is in the upper end of this birthweight range. Respiratory distress syndrome

might not be indicative of a major problem for neonates at the low end of this range (for example, those closer to 1,000 to 1,249 grams), because these neonates will most likely have multiple significant problems. Therefore, we are proposing that respiratory distress syndrome be classified as a major problem and included among the list of "principal or secondary diagnosis of major problem" for DRG 387.

In addition, we are proposing to revise the definition for the third defining component of DRG 387, "secondary diagnosis of major problem". This list of major problem diagnoses can only be secondary diagnoses because they are not among the list of principal diagnoses that defines MDC 15 for the Medicare DRG classification system. Based on NACHRI's recommendations, we are proposing to add and remove diagnoses from this list on the same basis as previously described for the list of "principal or secondary diagnosis of major problems" for DRG 387. That is, diagnoses are removed if, in the majority of instances, the condition does not represent a major problem for a newborn at or shortly after birth, and on average exhibits costs similar to the costs associated with neonates without a major problem. In addition, we are proposing to remove the asthma with status asthmaticus diagnosis codes, as these diagnosis codes pertain to newborns or other conditions arising in the perinatal period.

We are proposing to remove the following diagnosis codes from the list of "secondary diagnosis of major problem" for DRG 387:

- 276.5, Volume depletion
- 349.0, Reaction to spinal or lumbar puncture
- 457.2, Lymphangitis
- 493.01, Extrinsic asthma with status asthmaticus
- 493.11, Intrinsic asthma with status asthmaticus
- 493.91, Asthma, unspecified type, with status asthmaticus
- 578.1, Blood in stool
- 683, Acute lymphadenitis
- 693.0, Dermatitis due to drugs and medicines taken internally
- 695.0, Toxic erythema
- 708.0, Allergic urticaria
- 745.4, Ventricular septal defect
- 785.0, Tachycardia, unspecified
- 995.2, Unspecified adverse effect of drug, medicinal and biological substance, not elsewhere classified
- 999.5, Other serum reaction, not elsewhere classified
- 999.6, ABO incompatibility reaction, not elsewhere classified

- 999.7, Rh incompatibility reaction, not elsewhere classified
- 999.8, Other transfusion reaction, not elsewhere classified

We are proposing to add the following 65 diagnosis codes to the list of "secondary diagnosis of major problem" for DRG 387:

- 416.0, Primary pulmonary hypertension
- 416.8, Other chronic pulmonary heart diseases
- 425.3, Endocardial fibroelastosis
- 425.4, Other primary cardiomyopathies
- 427.0, Paroxysmal supraventricular tachycardia
- 427.1, Paroxysmal ventricular tachycardia
- 466.11, Acute bronchiolitis due to respiratory syncytial virus (RSV)
- 466.19, Acute bronchiolitis due to other infectious organisms
- 478.74, Stenosis of larynx
- 480.0, Pneumonia due to adenovirus
- 480.1, Pneumonia due to respiratory syncytial virus
- 480.2, Pneumonia due to parainfluenza virus
- 480.8, Pneumonia due to other virus not elsewhere classified
- 480.9, Viral pneumonia, unspecified
- 745.0, Common truncus
- 745.10, Complete transposition of great vessels
- 745.11, Double outlet right ventricle
- 745.12, Corrected transposition of great vessels
- 745.19, Other transposition of great vessels
- 745.2, Tetralogy of Fallot
- 745.3, Common ventricle
- 745.60, Endocardial cushion defect, unspecified type
- 745.61, Ostium primum defect
- 745.69, Other endocardial cushion defects
- 746.01, Atresia of pulmonary valve, congenital
- 746.1, Tricuspid atresia and stenosis, congenital
- 746.2, Ebstein's anomaly
- 746.7, Hypoplastic left heart syndrome
- 746.81, Subaortic stenosis, congenital
- 746.82, Cor triatriatum
- 746.84, Obstructive anomalies of heart, congenital, not elsewhere classified
- 746.86, Congenital heart block
- 747.10, Coarctation of aorta (preductal) (postductal)
- 747.11, Interruption of aortic arch
- 747.41, Total anomalous pulmonary venous connection
- 747.81, Anomalies of cerebrovascular system, congenital
- 748.3, Other congenital anomalies of larynx, trachea, and bronchus

- 748.4, Cystic lung, congenital
- 748.5, Agenesis, hypoplasia, and dysplasia of lung, congenital
- 750.3, Tracheoesophageal fistula, esophageal atresia and stenosis, congenital
- 751.1, Atresia and stenosis of small intestine, congenital
- 751.2, Atresia and stenosis of large intestine, rectum, and anal canal, congenital
- 751.3, Hirschsprung's disease and other congenital functional disorders of colon
- 751.4, Anomalies of intestinal fixation, congenital
- 751.62, Congenital cystic disease of liver
- 751.69, Other congenital anomalies of gall bladder, bile ducts, and liver
- 751.7, Anomalies of pancreas, congenital
- 753.0, Renal agenesis and dysgenesis
- 753.5, Exstrophy of urinary bladder
- 756.51, Osteogenesis imperfecta
- 756.6, Anomalies of diaphragm, congenital
- 756.70, Congenital anomaly of abdominal wall, unspecified
- 756.71, Prune belly syndrome
- 756.79, Other congenital anomalies of abdominal wall
- 758.1, Patau's Syndrome
- 758.2, Edwards' Syndrome
- 758.3, Autosomal deletion syndromes
- 759.4, Conjoined twins
- 759.7, Multiple congenital anomalies, so described
- 759.81, Prader-Willi Syndrome
- 759.89, Other specified anomalies
- 7797, Periventricular leukomalacia
- 785.51, Cardiogenic shock
- 785.59, Other shock without mention of trauma
- 789.5, Ascites

d. DRG 388 (Prematurity Without Major Problems)

We are proposing to revise the definition for prematurity for DRG 388 ((Prematurity without Major Problems) in the same manner that we proposed to revise the definition of prematurity for DRG 387 (Prematurity with Major Problems).

We are proposing to remove the following five diagnosis codes from the list of codes pertaining to the "principal or secondary diagnosis of prematurity" for DRG 388:

- 765.10, Other preterm infants unspecified (weight)
- 765.11, Other preterm infants, less than 500 grams
- 765.12, Other preterm infants, 500–749 grams
- 765.13, Other preterm infants, 750–999 grams

- 765.19, Other preterm infants, 2,500+ grams

We are proposing to add the following seven diagnosis codes to the definition of principal or secondary diagnosis of prematurity for DRG 388:

- 765.04, Extreme immaturity, 1000–1249 grams
- 765.05, Extreme immaturity, 1250–1499 grams
- 765.24, 27–28 completed weeks of gestation
- 765.25, 29–30 completed weeks of gestation
- 765.26, 31–32 completed weeks of gestation
- 765.27, 33–34 completed weeks of gestation
- 765.28, 35–36 completed weeks of gestation

e. DRG 389 (Full Term Neonate With Major Problem)

We are proposing to revise the definition of “principal or secondary diagnosis of major problem” for DRG 389 (Full Term Neonate with Major Problem) in the same manner that we proposed to revise the definition for DRG 387 (Prematurity with Major Problem).

f. DRG 390 (Neonate With Other Significant Problems)

DRG 390 is defined as patients with “principal or secondary diagnosis of newborn or neonate, with other significant problems, not assigned to DRG 385 through 389, 391, or 469 (principal diagnosis invalid as discharge diagnosis). As a result of our proposed changes to other neonatal DRGs, we are proposing to make conforming changes related to diagnosis codes assigned to DRG 390.

g. DRG 391 (Normal Newborn)

DRG 391 (Normal Newborn) is defined by a list of principal diagnoses (for example, V30, Newborn codes plus certain minor newborn problems) and no secondary diagnoses or only certain secondary diagnoses (that is, minor problem diagnoses). NACHRI recommended that the definition of DRG 391 be modified to expand the number of minor problem newborn diagnoses included in both the list of principal diagnoses and the list of only certain secondary diagnoses that define DRG 391. The diagnoses that we are proposing to add to DRG 391 are conditions that NACHRI has identified as occurring with some frequency in the newborn population and having costs more similar to that of DRG 391 than DRG 390 (Neonates with Other Significant Problems).

We are proposing to add the following diagnosis codes to the list of “principal diagnosis” that defines DRG 391:

- 764.00, “Light-for-dates” without mention of fetal malnutrition, unspecified (weight)
- 764.90, Fetal growth retardation unspecified (weight)
- 765.10, Other preterm infants unspecified (weight)
- 765.19, Other preterm infants, 2,500+ grams
- 765.20, Unspecified weeks of gestation
- 765.29, 37 or more completed weeks of gestation

We also are proposing to add the above six diagnosis codes to the list of “only certain secondary diagnosis” that defines DRG 391, as indicated below. Of these diagnosis codes, NACHRI indicates that the highest volume diagnosis code is 765.19 (Other preterm infants, 2,500+ grams). NACHRI notes that when this diagnosis code is recorded and no major problem or significant problem diagnosis is recorded, these patients have costs that are not much different than those for other normal newborns.

We are proposing to add the following codes to the list of “only certain secondary diagnosis” that defines DRG 391:

- 216.0, Benign neoplasm of skin of lip
- 216.1, Benign neoplasm of eyelid, including canthus
- 216.2, Benign neoplasm of ear and external auditory canal
- 216.3, Benign neoplasm of skin of other and unspecified parts of face
- 216.4, Benign neoplasm of scalp and skin of neck
- 216.5, Benign neoplasm of skin of trunk, except scrotum
- 216.6, Benign neoplasm of skin of upper limb, including shoulder
- 216.7, Benign neoplasm of skin of lower limb, including hip
- 216.8, Benign neoplasm of other specified sites of skin
- 216.9, Benign neoplasm of skin, site unspecified
- 228.00, Hemangioma of unspecified site
- 228.01, Hemangioma of skin and subcutaneous tissue
- 228.1, Lymphangioma, any site
- 379.8, Other specified disorders of eye and adnexa
- 379.90, Disorder of eye, unspecified
- 379.92, Swelling or mass of eye
- 379.93, Redness or discharge of eye
- 379.99, Other ill-defined disorders of eye
- 427.60, Premature beats, unspecified
- 427.61, Supraventricular premature beats

- 427.9, Cardiac dysrhythmia, unspecified
- 528.4, Cysts of oral soft tissues
- 553.1, Umbilical hernia without mention of obstruction or gangrene
- 603.8, Other specified types of hydrocele
- 603.9, Hydrocele, unspecified
- 607.89, Other specified disorders of penis
- 607.9, Unspecified disorder of penis and perineum
- 624.9, Unspecified noninflammatory disorder of vulva and perineum
- 692.9, Contact dermatitis and other eczema unspecified cause
- 701.1, Keratoderma, acquired
- 701.3, Striae atrophicae
- 701.8, Other specified hypertrophic and atrophic conditions of skin
- 701.9, Unspecified hypertrophic and atrophic conditions of skin
- 702.8, Other specified dermatoses
- 705.1, Prickly heat
- 706.1, Other acne
- 706.2, Sebaceous cyst
- 709.8, Other specified disorders of skin
- 709.9, Unspecified disorder of skin and subcutaneous tissue
- 719.61, Other symptoms referable to joint of shoulder region
- 719.65, Other symptoms referable to joint of pelvic region and thigh
- 755.00, Polydactyly, unspecified digits
- 755.01, Polydactyly of fingers
- 755.02, Polydactyly of toes
- 755.10, Syndactyly of multiple and unspecified sites
- 755.11, Syndactyly of fingers without fusion of bone
- 755.12, Syndactyly of fingers with fusion of bone
- 755.13, Syndactyly of toes without fusion of bone
- 755.14, Syndactyly of toes with fusion of bone
- 755.66, Other congenital anomalies of toes
- 755.67, Anomalies of foot, congenital, not elsewhere classified
- 755.9, Unspecified congenital anomaly of unspecified limb
- 757.2, Dermatoglyphic anomalies
- 757.32, Vascular hamartomas
- 757.39, Other specified congenital anomalies of skin
- 757.4, Specified congenital anomalies of hair
- 757.5, Specified congenital anomalies of nails
- 757.6, Specified congenital anomalies of breast
- 757.8, Other specified congenital anomalies of the integument
- 757.9, Unspecified congenital anomaly of the integument
- 760.0, Maternal hypertensive disorders affecting fetus or newborn

- 760.1, Maternal renal and urinary tract diseases affecting fetus or newborn
- 760.2, Maternal infections affecting fetus or newborn
- 760.3, Other chronic maternal circulatory and respiratory diseases affecting fetus or newborn
- 760.4, Maternal nutritional disorders affecting fetus or newborn
- 760.5, Maternal injury affecting fetus or newborn
- 760.6, Surgical operation on mother affecting fetus or newborn
- 760.70, Unspecified noxious substance affecting fetus or newborn via placenta or breast milk
- 760.74, Anti-infectives affecting fetus or newborn via placenta or breast milk
- 760.76, Diethylstilbestrol (DES) exposure affecting fetus or newborn via placenta or breast milk
- 760.79, Other noxious influences affecting fetus or newborn via placenta or breast milk
- 760.8, Other specified maternal conditions affecting fetus or newborn
- 760.9, Unspecified maternal condition affecting fetus or newborn
- 761.0, Incompetent cervix affecting fetus or newborn
- 761.1, Premature rupture of membranes affecting fetus or newborn
- 761.5, Multiple pregnancy affecting fetus or newborn
- 761.7, Malpresentation before labor affecting fetus or newborn
- 761.8, Other specified maternal complications of pregnancy affecting fetus or newborn
- 761.9, Unspecified maternal complication of pregnancy affecting fetus or newborn
- 762.8, Other specified abnormalities of chorion and amnion affecting fetus or newborn
- 762.9, Unspecified abnormality of chorion and amnion affecting fetus or newborn
- 763.4, Cesarean delivery affecting fetus or newborn
- 763.5, Maternal anesthesia and analgesia affecting fetus or newborn
- 763.7, Abnormal uterine contractions affecting fetus or newborn
- 763.89, Other specified complications of labor and delivery affecting fetus or newborn
- 764.00, "Light-for-dates" without mention of fetal malnutrition, unspecified (weight)
- 764.90, Fetal growth retardation unspecified (weight)
- 765.10, Other preterm infants unspecified (weight)
- 765.19, Other preterm infants, 2,500+ grams
- 765.20, Unspecified weeks of gestation
- 765.29, 37 or more completed weeks of gestation
- 767.2, Fracture of clavicle due to birth trauma
- 767.3, Other injuries to skeleton due to birth trauma
- 767.8, Other specified birth trauma
- 767.9, Unspecified birth trauma
- 768.2, Fetal distress before onset of labor, in liveborn infant
- 768.3, Fetal distress first noted during labor, in liveborn infant
- 768.4, Fetal distress, unspecified as to time of onset, in liveborn infant
- 768.9, Unspecified severity of birth asphyxia in liveborn infant
- 70.9, Unspecified respiratory condition of fetus and newborn
- 772.8, Other specified hemorrhage of fetus or newborn
- 772.9, Unspecified hemorrhage of newborn
- 773.1, Hemolytic disease due to ABO isoimmunization of fetus or newborn
- 773.2, Hemolytic disease due to other and unspecified isoimmunization of fetus or newborn
- 773.5, Late anemia due to isoimmunization of fetus or newborn
- 775.6, Neonatal hypoglycemia
- 775.9, Unspecified endocrine and metabolic disturbances specific to the fetus and newborn
- 776.4, Polycythemia neonatorum
- 776.8, Other specified transient hematological disorders of fetus or newborn
- 776.9, Unspecified hematological disorder specific to fetus or newborn
- 777.1, Meconium obstruction in fetus or newborn
- 777.3, Hematemesis and melena due to swallowed maternal blood of newborn
- 777.8, Other specified perinatal disorders of digestive system
- 777.9, Unspecified perinatal disorder of digestive system
- 778.3, Other hypothermia of newborn
- 778.4, Other disturbances of temperature regulation of newborn
- 778.6, Congenital hydrocele
- 778.7, Breast engorgement in newborn
- 778.9, Unspecified condition involving the integument and temperature regulation of fetus and newborn
- 779.9, Unspecified condition originating in the perinatal period
- 780.6, Fever
- 781.0, Abnormal involuntary movements
- 781.3, Lack of coordination
- 782.1, Rash and other nonspecific skin eruption
- 782.2, Localized superficial swelling, mass, or lump
- 782.4, Jaundice, unspecified, not of newborn
- 782.61, Pallo
- 782.62, Flushin
- 782.7, Spontaneous ecchymose
- 782.8, Changes in skin texture
- 782.9, Other symptoms involving skin and integumentary tissues
- 783.3, Feeding difficulties and mismanagement
- 784.2, Swelling, mass, or lump in head and neck
- 784.9, Other symptoms involving head and neck
- 785.2, Undiagnosed cardiac murmurs
- 785.3, Other abnormal heart sounds
- 785.9, Other symptoms involving cardiovascular system
- 786.00, Respiratory abnormality, unspecified
- 786.7, Abnormal chest sounds
- 786.9, Other symptoms involving respiratory system and chest
- 787.3, Flatulence, eructation, and gas pain
- 790.6, Other abnormal blood chemistry
- 790.7, Bacteremia
- 790.99, Other nonspecific findings on examination of blood
- 795.6, False positive serological test for syphilis
- 795.79, Other and unspecified nonspecific immunological findings
- 796.1, Abnormal reflex
- 910.0, Abrasion or frictions burn of face, neck, and scalp except eye, without mention of infection
- 910.2, Blister of face, neck, and scalp except eye, without mention of infection
- 910.8, Other and unspecified superficial injury of face, neck, and scalp, without mention of infection
- 920, Contusion of face, scalp, and neck except eye(s)
- 999.5, Other serum reaction, not elsewhere classified
- 999.6, ABO incompatibility reaction, not elsewhere classified
- V01.1, Contact with or exposure to tuberculosis
- V01.6, Contact with or exposure to venereal diseases
- V01.7, Contact with or exposure to other viral diseases
- V01.81, Contact with or exposure to communicable diseases, anthrax
- V01.89, Contact with or exposure to communicable diseases, other communicable diseases
- V01.9, Contact with or exposure to unspecified communicable disease
- V02.3, Carrier or suspected carrier of other gastrointestinal pathogens
- V05.3, Need for prophylactic vaccination and inoculation against viral hepatitis
- V05.4, Need for prophylactic vaccination and inoculation against varicella

- V05.8, Need for prophylactic vaccination and inoculation against other specified disease
- V05.9, Need for prophylactic vaccination and inoculation against unspecified single disease
- V07.8, Need for other specified prophylactic measure
- V07.9, Need for unspecified prophylactic measure
- V18.0, Family history of diabetes mellitus
- V18.1, Family history of other endocrine and metabolic diseases
- V18.2, Family history of anemia
- V18.3, Family history of other blood disorders
- V18.8, Family history of infectious and parasitic diseases
- V19.2, Family history of deafness or hearing loss
- V19.8, Family history of other condition
- V71.9, Observation for unspecified suspected condition
- V72.0, Examination of eyes and vision
- V72.6, Laboratory examination
- V73.89, Special screening examination for other specified viral diseases
- V73.99, Special screening examination for unspecified viral disease

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

In the August 1, 2001 final rule, we included in Table 6A—New Diagnosis Codes (66 FR 40064) code V10.53 (History of malignancy, renal pelvis), which was approved by the ICD-9-CM Coordination and Maintenance Committee as a new code effective October 1, 2001. We assigned the code to DRG 411 (History of Malignancy without Endoscopy) and DRG 412 (History of Malignancy with Endoscopy).

We received correspondence which suggested that we should have also assigned code V10.53 to DRG 465 (Aftercare with History of Malignancy as Secondary Diagnosis). The correspondent pointed out that all other codes for a history of malignancy are included in DRG 465.

We agree that code V10.53 should be included in the list of the history of malignancy codes within DRG 465. Therefore, we are proposing to add V10.53 to the list of secondary diagnosis in DRG 465.

8. Pre-MDC: Tracheostomy

DRG 483 (Tracheostomy Except for Face, Mouth and Neck Diagnoses) is used to classify patients who require long-term mechanical ventilation.

Mechanical ventilation can be administered through an endotracheal tube for a limited period of time. When an endotracheal tube is used for an extended period of time (beyond 7 to 10 days), the patient runs a high risk of permanent damage to the trachea. In order to maintain a patient on mechanical ventilation for a longer period of time, the endotracheal tube is removed and a tracheostomy is performed. The mechanical ventilation is then administered through the tracheostomy.

A tracheostomy also may be performed on patients for therapeutic purposes unrelated to the administration of mechanical ventilation. Patients with certain face, mouth, and neck disease may have a tracheostomy performed as part of the treatment for the face, mouth, or neck disease. These patients are assigned to DRG 482 (Tracheostomy for Face, Mouth and Neck Diagnoses).

Therefore, patients assigned to DRGs 482 and 483 are differentiated based on the principal diagnosis of the patient. At certain times, selecting the appropriate principal diagnosis for the patients receiving tracheostomies for assignment to a DRG can be difficult. The overall number of tracheostomy patients increased by 13 percent between 1994 and 1999. During the same period, the percent of tracheostomy patients in DRG 483 (patients without certain face, mouth, or neck diseases) versus DRG 482 increased from 83.6 percent to 87.6 percent.

The payment weight for DRG 483 is more than four times greater than the DRG 482 payment weight, and this has led to concerns about coding compliance. Specifically, the fact that cases are assigned to DRG 483 based on the absence of a code indicating face, mouth, or neck diagnosis creates an incentive to omit codes indicating these diagnoses.

To address issues of possible coding noncompliance, we are proposing to modify DRGs 482 and 483 to differentiate the assignment to either DRG based on the presence or absence of continuous mechanical ventilation that lasts more than 96 hours (code 96.72). This modification would ensure that the patients assigned to DRG 483 are patients who had the tracheostomy for long-term mechanical ventilation. Based on an examination of claims data from the FY 2001 MedPAR file, we found that many patients assigned to DRG 483 do not have the code 96.72 for mechanical ventilation greater than 96 hours recorded. In part, this is the result of the limited number of procedure codes (six) that can be submitted on the

current uniform hospital claim form, and the fact that code 96.72 does not currently affect the DRG assignment.

We found that many of the patients who are assigned to DRG 483 have multiple procedures, making it impossible for all procedures performed to be submitted on the hospital claim form. Because of the current underreporting of code 96.72 for continuous mechanical ventilation greater than 96 hours, we do not believe we can accurately determine the payment weights for modified DRGs 482 and 483 as described above.

In order to encourage the reporting of the code 96.72 for continuous mechanical ventilation for greater than 96 hours, we are proposing to change the definition of DRG 483 so that patients who have a tracheostomy and continuous mechanical ventilation greater than 96 hours (code 96.72) with a principal diagnosis unrelated to disease of the face, mouth, or neck would be assigned to DRG 483. DRG 483 would be retitled “Tracheostomy/ Mechanical Ventilation 96+ Hours Except Face, Mouth, and Neck Diagnosis.”

We will give future consideration to modifying DRGs 482 and DRG 483 based on the presence of code 96.72, and invite comments on this area.

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.

The MCE includes an edit for “nonspecific principal diagnosis” that identifies a group of codes that are valid according to the ICD-9-CM coding scheme, but are not as specific as the coding scheme permits. The fiscal intermediaries use cases identified in this edit for educational purposes for hospitals only. That is, when a hospital reaches a specific threshold of cases (usually 25) in this edit, the fiscal intermediary will contact the hospital and educate it on how to code diagnoses using more specific codes in the ICD-9-CM coding scheme. The claims identified in this nonspecific principal diagnosis edit are neither denied nor returned to the hospital.

Code 436 (Acute, but ill-defined, cerebrovascular disease) is one of the codes included in the groups of codes identified in the nonspecific principal diagnosis edit, and is widely used in smaller hospitals where testing mechanisms are not available to more specifically identify the location and condition of cerebral and precerebral vessels. Because of the frequent use of code 436 among smaller hospitals, we

are proposing to remove the code from the nonspecific principal diagnosis edit in the MCE. We address the use of code 436 in section II.B.3. of this proposed rule under the discussion of MDC 5 changes with regard to the remodeling of DRGs 14 and 15.

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. Its application 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 searches 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, these procedures should only be considered if no other procedure more closely related to the diagnoses in the MDC has been performed.

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 since, as a result of the hierarchy change, the average charges are likely to shift such that the higher-ordered surgical class has a lower average charge than the class ordered below it.

Based on the preliminary recalibration of the DRGs, we are proposing modifications of the surgical hierarchy as set forth below.

At this time, we are proposing to revise the surgical hierarchy for the pre-MDC DRGs and for MDC 5 (Diseases and Disorders of the Circulatory System) as follows:

- In the pre-MDC DRGs, we are proposing to reorder DRG 495 (Lung Transplant) above DRG 512 (Simultaneous Pancreas/Kidney Transplant).
- In MDC 5, we are proposing to reorder DRG 525 (Heart Assist System Implant) above DRGs 104 and 105 (Cardiac Valve and Other Major Cardiothoracic Procedures with and without Cardiac Catheterization, respectively).

11. Refinement of Complications and Comorbidities (CC) List

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

In the May 19, 1987 proposed notice (52 FR 18877) concerning changes to the DRG classification system, we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another (as subsequently corrected in the September 1, 1987 final notice (52 FR 33154)).
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another.
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another.
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another.
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. The FY 1988 revisions were intended only as a first step toward refinement of the CC list in that the criteria used for eliminating certain diagnoses from consideration as CCs were intended to identify only the most obvious diagnoses that should not be

considered CCs of another diagnosis. For that reason, and in light of comments and questions on the CC list, we have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. (See the September 30, 1988 final rule (53 FR 38485) for the revision made for the discharges occurring in FY 1989; the September 1, 1989 final rule (54 FR 36552) for the FY 1990 revision; the September 4, 1990 final rule (55 FR 36126) for the FY 1991 revision; the August 30, 1991 final rule (56 FR 43209) for the FY 1992 revision; the September 1, 1992 final rule (57 FR 39753) for the FY 1993 revision; the September 1, 1993 final rule (58 FR 46278) for the FY 1994 revisions; the September 1, 1994 final rule (59 FR 45334) for the FY 1995 revisions; the September 1, 1995 final rule (60 FR 45782) for the FY 1996 revisions; the August 30, 1996 final rule (61 FR 46171) for the FY 1997 revisions; the August 29, 1997 final rule (62 FR 45966) for the FY 1998 revisions; the July 31, 1998 final rule (63 FR 40954) for the FY 1999 revisions, the August 1, 2000 final rule (65 FR 47064) for the FY 2001 revisions; and the August 1, 2001 final rule (66 FR 39851) for the FY 2002 revisions. In the July 30, 1999 final rule (64 FR 41490), we did not modify the CC Exclusions List for FY 2000 because we did not make any changes to the ICD-9-CM codes for FY 2000.

We are proposing a limited revision of the CC Exclusions List to take into account the proposed changes that will be made in the ICD-9-CM diagnosis coding system effective October 1, 2002. (See section IL.B.13. of this preamble for a discussion of ICD-9-CM changes.) These proposed changes are being made in accordance with the principles established when we created the CC Exclusions List in 1987.

Tables 6G and 6H in the Addendum to this proposed rule contain the revisions to the CC Exclusions List that would be effective for discharges occurring on or after October 1, 2002. 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, 2002, the indented diagnoses would not be recognized by the GROUPER as valid

CCs for the asterisked principal diagnosis.

CCs that are deleted from the list are in Table 6H—Deletions from the CC Exclusions List. Beginning with discharges on or after October 1, 2002, the indented diagnoses would be recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

Copies of the original CC Exclusions List applicable to FY 1988 can be obtained from the National Technical Information Service (NTIS) of the Department of Commerce. It is available in hard copy for \$133.00 plus shipping and handling. A request for the FY 1988 CC Exclusions List (which should include the identification accession number (PB) 88-133970) should be made to the following address: National Technical Information Service, United States Department of Commerce, 5285 Port Royal Road, Springfield, VA 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, and 2002) and those in Tables 6F and 6G of the final rule for FY 2003 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, 2002. (Note: There was no CC Exclusions List in FY 2001 because we did not make changes to the ICD-9-CM codes for FY 2001.)

Alternatively, the complete documentation of the GROUPER logic, including the current CC Exclusions List, is available from 3M/Health Information Systems (HIS), which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. The current DRG Definitions Manual, Version 19.0, is available for \$225.00, which includes \$15.00 for shipping and handling. Version 20.0 of this manual, which includes the final FY 2002 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 NEC
- 60.81 Incision of periprostatic tissue
- 60.82 Excision of periprostatic tissue
- 60.93 Repair of prostate
- 60.94 Control of (postoperative) hemorrhage of prostate
- 60.95 Transurethral balloon dilation of the prostatic urethra
- 60.99 Other operations on prostate

All remaining O.R. procedures are assigned to DRGs 468 and 477, with DRG 477 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis. The original list of the ICD-9-CM procedure codes for the procedures we consider nonextensive procedures, if performed with an unrelated principal diagnosis, was published in Table 6C in section IV. of the Addendum to the September 30, 1988 final rule (53 FR 38591). As part of the final rules published on September 4, 1990 (55 FR 36135), August 30, 1991 (56 FR 43212), September 1, 1992 (57 FR 23625), September 1, 1993 (58 FR 46279), September 1, 1994 (59 FR 45336), September 1, 1995 (60 FR 45783), August 30, 1996 (61 FR 46173), and August 29, 1997 (62 FR 45981), we moved several other procedures from DRG 468 to 477, and some procedures from DRG 477 to 468. No procedures were moved in FY 1999, as noted in the July 31, 1998 final rule (63 FR 40962); in FY 2000, as noted in the July 30, 1999 final rule (64 FR 41496); in FY 2001, as noted in the August 1, 2000 final rule (65 FR 47064); or in FY 2002, as noted in the August 1, 2001 final rule (66 FR 39852).

a. Moving Procedure Codes From DRGs 468 or 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 identified those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical DRGs for the MDC in which the diagnosis falls. Based on this year's review, we did not identify any necessary changes in procedures under

DRG 477. Therefore, we are not proposing to move any procedures from DRG 477 to one of the surgical DRGs. However, we have identified a number of procedure codes that should be removed from DRG 468 and put into more clinically coherent DRGs. The proposed assignments of these codes are specified in the charts below.

MOVEMENT OF PROCEDURE CODES FROM DRG 468

Procedure Code	Description	Included in DRG	Description
MDC 6—Diseases and Disorders of the Digestive System			
387	Interruption vena cava	170	Other Digestive System O.R. Procedures with CC.
387	Interruption vena cava	171	Other Digestive System O.R. Procedures without CC.
3950	Angioplasty or atherectomy of noncoronary vessel ..	170	Other Digestive System O.R. Procedures with CC.
3950	Angioplasty or atherectomy of noncoronary vessel ..	171	Other Digestive System O.R. Procedures without CC.
MDC 7—Diseases and Disorders of the Hepatobiliary System and Pancreas			
387	Interruption vena cava	201	Other Hepatobiliary & Pancreas Procedures.
3949	Other revision of vascular procedure	201	Other Hepatobiliary & Pancreas Procedures.
3950	Angioplasty or atherectomy of noncoronary vessel ..	201	Other Hepatobiliary & Pancreas Procedures.
MDC 8—Diseases and Disorders of the Musculoskeletal System and Connective Tissue			
387	Interruption vena cava	233	Other Musculoskeletal System & Connective Tissue O.R. Procedures with CC.
387	Interruption vena cava	234	Other Musculoskeletal System & Connective Tissue O.R. Procedures without CC.
3950	Angioplasty or atherectomy of noncoronary vessel ..	233	Other Musculoskeletal System & Connective Tissue O.R. Procedures with CC.
3950	Angioplasty or atherectomy of noncoronary vessel ..	234	Other Musculoskeletal System & Connective Tissue O.R. Procedures without CC.
MDC 9—Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast			
8344	Other fasciectomy	269	Other Skin, Subcutaneous Tissue & Breast Procedures with CC.
8344	Other fasciectomy	270	Other Skin, Subcutaneous Tissue & Breast Procedures without CC.
8345	Other myectomy	269	Other Skin, Subcutaneous Tissue & Breast Procedures with CC.
8345	Other myectomy	270	Other Skin, Subcutaneous Tissue & Breast Procedures without CC.
8382	Muscle or fascia graft	269	Other Skin, Subcutaneous Tissue & Breast Procedures with CC.
8382	Muscle or fascia graft	270	Other Skin, Subcutaneous Tissue & Breast Procedures without CC.
MDC 10—Endocrine, Nutritional and Metabolic Diseases and Disorders			
387	Interruption vena cava	292	Other Endocrine, Nutritional, & Metabolic O.R. Procedures with CC.
387	Interruption vena cava	293	Other Endocrine, Nutritional, & Metabolic O.R. Procedures without CC.
5459	Other Lysis of Peritoneal adhesions	292	Other Endocrine, Nutritional, & Metabolic O.R. Procedures with CC.
5459	Other Lysis of Peritoneal adhesions	293	Other Endocrine, Nutritional, & Metabolic O.R. Procedures without CC.
MC 11—Diseases and Disorders of the Kidney and Urinary Tract			
0492	Implantation or replacement of peripheral neurostimulator.	315	Other Kidney & Urinary Tract O.R. Procedures.
3821	Blood vessel biopsy	315	Other Kidney & Urinary Tract O.R. Procedures.
387	Interruption vena cava	315	Other Kidney & Urinary Tract O.R. Procedures.
3949	Other revision of vascular procedure	315	Other Kidney & Urinary Tract O.R. Procedures.

MOVEMENT OF PROCEDURE CODES FROM DRG 468—Continued

Procedure Code	Description	Included in DRG	Description
MDC 12—Diseases and Disorders Male Reproductive System			
387	Interruption vena cava	344	Other Male Reproductive System O.R. Procedures for Malignancy.
387	Interruption vena cava	345	Other Male Reproductive System O.R. Procedures Except for Malignancy.
8622	Excisional debridement of wound, infection, or burn	344	Other Male Reproductive System O.R. Procedures for Malignancy.
8622	Excisional debridement of wound, infection, or burn	345	Other Male Reproductive System O.R. Procedures Except for Malignancy.
MDC 13—Diseases and Disorders of the Female Reproductive System			
387	Interruption vena cava	365	Other Female Reproductive System O.R. Procedures.
MDC 16—Diseases and Disorders of the Blood, Blood Forming Organs, Immunological Disorders			
387	Interruption vena cava	394	Other O.R. Procedures of the Blood & Blood Forming Organs.

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

We also annually review the list of ICD-9-CM procedures that, when in combination with their principal diagnosis code, result in assignment to DRGs 468, 476, and 477, to ascertain if any of those procedures should be reassigned from one of these DRGs to another of these DRGs based on average charges and length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting DRG assignment illogical. If we find these shifts, we would propose moving cases to keep the DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data. Based on our review this year, we are not proposing to move any procedures from DRG 468 to DRGs 476 or 477, from DRG 476 to DRGs 468 or 477, or from DRG 477 to DRGs 468 or 476.

c. Adding Diagnosis Codes to MDCs

Based on our review this year, we are not proposing to add any diagnosis codes to MDCs.

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 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) (formerly American Medical Record Association (AMRA)), the American Hospital Association (AHA), and various physician specialty groups as well as physicians, medical record administrators, health information management professionals, and other members of the public, to contribute

ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2003 at public meetings held on May 17 and 18, 2001, and November 1 and 2, 2001, and finalized the coding changes after consideration of comments received at the meetings and in writing by January 8, 2002.

Copies of the Coordination and Maintenance Committee minutes of the 2001 meetings can be obtained from the CMS home page at: <http://www.cms.gov/medicare/icd9cm.htm>. Paper copies of these minutes are no longer available and the mailing list has been discontinued. 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 1100; 6525 Belcrest 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, Purchasing Policy Group, Division of Acute Care; C4-08-06; 7500 Security Boulevard; Baltimore, MD 21244-1850. Comments may be sent by E-mail to: pbrooks@cms.hhs.gov.

The ICD-9-CM code changes that have been approved will become effective October 1, 2002. The new ICD-

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

Further, the Committee has approved the expansion of certain ICD-9-CM codes to require an additional digit for valid code assignment. 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, 2002. For codes that have been replaced by new or expanded codes, the corresponding new or expanded diagnosis codes are included in Table 6A (New Diagnosis Codes). New procedure codes are shown in Table 6B. Table 6C contains invalid diagnosis codes. There are no invalid procedure codes for FY 2002 (Table 6D). Revisions to diagnosis code titles are in Table 6E (Revised Diagnosis Code Titles), which also includes the DRG assignments for these revised codes. Revisions to procedure code titles are in Table 6F (Revised Procedure Codes Titles).

14. Other Issues

In addition to the specific topics discussed in section II.B.1. through 13. of this proposed rule, we examined a number of other DRG-related issues. Below is a summary of the issues that were addressed. However, we are not proposing any changes at this time.

a. Intestinal Transplantation

We examined our data to determine whether it is appropriate to propose a new intestinal transplant DRG. There were nine intestinal transplantation cases reported by two facilities. Two of the cases involved a liver transplant during the same admission and, therefore, would be assigned to DRG 480 (Liver Transplant). We do not believe that this is a sufficient sample size to warrant the creation of a new DRG.

b. Myasthenia Gravis

Myasthenia Gravis is an autoimmune disease manifested by a syndrome of fatigue and exhaustion of the muscles that is aggravated by activity and

relieved by rest. The weakness of the muscles can range from very mild to life-threatening.

This disease is classified to ICD-9-CM diagnosis code 358.0 and is assigned to DRG 12 (Degenerative Nervous System Disorders). Myasthenia Gravis in crisis patients is being treated with extensive plasmapheresis. We received a request to analyze the charges associated with Myasthenia Gravis in crisis patients receiving plasmapheresis to determine whether DRG 12 is an equitable DRG assignment for these cases. We are currently unable to differentiate between the mild and severe forms of this disease because all types are classified to code 358.0. Therefore, we have requested the NCHS to create a new diagnosis code for Myasthenia Gravis in crisis so that we can uniquely identify these cases to ensure the DRG assignment is appropriate.

c. Cardiac Mapping and Ablation

In the August 1, 2001 final rule (66 FR 39840), in response to a comment received, we agreed to continue to evaluate DRGs 516 (Percutaneous Cardiovascular Procedure with Acute Myocardial Infarction (AMI)), 517 (Percutaneous Cardiovascular Procedure with Coronary Artery Stent without AMI), and 518 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI) in MDC 5. We reviewed code 37.26 (Cardiac electrophysiologic stimulation and recording studies), code 37.27 (Cardiac mapping), and code 37.34 (Catheter ablation of lesion or tissues of heart). The commenter had recommended that CMS either create a separate DRG for cardiac mapping and ablation procedures, or assign codes 37.27 and 37.34 to DRG 516 after retitling the DRG. We have reviewed FY 2001 MedPAR data on these specific codes. Over 97 percent of cases with these codes were assigned to DRG 518 and had average charges of \$1,741 below the average for all cases in the DRG. Therefore, the data do not support making any DRG changes for these procedure codes.

d. Aortic Endograft

In the August 1, 2001 final rule (66 FR 39841), we responded to a comment concerning the placement of aortic endografts in DRG 110 (Major Cardiovascular Procedures with CC) and DRG 111 (Major Cardiovascular Procedures without CC). The commenter noted that the cost of the device alone is greater than the entire payment for DRG 111 and recommended that these cases be assigned specifically to DRG 110. Our

response at that time was that DRGs 110 and 111 are paired DRGs, differing only in the presence or absence of a CC.

We reviewed the MedPAR data again for FY 2001 using the following criteria: all cases were either in DRG 110 or 111, had a principal diagnosis of 441.4 (Abdominal aneurysm without mention of rupture), and included procedure code 39.71 (Endovascular implantation of graft in abdominal aorta). Our conclusion is that the majority of aneurysm cases are already grouped to DRG 110, where they are appropriately compensated. Therefore, we are not proposing to assign cases without CCs from DRG 111 to DRG 110. We reiterate that hospitals should code their records completely and record and submit all relevant diagnosis and procedure codes that have a bearing on the current admission (in particular, any complications or comorbidities associated with a case).

e. Platelet Inhibitors

In the August 1, 2002 final rule (66 FR 39840), we addressed a commenter's concern that modifications to MDC 5 involving percutaneous cardiovascular procedures would fail to account for the use of GP IIB-IIIa platelet inhibiting drugs for cases with acute coronary syndromes. GROUPER does not recognize procedure code 99.20 (Injection or infusion of platelet inhibitor) as a procedure. Therefore, its presence on a claim does not affect DRG assignment. We agreed to continue to evaluate this issue.

We reviewed cases in the FY 2001 MedPAR file for DRG 121 (Circulatory Disorders with AMI and Major Complication, Discharged Alive), DRG 122 (Circulatory Disorders with AMI without Major Complication, Discharged Alive) and DRGs 516, 517, and 518. We looked at all cases in these DRGs containing procedure code 99.20 by total number of procedures and by average charges. There were a total of 73,480 cases where platelet inhibitors were administered, with 70,216 of these cases in DRGs 516, 517, and 518. The average charges for platelet inhibitor cases in these three DRGs are actually slightly below the average for all cases in the respective DRGs. Therefore, we believe these cases are appropriately placed in the current DRGs, and are not proposing any changes to the assignment of these procedure codes.

f. Drug-Eluting Stents

The drug-eluting stents technology has been developed to combat the problem of restenosis of previously treated blood vessels. The drug is placed onto the stent with a special polymer

and slowly released into the vessel wall tissue over a period of 30 to 45 days, and is intended to prevent the build-up of scar tissue that can narrow the reopened artery.

In Table 6B of the Addendum to this proposed rule, we list a new procedure code 36.07 (Insertion of drug-eluting coronary artery stents(s)) that will be effective for use October 1, 2002. We also are proposing to add code 00.55 (Insertion of drug-eluting noncoronary artery stent).

A manufacturer of this technology requested that code 36.07 be assigned to DRG 516 (Percutaneous Cardiovascular Procedure with Acute Myocardial Infarction (AMI)) even without the presence of AMI. The manufacturer asserted that this technology is significantly more costly than other technologies currently assigned to DRG 517 (Percutaneous Cardiovascular Procedure with Coronary Artery Stent without AMI) (average charges of \$29,189 compared to average charges of \$22,998), and warrants this DRG assignment.

In addition, the manufacturer argued that this technology should be given preferential treatment because it will fundamentally change the treatment of multivessel disease. Specifically, the manufacturer stated that due to the absence of restenosis in patients treated with the drug-eluting stents based on the preliminary trial results, bypass surgery may no longer be the preferred treatment for many patients.¹ The manufacturer believes lower payments due to the decline in Medicare bypass surgeries will offset the higher payments associated with assigning all cases receiving the drug-eluting stent to DRG 516.

Currently, this technology has not been approved for use by the FDA. If the technology is approved by the FDA and further evidence is presented to us regarding the clinical efficacy and the impact that this technology has on the treatment of multivessel disease, we may reassign this code to another DRG or reassess the construct of all affected DRGs. We also are specifically soliciting comments on our proposal to treat the new codes cited above consistent with the current DRG assignment for stents.

g. Cardiac Resynchronization Therapy

Cardiac resynchronization therapy for heart failure provides strategic electrical stimulation to the right atrium, right ventricle, and left ventricle, in order to

coordinate ventricular contractions and improve cardiac output. This therapy includes cardiac resynchronization therapy pacemakers (CRT-P) and cardiac resynchronization therapy defibrillators (CRT-D). While similar to conventional pacemakers and internal cardioverter-defibrillators, cardiac resynchronization therapy is different because it requires the implantation of a special electrode within the coronary vein, so that it can be attached to the exterior wall of the left ventricle.

Currently, defibrillator cases are assigned to either DRG 514 (Cardiac Defibrillator Implant with Cardiac Catheterization) or DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheterization). DRG 514 has a higher relative weight than DRG 515. We received a recommendation that we assign implantation of CRT-D (code 00.51, effective October 1, 2002) to either DRG 104 (Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization) or DRG 514 (Cardiac Defibrillator Implant With Cardiac Catheterization). It is argued that the change should be made because the current DRG structure for cardioverter-defibrillator implants does not recognize the significant amount of additional surgical resources required for cases involving patients with heart failure.

The recommendation supported assigning new code 00.50 (Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system [CRT-P]) to DRG 115 (Permanent Cardiac Pacemaker Implantation With AMI, Heart Failure, or Shock, or AICD Lead or Generator Procedure). Currently, pacemaker implantation procedures are assigned to either DRG 115 (Permanent Cardiac Pacemaker Implant with AMI, Heart Failure, or Stroke, or AICD Lead or Generator Procedure) or DRG 116 (Other Permanent Cardiac Pacemaker Implant). DRG 115 has the higher relative weight. Because DRG 115 recognizes patients with heart failure, the manufacturer believed CRT-P cases would be appropriately classified to DRG 115.

Our proposed DRG assignment for code 00.51 would be to DRG 514 or 515. Our proposed DRG assignment for code 00.50 would be to DRG 115 and 116. However, we are soliciting comments on these proposed DRG assignments and will carefully consider any relevant evidence about the clinical efficacy and costs of this technology.

h. Hip and Knee Revisions

We received a request to consider assigning hip and knee revisions (codes 81.53 and 81.55) out of DRG 209 (Major

Joint and Limb Reattachment Procedures of Lower Extremity) because these revisions are significantly more resource intensive and costly than initial insertions of these joints.

We examined claims data and concluded that, while the charges for the hip and knee revision cases were somewhat higher than other cases within DRG 209, they do not support the establishment of a separate DRG.

i. Multiple Level Spinal Fusions

We received a comment suggesting that we create new spinal fusion DRGs that differentiate by the number of discs that are fused in a spinal fusion. The commenter indicated that the existing ICD-9-CM codes do not identify the number of discs that are fused. Codes were modified for FY 2002 to clearly differentiate between fusions and refusions, and new codes were created for the insertion of interbody spinal fusion device (84.51), 360 degree spinal fusion, single incision approach (81.61), and the insertion of recombinant bone morphogenetic protein (84.52) (66 FR 39841 through 39844).

ICD-9-CM codes have not historically been used to differentiate among cases by the number of repairs or manipulations performed in the course of a single procedure. However, we will explore the possibility of creating codes to differentiate cases by the number of discs fused during a spinal fusion procedure at the scheduled April 18 and 19, 2002 meeting of the ICD-9-CM Coordination and Maintenance Committee.

We also note that DRGs generally do not segregate cases based on the number of repairs or devices that occur in the course of a single procedure. For instance, DRGs are not split based on the number of vessels bypassed in cardiac surgery, nor are they split based on the number of cardiac valves repaired. Therefore, we are not proposing DRG changes for multiple level spinal fusions in this proposed rule.

j. Open Wound of the Hand

We received a recommendation that we move code 882.0 (Open Wound of Hand Except Finger(s) Alone Without Mention of Complication) from its current location in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) under DRGs 280 through 282 (Trauma to the Skin, Subcutaneous Tissue and Breast Age >17 with CC, Age >17 without CC, and Age 0-17, respectively) into MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) under DRGs 444 through 446 (Traumatic Injury Age >17 with CC, Age

¹ "Comparison of Coronary-Artery Bypass Surgery and Stenting for the Treatment of Multivessel Disease," Serruys, P. W., Unger, F., et. al., *The New England Journal of Medicine*, April 12, 2001, Vol. 344, No. 15, p. 1117.

>17 without CC, and Age 0–17, respectively).

In examining our data, we found relatively few cases with code 882.0. These cases had charges that were less than the average charges for DRGs to which they are currently assigned. The data do not support a DRG change. Our medical consultants also believe that the cases are appropriately assigned to DRGs 280 through 282.

k. Cavernous Nerve Stimulation

As discussed in August 1, 2001 final rule (66 FR 39845), we reviewed data in MDC 12 (Diseases and Disorders of the Male Reproductive System). We looked specifically for code 89.58 (Plethysmogram) in DRG 334 (Major Male Pelvic Procedures with CC), and DRG 335 (Major Male Pelvic Procedures without CC).

Our data show that very few (six) of these procedures were reported on FY 2001 claims. It is not clear whether the small number reflects the fact that the procedure is not being performed, the ICD–9–CM code is not recorded, or the code is recorded but it is not in the top six procedures being performed. However, in all six cases where this procedure was performed, it occurred in conjunction with radical prostatectomy, so we are confident that these cases are consistent with the DRGs to which they have been grouped. Therefore, we are not proposing any DRG assignment changes to code 89.58 or DRGs 334 and 335.

C. Recalibration of DRG Weights

We are proposing to use the same basic methodology for the FY 2003 recalibration as we did for FY 2002 (August 1, 2001 final rule (66 FR 39828)). That is, we would recalibrate the weights based on charge data for Medicare discharges. However, we are proposing to use the most current charge information available, the FY 2001 MedPAR file. (For the FY 2002 recalibration, we used the FY 2000 MedPAR file.) The MedPAR file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills.

FY 2001 MedPAR data include discharges occurring between October 1, 2000 and September 30, 2001, based on bills received by CMS through December 31, 2001, from all hospitals subject to the acute care hospital inpatient prospective payment system and short-term acute care hospitals in waiver States. The FY 2001 MedPAR file includes data for approximately 11,420,001 Medicare discharges. The data include hospitals that subsequently became CAHs, although no data are

included for hospitals after the point they are certified as CAHs. Section IX. of this preamble contains information about how to obtain the MedPAR data.

The proposed methodology used to calculate the DRG relative weights from the FY 2001 MedPAR file is as follows:

- To the extent possible, all the claims were regrouped using the DRG classification revisions discussed in section II.B. of this preamble.
- Charges were standardized to remove the effects of differences in area wage levels, indirect medical education and disproportionate share payments, and, for hospitals in Alaska and Hawaii, the applicable cost-of-living adjustment. (See section IX.A.15. of this proposed rule for information on the availability of the prospective payment system standardizing file.)
- The average standardized charge per DRG was calculated by summing the standardized charges for all cases in the DRG and dividing that amount by the number of cases classified in the DRG. A transfer case is counted as a fraction of a case based on the ratio of its transfer payment under the per diem payment methodology to the full DRG payment for nontransfer cases. That is, transfer cases paid under the transfer methodology equal to half of what the case would receive as a nontransfer would be counted as 0.5 of a total case.
- We then eliminated statistical outliers, using the same criteria used in computing the current weights. That is, all cases that are outside of 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 are eliminated.
- 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.
- We established the relative weight for heart and heart-lung, liver, and lung transplants (DRGs 103, 480, and 495) in a manner consistent with the methodology for all other DRGs except that the transplant cases that were used to establish the weights were limited to those Medicare-approved heart, heart-lung, liver, and lung transplant centers that have cases in the FY 1999 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.)
- Acquisition costs for kidney, heart, heart-lung, liver, lung, and pancreas transplants continue to be paid on a reasonable cost basis. Unlike other excluded costs, the acquisition costs are

concentrated in specific DRGs: DRG 302 (Kidney Transplant); DRG 103 (Heart Transplant); DRG 480 (Liver Transplant); DRG 495 (Lung Transplant); and DRGs 512 (Simultaneous Pancreas/Kidney Transplant) and 513 (Pancreas Transplant). Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to make an adjustment to exclude them from the relative weights for these DRGs. Therefore, we subtracted the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average charge for the DRG and before eliminating statistical outliers.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We used that same case threshold in recalibrating the proposed DRG weights for FY 2003. Using the FY 2001 MedPAR data set, there are 41 DRGs that contain fewer than 10 cases. We computed the weights for these 41 low-volume DRGs by adjusting the FY 2002 weights of these DRGs by the percentage change in the average weight of the cases in the other DRGs.

The proposed new weights are normalized by an adjustment factor (1.43430) 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 prospective payment system.

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

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

1. Background

Section 533(b) of Public Law 106–554 amended section 1886(d)(5) of the Act to add subparagraphs (K) and (L) to establish a process of identifying and ensuring adequate payment for new medical services and technologies under Medicare. 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 . . . 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).

In the September 7, 2001 final rule (66 FR 46902), we established that a new technology would 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 (§ 412.87(b)(1)).

We also established that new technologies meeting this clinical definition must be demonstrated to be inadequately paid otherwise under the DRG system to receive special payment treatment (§ 412.87(b)(3)). To assess whether technologies would be inadequately paid under the DRGs, we established this threshold at one standard deviation beyond the geometric mean standardized charge for all cases in the DRGs to which the new technology is assigned (or the case-weighted average of all relevant DRGs, if the new technology occurs in many different DRGs) (§ 412.87(b)(3)).

Table 10 in the Addendum to this proposed rule lists the proposed qualifying criteria by DRG based on the discharge data used to calculate the proposed FY 2003 DRG weights. The thresholds published in the final rule will be used to evaluate applicants for new technology add-on payments during FY 2004 (beginning October 1, 2003). Similar to the timetable for applying for new technology add-on payments during FY 2003, we are proposing that applicants for FY 2004 must submit a significant sample of the data no later than early October 2002. Subsequently, we are proposing that a complete database must be submitted no later than mid-December 2002.

In addition to the clinical and cost criteria, we established that, in order to qualify for the special payment treatment, 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 2001 are used to calculate the proposed FY 2003 DRG weights in this proposed rule.

Technology may be considered “new” for purposes of this provision within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the technology. After CMS has 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 2001 would be eligible to receive add-on payments as a new technology until FY 2004 (discharges occurring before October 1, 2003), when data reflecting the costs of the technology would be used to recalibrate the DRG weights. Because the FY 2004 DRG weights will be calculated using FY 2002 MedPAR data, the costs of such a new technology would be reflected in the FY 2004 DRG weights.

For technologies that do not qualify for special payments under § 412.87, we will continue our past practice of evaluating whether existing procedures are appropriately classified to a DRG. To the extent the introduction of a new code for existing technology helps to better identify higher costs associated with a procedure, we would work to expedite the appropriate assignment of that code (for example, using more recent MedPAR data).

In the September 7, 2001 final rule, we established that Medicare would provide higher payments for cases with higher costs involving identified 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 would pay a marginal cost factor of 50 percent for the costs of the new technology in excess of

the full DRG payment. If the costs of a new technology case exceed the DRG payment by more than the estimated costs of the new technology, Medicare payment would be limited to the DRG payment plus 50 percent of the estimated costs of the new technology.

The report language accompanying section 533 of Public Law 106–554 indicated Congressional intent that the Secretary implement the new mechanism on a budget neutral basis (H.R. Conf. Rep. No. 106–1033, 106th Cong., 2d 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 this provision for new technology 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.

Because any additional payments directed toward new technology under this provision would be offset to ensure budget neutrality, it is important to carefully consider 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 will discuss in the annual proposed and final rules those technologies that were considered under this provision; our determination as to whether a particular new technology meets our criteria for a new technology; 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 appropriately balance 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 special payments for new technology under the provisions of section 533(b) of Public Law 106–554 at 1.0 percent of estimated total operating prospective payments.

If invoked, the target limit 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 will be reduced, this would be offset by large overall payments to hospitals for new technologies under this provision.

2. Applicants for FY 2003

We received five applications for new technologies to be designated eligible for inpatient add-on payments under the policy we implemented in the September 7, 2001 final rule. One of these applications was subsequently withdrawn. The remaining four applicants are discussed below.

a. Drotrecogin Alfa (Activated)—Xigris™

Eli Lilly and Company (Lilly) developed drotrecogin alfa (activated), trade name Xigris™, as a new technology and submitted an application to us for consideration under the new technology add-on provision. Xigris™ is used to treat patients with severe sepsis.

According to the application—“Approximately 750,000 cases of sepsis associated with acute organ dysfunction (severe sepsis) occur annually in the United States. The mortality rates associated with severe sepsis in the United States range from 28 percent to 50 percent and have remained essentially unchanged for several decades. Each year, 215,000 deaths are associated with severe sepsis; deaths after acute myocardial infarction occur at approximately an equal rate.”

Xigris™ is a biotechnology product that is a recombinant version of naturally occurring Activated Protein C (APC). APC is needed to ensure the control of inflammation and clotting in the blood vessels. In patients with severe sepsis, Protein C cannot be converted in sufficient quantities to the activated form. It appears that Xigris™ has the ability to bring blood clotting and inflammation back into balance and restore blood flow to the organs.

In support of its application, Lilly submitted data from the Phase III Protein C Worldwide Evaluation in Severe Sepsis (PROWESS) trial. According to Lilly, this was “an international, multicenter, randomized, double-blind, placebo-controlled trial in which 1,690 patients with severe sepsis received either placebo (n = 840) or drotrecogin alfa (activated) (n = 850).” The results of the trial were published

in an article in the March 8, 2001 edition of *The New England Journal of Medicine* (Bernard, G. R., Vincent, J. L., et. al., “Efficacy and Safety of Recombinant Human Activated Protein C for Severe Sepsis,” Vol. 344, No. 10, p. 699).

A 6.1 percent reduction in mortality was reported. This conclusion was based on a measure of 28-day all-cause mortality. However, at 28 days, over 10 percent of the study participants were still hospitalized. Whether these patients subsequently went on to recover or died was not reported.

Because the reduction in mortality was the result of a treatment effect in a relatively small number of patients and mortality was looked at only 28 days after treatment, we plan to review unpublished data on all-cause mortality at the time of hospital discharge for all patients enrolled in the study using an intent-to-treat analysis. We have asked the trial sponsor to provide CMS with these unpublished data and the analyses performed in the original report, including confidence intervals and Kaplan-Meier curve with log-rank statistics, for death from any cause assessed at the time of hospital discharge. A small increase in the number of deaths among treated patients still hospitalized at 28 days could nullify the survival advantage attributed to the use of Xigris™.

The study had a number of other important methodological limitations that also merit further consideration. Therefore, we are unable to conclude, based on the published data, that Xigris™ represents an advance that substantially improves, relative to technology previously available, treatment for Medicare beneficiaries. However, we are continuing our assessment and will announce our final determination in the final rule. If we subsequently determine that Xigris™ represents a substantial improvement, payment would likely be limited to a subpopulation of patients with severe sepsis, consistent with the FDA labeling and possible other restrictions.

Detailed bills were available for 604 of 705 patients in the United States in the PROWESS clinical trial (303 placebo patients and 301 treatment patients). In all, 83 hospitals submitted detailed bills. These data included an indicator whether the patient received the treatment or a placebo, total charges and standardized charges for the stay as well as for the biological, and the patients' APACHE II scores (an assessment of the risk of mortality based on acute physiology and chronic health evaluation). The FDA's approval letter (issued November 21, 2001) stated

“drotrecogin alfa (activated) is indicated for the reduction of mortality in adult patients with severe sepsis (sepsis associated with acute organ dysfunction) who have a high risk of death (e.g., as determined by APACHE II).”

Of the 604 cases with detailed billing data, 274 were patients age 65 or older. The average total charge for these 274 cases, including the average standardized charge for the biological, was \$86,184 (adjusted for inflation using the applicable hospital market baskets, as patients were enrolled in the trial from July 1998 through June 2000). The inflated average standardized charge of the biological only for these cases was \$15,562.

Lilly also submitted detailed ICD-9-CM diagnosis and procedure codes for a subset of 157 of the 604 U.S. patients with billing data from the PROWESS trial. These data were not requested as part of the trial, but were sent in separately. Of these 157 patients, 82 were over 65 years of age. These 82 patients grouped into 23 DRGs. Approximately 75 percent of these 82 cases were in 5 DRGs: 29 percent were in DRG 475 (Respiratory System Diagnosis with Ventilator Support); 17 percent were in DRG 483 (Tracheostomy Except for Face, Mouth, and Neck Diagnoses); 15 percent were in DRG 416 (Septicemia Age >17); 7 percent were in DRG 415 (OR Procedure for Infectious and Parasitic Diseases); and 5 percent were in DRG 148 (Major Small and Large Bowel Procedures With CC).

Using the methodology described in the September 7, 2001 final rule (66 FR 46918), we calculated a case-weighted threshold based on the distribution of these 82 cases across 23 DRGs. In order to qualify for new technology payments based on these DRGs, the threshold would be \$82,882 (compared to the average standardized charge of \$86,184 noted above).

In the September 7, 2001 final rule, we stated that the data submitted must be of a sufficient sample size to demonstrate a significant likelihood that the sample mean approximates the true mean across all cases likely to receive the new technology. Using a standard statistical methodology for determining the needed (random) sample size based on the standard deviations of the DRGs identified in the trial as likely to include cases receiving Xigris™, we have determined that a random sample of 274 cases can be reasonably expected to produce an estimate within \$3,500 of the true mean.¹ Of course, the data

¹ The formula is $n = 4\sigma^2/\beta^2$, where σ is the standard deviation of the population, and β is the

submitted do not represent a random sample.

The 274 case sample was for all U.S. patients over age 65 included in the PROWESS trial. In the September 7, 2001 final rule, we indicated our preference for using Medicare cases identifiable in our MedPAR database, although data from a trial without matching MedPAR data could be considered. We also indicated our intention to independently verify the data submitted.

According to Lilly, the patient consent agreements for the PROWESS trial did not provide for the collection and submission of data to CMS. Therefore, we have been unable to identify matching cases in our MedPAR database, or independently verify the data. Due to the passage of Public Law 106-554 in December 2000 and the publication of the final rule in September 2001, it is understandable that our data requirements in order to analyze applicants for new technology add-on payments were not accommodated in the design of the PROWESS trial. We will continue to work with Lilly to independently verify the data in the event it is determined that Xigris™ does represent a substantial clinical improvement.

In particular, we note that, even without the biological charges, the standardized mean charge for the cases submitted for analysis is well above the standardized case-weighted DRG mean (\$70,623 for the PROWESS trial cases compared to \$54,058 for all cases in the relevant DRGs). We are analyzing our MedPAR data to develop a cohort group of patients to assess the validity of the charges reported for the patients in the PROWESS trial and will report the result of our analysis in the final rule. We solicit comments on this and other approaches to verifying these data.

Cases where Xigris™ is administered will be identified by use of the new ICD-9-CM procedure code 00.11 (Infusion of drotrecogin alfa (activated)). According to Lilly, "(t)he net wholesale price for drotrecogin alfa (activated) is \$210 for a 5-milligram vial and \$840 for a 20-milligram vial. The average cost for a one-time 96-hour course of therapy for an average adult patient is \$6,800 (24 ug/kg/hr for 96 hours for a 70 kg person)." Because code 00.11 does not identify the actual amount of the drug administered per patient, any additional payment would be based on the average cost per patient of \$6,800. If this

technology were to be approved for add-on payment under § 412.88, cases involving the administration of Xigris™ would be eligible for additional payments of up to \$3,400 (50 percent of the average cost of the drug).

For purposes of budget neutrality, we need to estimate the additional payments that would be made under this provision during FY 2003. Lilly has estimated that, initially, 25,000 Medicare patients would receive drotrecogin alfa (activated). If the maximum \$3,400 add-on payment is made for all 25,000 of these patients, the total amount that would be paid for these cases would be an additional \$85 million. However, comparing the total standardized charges for the 274 patients age 65 or older, 56 percent had average standardized charges below the weighted average standardized charges for the 23 DRGs into which these cases were categorized. Therefore, assuming the costs for these cases would be below the payment received, these 56 percent of cases would not receive any additional payment. Therefore, for purposes of budget neutrality, we estimate the total payments likely to be made under this provision during FY 2003 for cases involving the administration of drotrecogin alfa (activated) would be \$37.4 million (44 percent of \$85 million).

b. Bone Morphogenetic Proteins (BMPs) for Spinal Fusions

BMPs have been isolated and shown to have the capacity to induce new bone formation. Using recombinant techniques, some BMPs (referred to as rhBMPs) can be produced in large quantities. This has cleared the way for their potential use in a variety of clinical applications such as in delayed unions and nonunions of fractured bones and spinal fusions. One such product, rhBMP-2, is developed for use instead of a bone graft with spinal fusions.

An application was submitted by Medtronic Sofamor Danek for the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device for approval as a new technology eligible for add-on payments. 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 is done in place of the more traditional use of autogenous iliac crest bone graft.

In 1997, in a pilot study conducted under a FDA approved device exemption, 14 patients were enrolled at

4 investigational sites. Eleven patients received rhBMP-2, with 3 control patients. Radiographs and computed tomography scans at 6, 12, and 24 months after surgery showed that all 11 patients who received rhBMP-2 had solid fusions, whereas only 2 of the 3 patients who received autogenous bone graft had solid fusions. Scores from the Oswestry Low Back Pain Disability Questionnaire showed that 6 of 11 patients treated with rhBMP-2 had a successful outcome at 3 months after surgery, compared with 0 of 3 control patients. After 6 months, the results had changed to 7 of 11 rhBMP-2 patients and 2 control patients with successful treatments; and at 12 months, 10 rhBMP-2 patients and 2 control patients were judged successful. The results were unchanged at 24 months. The trial results were presented in an article in the February 1, 2000 edition of SPINE (Bone, S., Zdeblick, T., et al., "The Use of rhBMP-2 in Interbody Fusion Cages-Definitive Evidence of Osteoinduction in Humans: A Preliminary Report"), Vol. 25, No. 3, p. 376.

The above study was then expanded to involve 281 patients at 16 sites, with 143 patients in the rhBMP-2 group and 138 patients in the autogenous iliac crest bone graft group. In the rhBMP-2 group, 76.9 percent of the patients showed an improvement of at least 15 points in their disability scores at 12 months postoperatively. This compared favorably to 75 percent of patients in the control group. At 6 months following surgery, 97 percent of patients in the rhBMP-2 group showed evidence of interbody fusion, as compared to 95.8 percent in the control group. At 12 months, 96.9 percent of patients in the rhBMP-2 group were fused as compared to 92.5 percent in the control group. At this time, the results of this study are unpublished.

On January 10, 2002, the FDA issued an approvable letter for this technology. At this point, however, the technology has not been approved by the FDA for general use. Therefore, we are not proposing to approve this technology for add-on payments in this proposed rule. We discuss thoroughly the data submitted with the application below. However, if the FDA approves the product for general use prior to our issuance of the final rule by August 1, 2002, we will issue a determination whether this technology represents a substantial clinical improvement under the criteria outlined in the September 7, 2001 final rule.

Cost data were submitted for 88 patients participating in the followup study described above. This trial was a single-level, anterior lumbar interbody

bound on the error of the estimate (the range within which the sample means can reliably predict the population mean). See *Statistics for Management and Economics*, Fifth Edition, by Mendenhall, W., Reinmuth, J., Beaver, R., and Duhan, D.

fusion clinical study. Of these 88 bills with cost data, the applicant calculated an average standardized charge for these single-level fusion cases of \$33,757. According to the applicant, "it is anticipated that a large number, if not the majority, of cases using BMP technology will, in practice, be multi-level fusions". The applicant reported the estimated hospital charges (based on general charging practices) to be \$17,780 for each level. In order to account for the use of this technology in multilevel spinal fusions, the applicant assumed 47 percent of spinal fusions were multilevel (based on analysis of Medicare spinal fusion cases). Increasing the average standardized charge for the cases in the trial by \$17,780, the applicant calculated a weighted average standardized charge (53 percent single-level and 47 percent multilevel) of \$45,556.

Of these 88 cases, 11 were assigned to DRG 497 (Spinal Fusion Except Cervical With CC) and 77 were assigned to DRG 498 (Spinal Fusion Except Cervical Without CC). In order to qualify for new technology payments based on these DRGs, the threshold would be \$37,815.

The applicant has submitted data that estimate between 2,300 and 4,600 Medicare spinal fusion procedures involving this technology in FY 2003. The cost of the technology is \$3,900 per level. For approximately 45 percent of spinal fusion involving multilevel fusions, the weighted cost of the technology is \$5,686, resulting in a maximum add-on payment amount of \$2,843. In reference to the utilization estimates above, the total amount for these cases if each case qualified for a new technology payment would be between \$6.5 million and \$13.0 million.

c. Zyvox™

Zyvox™ is the first antibiotic in the oxazolidinone class and is widely used by hospitals in the United States and other countries against the medically significant gram-positive bacteria, including those that are resistant to other therapies. Gram-positive bacterial infections have become increasingly prevalent in recent years, most commonly implicated in infections in the lower respiratory tract, skin and soft tissue, bone and bloodstream, and in meningitis. Significant morbidity and mortality trends are associated with such pathogens. Epinomics Research, Inc., submitted the application on behalf of Pharmacia Corporation (Pharmacia), which markets the drug.

The FDA approved Zyvox™ on April 18, 2000, for the treatment of serious infections caused by antibiotic-resistant bacteria. The applicant contends that this qualifies Zyvox™ for approval

within the 2-year to 3-year period referenced at § 412.87(b)(2). Furthermore, the applicant notes that the approval of the new ICD-9-CM code 00.14 (Injection or infusion of oxazolidinone class of antibiotics) effective October 1, 2002, will permit a more precise identification of these cases. 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 Zyvox™ are currently reflected in the DRG weights, Zyvox™ does not meet our criterion that a medical service or technology be "new". The FY 2001 MedPAR data used to calculate the proposed DRG weights for FY 2003 include cases where Zyvox™ was administered. The application itself noted that the use of Zyvox™ is widespread. Therefore, even though the existing code, 99.21 (Injection of antibiotic) is a general code used for the administration of various antibiotics including Zyvox™, and does not separately identify the administration of Zyvox™ as will be possible with the new code 00.14, the charges associated with these cases are reflected in the proposed FY 2003 DRG weights.

As stated above, we note that the applicant itself points out that Zyvox™ is widely used currently by hospitals. In its 4th quarter 2001 earnings report, Pharmacia reports total sales in the United States of \$97 million, which is an increase of 105 percent over the previous year. This would indicate expanding access to the drug.

We would point out that, in response to a comment that technologies should qualify as "new" beginning with the assignment of an appropriate tracking code, we clarified in the September 7, 2001 final rule that we would not consider technologies that have been on the market for more than 2 or 3 years to be "new" on the basis that a more precise ICD-9-CM procedure code has been created (66 FR 46914). However, although such technologies would not qualify for add-on payments under this provision, we did indicate that we would evaluate whether the existing DRG assignments of the technology are appropriate.

For example, currently the administration of Zyvox™ does not affect the DRG to which a case is assigned. In its application for add-on payments, Epinomics provided CMS data that included clinical trials as well as data from a sample that spanned MedPAR files from FY 2000 through FY 2002. For its sample study, Epinomics obtained patient records from 70 hospitals that used Zyvox™ treatment on 832 Medicare patients. The cases were distributed across 151 DRGs.

Epinomics calculated that the mean standardized charge for these 485 cases was \$74,174. The case-weighted mean standardized charge for all cases in these DRGs would be \$33,740 (based on the distribution of Zyvox™ cases across the 151 DRGs).

The unit price for the drug varies from approximately \$30 for a 100 milliliter bag (200 milligram linezolid) to approximately \$1,350 for 600 milligram tablets (unit doses of 30 tablets). Nevertheless, it appears the high average charges associated with patients receiving the drug are not directly attributable to the administration of Zyvox™. Therefore, we are not proposing any changes to the DRG assignment of these cases at this time. To the extent these cases are more expensive due to the severity of illness of the patients being treated, the current outlier policy will offset any extraordinarily high costs incurred.

d. Renew™ Radio Frequency Spinal Cord Stimulation Therapy

An application was submitted by Advanced Neuromodulation Systems (ANS) for the Renew™ Spinal Cord Stimulation Therapy for approval as a new technology eligible for add-on payments. ANS is a medical device company that deals with management of chronic pain that is severe, persistent, and unresponsive to drugs or surgery. Spinal cord stimulation (SCS) offers a treatment alternative to expensive ongoing comprehensive care. Renew™ SCS was introduced in July 1999 as a device for the treatment of chronic intractable pain of the trunk and limbs.

According to the applicant:

"SCS is a reversible method of pain control that works well for certain types of chronic intractable pain. SCS requires a surgical procedure to implant a receiver and leads. These implanted devices generate electrical stimulation that interrupts pain signals to the brain. SCS is considered to be a treatment of last resort, and is usually undertaken only when first and second-line therapies for chronic pain fail to provide adequate relief. SCS uses low-intensity electrical impulses to trigger nerve fibers selectively along the spinal cord. The stimulation of these nerve fibers diminishes or blocks the intensity of the pain message being transmitted to the brain. SCS replaces areas of intense pain with a more pleasant sensation * * *, masking the pain that is normally present.

Prior to Renew™, SCS systems offered few technical capabilities for treating complex chronic pain patients who suffered with pain that spanned

noncontiguous areas (multi-focal) or that varied in intensity over the painful area. The Renew™ system features a multiplex output mode that controls separate stimulation programs to allow outputs of varying frequencies to be used at the same time. According to ANS, “The significance of this technology is that it is now possible to multiplex (link and cycle) up to 8 programs to provide pain relieving paresthesia overlap of anatomical regions that are not contiguous or that cannot be captured by a single program.”

The Renew™ technology also allows the concomitant use of separate programs for patients who require different power settings for different areas that have pain. With this technology, separate programs can be programmed from the same unit, with electrical output parameters customized for each painful region. ANS contends that the clinical significance of this technology is that patients who find satisfactory pain relief will require fewer alternative treatments to treat unrelieved pain.

The ANS application specifically requests add-on payments for the costs of the Radio Frequency System (RF System). This system only requires one surgical placement and does not require additional surgeries to replace batteries as do other internal SCS systems. ANS estimates that there are 2,900 RF Systems implanted annually; only 10 percent are in the inpatient setting. ANS is the only company that offers a 16-channel/electrode system.

ANS provided the 2001 hospital acquisition cost for ANS Renew™ 8 and 16 Channel/Electrode RF SCS Systems as follows:

	ANS 2001 List Price
8 Channel/Electrode System:	
One Lead (8 Electrode)	\$2,750
One Extension (8 Electrode)	695
Receiver (8 Channel) ..	4,995
Transmitter (8 Channel)	4,995
Total System	13,435
16 Channel/Electrode System:	
Two Leads (16 Electrodes)	5,500
Two Extensions (16 Electrodes)	1,390
Receiver (16 Channel) ..	7,295
Transmitter (16 Channel)	7,295
Total System	21,480

Currently, implanting the ANS 8 or 16 Channel/Electrode SCS System falls into DRG 4 (Spinal Procedures) under ICD-9-CM procedure code, 03.93 (Insertion or replacement, spinal neurostimulation). According to the September 7, 2001 **Federal Register**, the threshold to qualify for additional new technology payments for services classified to DRG 4 would be \$38,242 (based on adding the geometric mean and the standard deviation of standardized charges) (66 FR 46922).

Relative to hospital invoice information, ANS provided the following estimates:

“* * * 90% of the U.S. hospital cost-to-charge ratios fall between .24 and .69, and 75% fall between .29 and .58. The median is .41. This median costs-to-charge ratio equates to an average hospital markup of 144%. If you apply the average hospital markup of 144% to the device acquisition cost plus the estimated facility cost, the result is an estimated hospital invoice for the SCS implant procedure of \$40,101.00, for the 8 Channel/Electrode System and \$59,731.00 for the 16 Channel/Electrode System.”

In support of its application, ANS provided detailed bills for 12 patients. Of the 12 cases with detailed billing data, 3 patients were age 65 or older. The average total charge for these 3 cases, including the average standardized charge for operating room costs, was \$42,820.

As noted previously, technology will no longer be considered new after the costs of the technology are reflected in the DRG weights. Because the Renew™ RF System was introduced in July 1999, the FY 2001 MedPAR data used to calculate the proposed DRG weights for FY 2003 includes any Medicare cases that involved the implantation of the Renew™ RF System. The charges associated with these cases are reflected in the proposed FY 2003 DRG weights. Therefore, the Renew™ RF System is not considered “new” under our criteria. However, we will continue to monitor these cases in DRG 4 to determine whether this is the most appropriate DRG assignment.

III. Proposed Changes to the Hospital Wage Index

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts “for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the

hospital compared to the national average hospital wage level.” In accordance with the broad discretion conferred under the Act, we currently define hospital labor market areas based on the definitions of Metropolitan Statistical Areas (MSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs) issued by the Office of Management and Budget (OMB). OMB also designates Consolidated MSAs (CMSAs). A CMSA is a metropolitan area with a population of one million or more, comprising two or more PMSAs (identified by their separate economic and social character). For purposes of the hospital wage index, we use the PMSAs rather than CMSAs since they allow a more precise breakdown of labor costs. If a metropolitan area is not designated as part of a PMSA, we use the applicable MSA. Rural areas are areas outside a designated MSA, PMSA, or NECMA. For purposes of the wage index, we combine all of the rural counties in a State to calculate a rural wage index for that State.

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

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

In a December 27, 2000 notice published in the **Federal Register** (65 FR 82228), OMB issued its revised standards for defining MSAs. In that notice, OMB indicated that it plans to announce in calendar year 2003 definitions of MSAs based on the new standards and the Census 2000 data. We will evaluate the new area designations and their possible effects on the

Medicare wage index, as well as other provider payment implications. Although the final construct of the redefined MSAs will not be known until 2003, we intend to work closely with OMB to begin to assess the potential ramifications of these changes.

Beginning October 1, 1993, section 1886(d)(3)(E) of the Act requires that we update the wage index annually. Furthermore, this section provides that the Secretary base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. The survey should measure, to the extent feasible, the earnings and paid hours of employment by occupational category, and must exclude the wages and wage-related costs incurred in furnishing skilled nursing services. As discussed below in section III.F. of this preamble, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating the wage index.

Section 304(c) of Public Law 106-554 amended section 1886(d)(3)(E) of the Act to provide for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. The initial collection of these data must be completed by September 30, 2003, for application beginning October 1, 2004 (the FY 2005 wage index).

In the May 4, 2001 proposed rule (66 FR 22674), we suggested possible occupational categories from the Occupational Employment Statistics (OES) survey conducted by the Bureau of Labor Statistics. In response to comments on the proposed rule, we agreed to work with the health care industry to develop a workable data collection tool. After we develop a method that appropriately balances the need to collect accurate and reliable data with the need to collect data that hospitals can be reasonably expected to have available, we will issue instructions as to the type of data to be collected, in advance of actually requiring hospitals to begin providing the data.

B. Proposed FY 2003 Wage Index Update

The proposed FY 2003 wage index values in section V. of the Addendum to this proposed rule (effective for hospital discharges occurring on or after October 1, 2002 and before October 1, 2003) are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting

periods beginning in FY 1999 (the FY 2002 wage index was based on FY 1998 wage data).

The proposed FY 2003 wage index includes the following categories of data associated with costs paid under the hospital inpatient prospective payment system (as well as outpatient costs), which were also included in the FY 2002 wage index:

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

Consistent with the wage index methodology for FY 2002, the proposed wage index for FY 2003 also continues to exclude the direct and overhead salaries and hours for services such as skilled nursing facility (SNF) services, home health services, and other subprovider components that are not paid under the hospital inpatient prospective payment system.

We calculate a separate Puerto Rico-specific wage index and apply it to the Puerto Rico standardized amount. (See 62 FR 45984 and 46041.) This wage index is based solely on Puerto Rico's data. Finally, section 4410 of Public Law 105-33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is not located in a rural area may not be less than the area wage index applicable to hospitals located in rural areas in that State.

C. FY 2003 Wage Index Proposal

1. Removal of Wage Costs and Hours Related to Graduate Medical Education (GME) and Certified Registered Nurse Anesthetists (CRNAs)

Because the hospital wage index is used to adjust payments to hospitals under the acute care hospital inpatient prospective payment system, the wage index should, to the extent possible, reflect the wage costs associated with those cost centers and units paid under the hospital inpatient prospective payment system. Costs related to graduate medical education (GME) (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs) are paid by Medicare separately from the hospital inpatient prospective payment system. In 1998, the AHA convened a workgroup to develop a consensus recommendation on this issue. The workgroup, which consisted of representatives from national and State hospital associations, recommended that costs related to GME and CRNAs be phased out of the wage index calculation over a 5-year period.

Based upon our analysis of hospitals' FY 1996 wage data, and consistent with the AHA workgroup's recommendation, we specified in the July 30, 1999 final rule (64 FR 41505) that we would phase out these costs from the calculation of the wage index over a 5-year period, beginning in FY 2000.

FY 2003 would be the fourth year of the phaseout. Therefore, the wage index calculation for FY 2003 would blend 20 percent of a wage index with GME and CRNA costs included and 80 percent of a wage index with GME and CRNA costs removed. FY 2004 would begin the calculation with 100 percent of the GME and CRNA costs removed. However, we are proposing to remove 100 percent of GME and CRNA costs from the FY 2003 wage index, as discussed below.

We have analyzed the FY 2003 wage index both with 100 percent of GME and CRNA costs removed and with 80 percent of these costs removed. We found that the majority of labor market areas, both rural and urban, would benefit by the removal of all of these costs (298 out of 373). Only two rural labor market areas would be negatively impacted by this change (Pennsylvania by -0.01 percent, and New Hampshire by -0.12 percent). We note that, as part of its Report to the Congress on Medicare in Rural America (June 2001), the MedPAC recommended fully implementing this phaseout during FY 2002. Similar to our findings, MedPAC found the effect of completely eliminating GME and CRNA costs "might not be negligible for some areas, but it would not be large in any case" (page 76). Of the urban labor market areas that would be negatively affected, the impacts on all but two areas are less than 0.50 percent, and the largest negative impact is 1.12 percent.

Because we believe removing GME and CRNA costs from the wage index calculation is appropriate, and the impact is generally positive and relatively small, we are proposing to remove 100 percent of GME and CRNA costs beginning with FY 2003 wage index.

2. Contract Labor for Indirect Patient Care Services

Our policy concerning the inclusion of contract labor costs for purposes of calculating the wage index has evolved with the increasing role of contract labor in meeting special personnel needs of many hospitals. In addition, improvements in the wage data have allowed us to more accurately identify contract labor costs and hours. As a result, effective with the FY 1994 wage index, we included the costs for direct patient care contract services in the

wage index calculation, and with the FY 1999 wage index, we included the costs for certain management contract services. (The August 30, 1996 final rule (61 FR 46181) provided an in-depth discussion of the issues related to the inclusion of contract labor costs in the wage index calculation.) Further, the FY 1999 wage index included the costs for contract physician Part A services, and the FY 2002 wage index included the costs for contract pharmacy and laboratory services.

We continue to consider whether to expand our contract labor definition to include more types of contract services in the wage index. In particular, we have examined whether to include the costs for acquired dietary and housekeeping services, as many hospitals now provide these services through contracts. Costs for these services tend to be below the average wages for all hospital employees. Therefore, excluding the costs and hours for these services if they are provided under contract, while including them if the services are provided directly by the hospital, creates an incentive for hospitals to contract for these services in order to increase their average hourly wage for wage index purposes.

It has also been suggested that we expand our definition to include all contract services, including both direct and indirect patient care services, in order to more appropriately calculate relative hospital wage costs. Our goal is to ensure that our wage index policy continues to be responsive to the changing need for contract labor and allow those hospitals that must depend on contract labor to supply needed services to reflect those costs in their wage data. At the same time, we are concerned about hospitals' ability to provide documentation that sufficiently details contract costs and hours. The added overhead, supplies, and miscellaneous costs typically associated with contract labor may result in higher costs for contract labor compared to salaried labor. If these costs are not separately identifiable and removed, they may cause distortions in the wage index.

We agree that it may be appropriate to include indirect patient care contract labor costs in the wage index. However, in light of concerns about hospitals' ability to accurately document and report these costs, we believe the best approach is to assess and include these costs incrementally. Through incremental changes, we can better determine the impact that specific costs have on area wage index values. Also, by including these costs incrementally,

hospitals and fiscal intermediaries are able to adjust to the additional documentation and review requirements associated with reporting the additional contract costs and hours.

In this proposed rule, we are proposing to begin collecting contract labor costs and hours for management services and the following overhead services: administrative and general, housekeeping, and dietary. We selected these three overhead services because they are provided at all hospitals, either directly or through contracts, and together they comprise about 60 percent of a hospital's overhead hours. In addition, consistent with our consideration of administrative and general services, we propose to collect costs and hours associated with contract management services that are not currently included on Worksheet S-3, Part II, Line 9 (that is, management services other than those of the chief executive officer, chief financial officer, chief operating officer, and nurse administrator).

We propose to revise the FY 2002 Medicare cost report (or the next available cost report) to provide for the separate reporting of contract management, administrative and general, housekeeping, and dietary costs and hours. After evaluating these data, we will determine the feasibility of adding these categories of contract labor to the wage index calculation.

D. Verification of Wage Data From the Medicare Cost Report

The data for the proposed FY 2003 wage index were obtained from Worksheet S-3, Parts II and III of the FY 1999 Medicare cost reports. The data file used to construct the wage index includes FY 1999 data submitted to us as of February 15, 2002. As in past years, we performed an intensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our fiscal intermediaries to revise or verify data elements that resulted in specific edit failures. Some unresolved data elements are included in the calculation of the proposed FY 2003 wage index, pending their resolution before calculation of the final FY 2003 wage index. We have instructed the intermediaries to complete their verification of questionable data elements and to transmit any changes to the wage data no later than April 5, 2002. We expect that all unresolved data elements will be resolved by that date. The revised data will be reflected in the final rule.

Also, as part of our editing process, we removed data for 96 hospitals that

failed edits. For 6 of these hospitals, we were unable to obtain sufficient documentation to verify or revise the data because the hospitals are no longer participating in the Medicare program, are under new ownership and the data cannot be verified, or are in bankruptcy status. We identified 90 hospitals with incomplete or inaccurate data resulting in zero or negative average hourly wages. Therefore, they were removed from the calculation. The data for these hospitals will be included in the final wage index if we receive corrected data that pass our edits. As a result, the proposed FY 2003 wage index is calculated based on FY 1999 wage data for 4,718 hospitals.

E. Computation of the Proposed FY 2003 Wage Index

The method used to compute the proposed FY 2003 wage index follows.

Step 1—As noted above, we based the proposed FY 2003 wage index on wage data reported on the FY 1999 Medicare cost reports. We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S-3, Parts II and III of the Medicare cost report for the hospital's cost reporting period beginning on or after October 1, 1998 and before October 1, 1999. In addition, we included data from some hospitals that had cost reporting periods beginning before October 1998 and reported a cost reporting period covering all of FY 1999. These data were included because no other data from these hospitals would be available for the cost reporting period described above, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 1999 data. We note that, if a hospital had more than one cost reporting period beginning during FY 1999 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 1998 and before October 1, 1999), we included wage data from only one of the cost reporting periods, the longest, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the latest period in the wage index calculation.

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

In calculating a hospital's average salaries plus wage-related costs, we subtracted from Line 1 (total salaries) the GME and CRNA costs reported on lines 2, 4.01, and 6, the Part B salaries

reported on Lines 3 and 5, home office salaries reported on Line 7, and excluded salaries reported on Lines 8 and 8.01 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the acute care hospital inpatient prospective payment system). We also subtracted from Line 1 the salaries for which no hours were reported on Line 4. To determine total salaries plus wage-related costs, we added to the net hospital salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 9, 9.01, 9.02, and 10), home office salaries and wage-related costs reported by the hospital on Lines 11 and 12, and nonexcluded area wage-related costs (Lines 13, 14, and 18).

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

Step 3—Hours—With the exception of wage-related costs, for which there are no associated hours, we computed total

hours using the same methods as described for salaries in Step 2.

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

overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5—For each hospital, we adjusted the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimated the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 1998 through April 15, 2000 for private industry hospital workers from the Bureau of Labor Statistics' *Compensation and Working Conditions*. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated below.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/98	11/15/98	1.04550
11/14/98	12/15/98	1.04325
12/14/98	01/15/99	1.04111
01/14/99	02/15/99	1.03880
02/14/99	03/15/99	1.03632
03/14/99	04/15/99	1.03369
04/14/99	05/15/99	1.03092
05/14/99	06/15/99	1.02801
06/14/99	07/15/99	1.02509
07/14/99	08/15/99	1.02230
08/14/99	09/15/99	1.01962
09/14/99	10/15/99	1.01687
10/14/99	11/15/99	1.01385
11/14/99	12/15/99	1.01056
12/14/99	01/15/2000	1.00710
01/14/2000	02/15/2000	1.00358
02/14/2000	03/15/2000	1.00000
03/14/2000	04/15/2000	0.99638

For example, the midpoint of a cost reporting period beginning January 1, 1999 and ending December 31, 1999 is June 30, 1999. An adjustment factor of 1.02509 would be applied to the wages of a hospital with such a cost reporting period. In addition, for the data for any cost reporting period that began in FY 1999 and covered a period of less than 360 days or more than 370 days, we annualized the data to reflect a 1-year

cost report. Annualization is accomplished by dividing the data by the number of days in the cost report and then multiplying the results by 365.

Step 6—Each hospital was assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B) or section 1886(d)(10) of the Act. Within each urban or rural labor market area, we added the total adjusted salaries plus

wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

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

Step 8—We added the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the nation and then divided the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage. Using the data as described above, the national average hourly wage is \$22.9949.

Step 9—For each urban or rural labor market area, we calculated the hospital wage index value by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10—Following the process set forth above, we developed a separate Puerto Rico-specific wage index for purposes of adjusting the Puerto Rico standardized amounts. (The national Puerto Rico standardized amount is adjusted by a wage index calculated for all Puerto Rico labor market areas based on the national average hourly wage as described above.) We added the total adjusted salaries plus wage-related costs (as calculated in Step 5) for all hospitals in Puerto Rico and divided the sum by the total hours for Puerto Rico (as calculated in Step 4) to arrive at an overall average hourly wage of \$10.8935 for Puerto Rico. For each labor market area in Puerto Rico, we calculated the Puerto Rico-specific wage index value by dividing the area average hourly wage (as calculated in Step 7) by the overall Puerto Rico average hourly wage.

Step 11—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. Furthermore, this wage index floor is to be implemented in such a manner as to ensure that aggregate prospective payment system payments are not greater or less than those that would have been made in the year if this section did not apply. For FY 2003, this change affects 163 hospitals in 40 MSAs. The MSAs affected by this provision are identified by a footnote in Table 4A in the Addendum of this proposed rule.

F. Revisions to the Wage Index Based on Hospital Redesignation

1. General

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the prospective payment system. Hospitals can elect to reclassify for the

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

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

Section 304(b) of Public Law 106–554 provides that, by October 1, 2001, the Secretary must establish a mechanism under which a statewide entity may apply to have all of the geographic areas in the State treated as a single geographic area for purposes of computing and applying a single wage index, for reclassifications beginning in FY 2003.

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

Section 402 of Public Law 106–113 provided that, for FYs 2001 and 2002, hospitals could elect whether to apply

standards developed by OMB in 1980 or 1990 in order to qualify for redesignation under section 1886(d)(8)(B) of the Act. However, we are proposing that, beginning with FY 2003, redesignation under section 1886(d)(8)(B) of the Act will be based on the standards published in the **Federal Register** by the Director of OMB based on the most recent decennial census.

2. Effects of Reclassification

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

- If including the wage data for the redesignated hospitals would reduce the wage index value for the area to which the hospitals are redesignated by 1 percentage point or less, the area wage index value determined exclusive of the wage data for the redesignated hospitals applies to the redesignated hospitals.

- If including the wage data for the redesignated hospitals reduces the wage index value for the area to which the hospitals are redesignated by more than 1 percentage point, the area wage index determined inclusive of the wage data for the redesignated hospitals (the combined wage index value) applies to the redesignated hospitals.

- If including the wage data for the redesignated hospitals increases the wage index value for the area to which the hospitals are redesignated, both the area and the redesignated hospitals receive the combined wage index value.

- The wage index value for a redesignated urban or rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located.

- Rural areas whose wage index values would be reduced by excluding the wage data for hospitals that have been redesignated to another area continue to have their wage index values calculated as if no redesignation had occurred.

- Rural areas whose wage index values increase as a result of excluding

the wage data for the hospitals that have been redesignated to another area have their wage index values calculated exclusive of the wage data of the redesignated hospitals.

- The wage data for a reclassified urban hospital is included in both the wage index calculation of the area to which the hospital is reclassified (subject to the rules described above) and the wage index calculation of the urban area where the hospital is physically located.

The proposed wage index values for FY 2003 are shown in Tables 4A, 4B, 4C, and 4F in the Addendum to this proposed rule. Hospitals that are redesignated should use the wage index values shown in Table 4C. Areas in Table 4C may have more than one wage index value because the wage index value for a redesignated urban or rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located.

Tables 3A and 3B in the Addendum of this proposed rule list the 3-year average hourly wage for each labor market area before the redesignation of hospitals, based on FY 1997, 1998, and 1999 wage data. Table 3A lists these data for urban areas and Table 3B lists these data for rural areas. In addition, Table 2 in the Addendum to this proposed rule includes the adjusted average hourly wage for each hospital from the FY 1997 and FY 1998 cost reporting periods, as well as the FY 1999 period used to calculate the FY 2003 wage index. The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously under computation of the proposed FY 2003 wage index) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its average hourly wage for the 3-year period is calculated based on the data available during that period.

At the time this proposed wage index was constructed, the MGCRB had completed its review of FY 2003 reclassification requests. We have included in this proposed rule a new Table 9, which shows hospitals that have been reclassified under either section 1886(d)(8)(B) or section 1886(d)(10)(D) of the Act. This table includes hospitals reclassified for FY 2003 by the MGCRB, as well as hospitals that were reclassified for the wage index in either FY 2001 or FY 2002 and are, therefore, in either the third or second year of their 3-year reclassification. There are 60 hospitals

reclassified for the wage index beginning during FY 2003. In addition, 369 hospitals are reclassified for FY 2003 based on their 3-year reclassification that became effective during FY 2001, and 170 hospitals are reclassified for FY 2003 based on their 3-year reclassification that became effective during FY 2002. There are 124 hospitals included in the 3-year reclassification from FY 2001 that were reclassified in accordance with section 152(b) of Public Law 106-113. In addition, there are 38 rural hospitals redesignated to an urban area under section 1886(d)(8)(B) of the Act, and 14 urban hospitals that have been designated rural in accordance with section 1886(d)(8)(E) of the Act. Finally, there are 61 hospitals reclassified by the MGCRB for the standardized amount for FY 2003 (including one hospital that is also redesignated under section 1886(d)(8)(B) of the Act to a different MSA). The final number of reclassifications may vary because some MGCRB decisions are still under review by the Administrator and because some hospitals may withdraw their requests for reclassification.

Table 9 shows the various reclassifications and redesignations discussed above by individual hospital. The table does not reflect any hospital withdrawals from reclassifications approved by the MGCRB or decisions of the CMS Administrator. In the final rule to be published by August 1, 2002, we will include a similar table that will include all final reclassifications for FY 2003.

Under § 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of this proposed rule in the **Federal Register**. In addition, hospitals may terminate an existing 3-year reclassification within 45 days of the publication of this proposed rule. The request for withdrawal of an application for reclassification or termination of an existing 3-year reclassification that would be effective in FY 2003 must be received by the MGCRB by June 24, 2002. A hospital that withdraws its application or terminates an existing 3-year reclassification may not later request reinstatement of the MGCRB decision, except by canceling such a withdrawal or termination in a subsequent year (see § 412.273(b)(2)(i), and the proposed changes and clarifications to the cancellation procedures in section V. of this preamble).

Any changes to the wage index that result from withdrawals of requests for

reclassification, wage index corrections, appeals, and the Administrator's review process will be incorporated into the wage index values published in the final rule following this proposed rule. The changes may affect not only the wage index value for specific geographic areas, but also the wage index value redesignated hospitals receive; that is, whether they receive the wage index value for the area to which they are redesignated, or a wage index value that includes the data for both the hospitals already in the area and the redesignated hospitals. Further, the wage index value for the area from which the hospitals are redesignated may be affected.

We are proposing limited changes and clarifications to the policies related to withdrawals, terminations, and cancellations of the 3-year wage index reclassifications. These are discussed in section V. of this preamble.

3. OMB Standards for Hospitals To Qualify for Redesignation

In the August 1, 2001 final rule, we implemented section 402 of Public Law 106-113. Section 402 provided that hospitals could elect whether to apply standards developed by OMB in 1980 or 1990 in order to qualify for redesignation under section 1886(d)(8)(B) of the Act. However, section 402 also states that, beginning with FY 2003, hospitals will be required to use the standards published in the **Federal Register** by the Director of OMB based on the most recent decennial census.

At this time, the 1990 standards are the most recent available. Although OMB is working to develop updated standards based on the 2000 census, that work is not yet completed. If the 2000 census population data become available prior to the preparation and publication of the final rule by August 1, 2002, CMS will work with the Population Distribution Branch within the Population Division of the U.S. Census Bureau to compile a list of hospitals that meet the established standards using the 2000 census population data. Otherwise, for purposes of redesignation for FY 2003 under section 1886(d)(8)(B) of the Act, qualifying hospitals must be located in counties meeting the 1990 standards.

In the August 1, 2001 final rule, we determined that three counties that qualified for redesignation under the 1980 standards qualified for redesignation to a different MSA using the 1990 standards (66 FR 39869). These counties, which will be redesignated to the MSA to which they qualify based on the 1990 standards, are as follows:

Rural county	1980 MSA designation	1990 MSA designation
Ionia, MI	Lansing-East Lansing, MI	Grand Rapids-Muskegon-Hollan, MI.
Caswell, NC	Danville, VA.	Greensboro-Winston Salem-High Point, NC.
Harnett, NC	Fayetteville, NC	Raleigh-Durham-Chapel Hill, NC.

Section 402 of Public Law 106-113 allowed hospitals to elect to use either the January 3, 1980 standards or March 30, 1990 standards for payments during FY 2001 and FY 2002. Several hospitals in counties that did not qualify under the January 3, 1980 standards elected to use those older standards so they would not receive the urban designation accorded them under section 402 because they would lose their special rural designation (that is, a sole community hospital (SCH) or Medicare-dependent hospital (MDH)). Under section 402, the option to make such an election was available only for FY 2001 and FY 2002. Effective for FY 2003, we are proposing that hospitals located in counties qualifying for redesignation under section 1886(d)(8)(B) of the Act based on the 1990 standards would be redesignated under this provision.

We also noted in the August 1, 2001 final rule that five rural counties no longer meet the qualifying criteria when we apply the 1990 OMB standards (66 FR 39870). These rural counties are as follows: Indian River, FL; Mason, IL; Owen, IN; Morrow, OH; and Lincoln, WV. Therefore, beginning FY 2003, hospitals in these counties will not be eligible for redesignation unless the counties again qualify when the standards based on the 2000 census data are available.

G. Requests for Wage Data Corrections

As stated in section II.D. of this preamble, the data used to construct the proposed wage index includes FY 1999 data submitted to CMS as of February 15, 2002. In a memorandum dated December 19, 2001, we instructed all Medicare intermediaries to inform the prospective payment hospitals they service of the availability of the wage data file and the process and timeframe for requesting revisions. The wage data file was made available on January 12, 2002, through the Internet at CMS's home page (<http://www.hcfa.gov>). We also instructed the intermediaries to advise hospitals of the availability of these data either through their representative hospital organizations or directly from CMS. Additional details on ordering this data file are discussed in section IX.A. of this preamble, "Requests for Data from the Public."

In addition, Table 2 in the Addendum to this proposed rule contains each hospital's adjusted average hourly wage

used to construct the proposed wage index values for the past 3 years, including the FY 1999 data used to construct the proposed FY 2003 wage index. It should be noted that the hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data and transmitted to CMS prior to February 15, 2002. Changes approved by a hospital's fiscal intermediary and forwarded to CMS by April 5, 2002, will be reflected in the final public use wage data file scheduled to be made available on or about May 10, 2002.

We believe hospitals have sufficient time to ensure the accuracy of their FY 1999 wage data. Moreover, the ultimate responsibility for accurately completing the cost report rests with the hospital, which must attest to the accuracy of the data at the time the cost report is filed. Hospitals should know what wage data were submitted on their cost reports. In addition, they are notified of any changes to their data as a result of their fiscal intermediary's review. However, if a hospital believed that its FY 1999 wage data were incorrectly reported, the hospital was to submit corrections along with complete, detailed supporting documentation to its intermediary by February 8, 2002. Hospitals were notified of this deadline, and of all other possible deadlines and requirements, through the December 19, 2001 memorandum referenced above.

After reviewing requested changes submitted by hospitals, fiscal intermediaries transmitted any revised cost reports to CMS and forwarded a copy of the revised Worksheet S-3, Parts II and III to the hospitals. In addition, fiscal intermediaries were to notify hospitals of the changes or the reasons that changes were not accepted. This procedure ensures that hospitals have every opportunity to verify the data that will be used to construct their wage index values. We believe that fiscal intermediaries are generally in the best position to make evaluations regarding the appropriateness of a particular cost and whether it should be included in the wage index data. However, if a hospital disagrees with the fiscal intermediary's resolution of a policy issue (whether a general category of cost is allowable in the wage data), the hospital may contact CMS in an effort to resolve policy disputes. We

note that the April 5, 2002 deadline also applies to these requested changes. During this review, we will not consider issues such as the adequacy of a hospital's supporting documentation, as these types of issues should have been resolved earlier in the process.

These deadlines are necessary to allow sufficient time to review and process the data so that the final wage index calculation can be completed for development of the final FY 2003 prospective payment rates to be published by August 1, 2002.

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

The final wage data public use file will be released on approximately May 10, 2002. Hospitals should examine both Table 2 of this proposed rule and the May 2002 final public use wage data file (which reflects revisions to the data used to calculate the values in Table 2) to verify the data CMS is using to calculate the wage index.

As with the file made available in January 2002, CMS will make the final wage data file released in May 2002 available to hospital associations and the public on the Internet. However, the May 2002 public use file will be made available solely for the limited purpose of identifying any potential errors made by CMS or the fiscal intermediary in the entry of the final wage data that result from the correction process described above (with the February 8 deadline). Hospitals are encouraged to review their hospital wage data promptly after the release of the May 2002 file. Data presented at this time cannot be used by hospitals to initiate new wage data correction requests.

If, after reviewing the final file, a hospital believes that its wage data are incorrect due to a fiscal intermediary or CMS error in the entry or tabulation of the final wage data, it should send a letter to both its fiscal intermediary and CMS. The letters should outline why the hospital believes an error exists and provide all supporting information, including dates. These requests must be received by CMS and the fiscal intermediaries no later than June 7, 2002. Requests mailed to CMS should be sent to: Center for Medicare & Medicaid Services, Center for Health Plans and Providers, Attention: Wage Index Team, Division of Acute Care, C4-07-05, 7500 Security Boulevard, Baltimore, MD 21244-1850. Each request must also be sent to the hospital's fiscal intermediary. The intermediary will review requests upon receipt and contact CMS immediately to discuss its findings.

At this point in the process, that is, between release of the May 2002 wage index file and June 7, 2002, changes to the hospital wage data will only be made in those very limited situations involving an error by the intermediary or CMS that the hospital could not have known about before its review of the final wage data file. Specifically, neither the intermediary nor CMS will accept the following types of requests at this stage of the process:

- Requests for wage data corrections that were submitted too late to be included in the data transmitted to CMS by fiscal intermediaries on or before April 5, 2002.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 2002 wage data file.
- Requests to revisit factual determinations or policy interpretations made by the intermediary or CMS during the wage data correction process.

Verified corrections to the wage index received timely (that is, by June 7, 2002) will be incorporated into the final wage index to be published by August 1, 2002 and effective October 1, 2002.

Again, we believe the wage data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage data to the fiscal intermediaries' attention. Moreover, because hospitals will have access to the final wage data by May 2002, they will have the opportunity to detect any data entry or tabulation errors made by the fiscal intermediary or CMS before the development and publication of the FY 2003 wage index by August 1, 2002, and the implementation of the FY 2003 wage index on October 1, 2002. If hospitals

avail themselves of this opportunity, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified after that date, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with § 412.63(x)(2) of our existing regulations, we make midyear corrections to the wage index only in those limited circumstances in which a hospital can show (1) that the intermediary or CMS made an error in tabulating its data; and (2) that the hospital could not have known about the error, or did not have an opportunity to correct the error, before the beginning of FY 2003 (that is, by the June 7, 2002 deadline). As indicated earlier, since a hospital will have the opportunity to verify its data, and the fiscal intermediary will notify the hospital of any changes, we do not expect that midyear corrections would be necessary. However, if the correction of a data error changes the wage index value for an area, the revised wage index value is effective prospectively from the date the correction is approved.

This policy for applying prospective corrections to the wage index was originally set forth in the preamble to the January 3, 1984 final rule (49 FR 258) implementing the hospital inpatient prospective payment system. It has been our longstanding policy to make midyear corrections to the hospital wage data and adjust the wage index for the affected areas on a prospective basis.

Section 412.63(x)(3) states that revisions to the wage index resulting from midyear corrections to the wage index values are incorporated in the wage index values for other areas at the beginning of the next Federal fiscal year. Prior to October 1, 1993, the wage index was based on a wage data survey submitted by all hospitals (prior to that, the data came from the Bureau of Labor Statistics' hospital wage and employment data file). Beginning October 1, 1993, as required by section 1886(d)(3)(E) of the Act, we began updating the wage index data on an annual basis. Because the wage index has been updated annually since FY 1994, § 412.63(x)(3) is no longer necessary, and we are proposing to delete it. Similarly, § 412.63(x)(4) provides that the effect on program payments of midyear corrections to the wage index values is taken into account in establishing the standardized amounts for the following year. Again, the wage data are now updated annually. Therefore, § 412.63(x)(4) is no

longer necessary, and we are proposing to delete it as well.

Finally, we are proposing to revise § 412.63(x)(2) to clarify that CMS will make a midyear correction to the wage index for an area only if a hospital can show that the intermediary or CMS made an error in tabulating the hospital's own data. That is, this provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index. As described above, the requesting hospital must show that it could not have known about the error, or that it did not have the opportunity to correct the error, before the beginning of the Federal fiscal year.

IV. Proposed Rebasings and Revision of the Hospital Market Baskets

A. Operating Costs

1. Background

Effective for cost reporting periods beginning on or after July 1, 1979, we developed and adopted a hospital input price index (that is, the hospital "market basket") for operating costs. Although "market basket" technically describes the mix of goods and services used to produce hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term "market basket" as used in this document refers to the hospital input price index.

The percentage change in the market basket reflects the average change in the price of goods and services hospitals purchased in order to furnish inpatient care. We first used the market basket to adjust hospital cost limits by an amount that reflected the average increase in the prices of the goods and services used to furnish hospital inpatient care. This approach linked the increase in the cost limits to the efficient utilization of resources.

With the inception of the acute care hospital inpatient prospective payment system, the projected change in the hospital market basket has been the integral component of the update factor by which the prospective payment rates are updated every year. For FY 2003, payment rates will be updated by the projected increase in the hospital market basket minus 0.55 percentage points. A detailed explanation of the hospital market basket used to develop the prospective payment rates was published in the **Federal Register** on September 3, 1986 (51 FR 31461). We also refer the reader to the August 29, 1997 **Federal Register** (62 FR 45966) in

which we discussed the previous rebasing of the hospital input price index.

The hospital market basket is a fixed-weight, Laspeyres-type price index that is constructed in three steps. First, a base period is selected and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories based upon type of expenditure. Then, the proportion of total operating costs that each category represents is determined. These proportions are called cost or expenditure weights. Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a price proxy. These price proxies are price levels derived from publicly available statistical series and are published on a consistent schedule, preferably at least on a quarterly basis.

Finally, the expenditure weight for each category is multiplied by the level of the respective price proxy. The sum of these products (that is, the expenditure weights multiplied by the price levels) for all cost categories yields the composite index level of the market basket in a given year. Repeating this step for other years produces a series of market basket index levels over time. Dividing one index level by an earlier index level produces rates of growth in the input price index over that time.

The market basket is described as a fixed-weight index because it answers the question of how much it would cost, at another time, to purchase the same mix of goods and services that was purchased in the base period. The effects on total expenditures resulting from changes in the quantity or mix of goods and services (intensity) purchased subsequent to the base period are not measured. For example, shifting a traditionally inpatient type of care to an outpatient setting might affect the volume of inpatient goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed weight hospital market basket. In this manner, the index measures only the pure price change. Only rebasing (changing the base year) the index would capture these quantity and intensity effects. Therefore, we rebase the market basket periodically so the cost weights reflect changes in the mix of goods and services that hospitals purchase (hospital inputs) in furnishing inpatient care. We last rebased the hospital market basket cost weights in 1997, effective for FY 1998 (62 FR 45993). This market basket, still used through FY 2002, reflects base year data from FY 1992 in the construction of the cost weights.

We note that there are separate market baskets for acute care hospital inpatient prospective payment system hospitals and excluded hospitals and hospital units. In addition, we are in the process of conducting the necessary research to determine if separate market baskets for the inpatient rehabilitation, long-term care, and psychiatric hospital prospective payment systems can be developed. However, for the purpose of this preamble, we are only discussing the market basket based on all excluded hospitals together.

2. Rebasing and Revising the Hospital Market Basket

The terms rebasing and revising, while often used interchangeably, actually denote different activities. Rebasing means moving the base year for the structure of costs of an input price index (for example, we are proposing to shift the base year cost structure from FY 1992 to FY 1997). Revising means changing data sources, cost categories, or price proxies used in the input price index.

We are proposing to use a rebased and revised hospital market basket in developing the FY 2003 update factor for the prospective payment rates. The new market basket would be rebased to reflect FY 1997, rather than FY 1992, cost data. The 1992-based market baskets contained expenditure data for hospitals from Medicare cost reports for cost reporting periods beginning on or after October 1, 1991, and before October 1, 1992. The 1997-based market baskets use data for hospitals from Medicare cost reports for cost reporting periods beginning on or after October 1, 1996, and before October 1, 1997. Fiscal year 1997 was selected as the new base year because 1997 is the most recent year for which relatively complete data are available. These include data from FY 1997 Medicare cost reports as well as 1997 data from two U.S. Department of Commerce publications: the Bureau of the Census' Business Expenditure Survey (BES) and the Bureau of Economic Analysis' Annual Input-Output Tables. In addition, preliminary analysis of FYs 1998 and 1999 Medicare cost report data showed little difference in cost shares from FY 1997 data.

In developing the proposed rebased and revised market baskets, we reviewed hospital operating expenditure data for the market basket cost categories in determining the cost weights. We relied primarily on Medicare hospital cost report data for the proposed rebasing. We prefer to use cost report data wherever possible because these are the cost data supplied directly from hospitals. Other data

sources such as the BES and the input-output tables serve as secondary sources used to fill in where cost report data are not available or appear to be incomplete. Below we are providing a detailed discussion of the process for calculating cost share weights.

Cost category weights for the proposed FY 1997-based market baskets were developed in several stages. First, base weights for several of the categories (Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals and Blood and Blood Products) were derived from the FY 1997 Medicare cost reports for operating costs. The expenditures for these categories were calculated as a percentage of total operating costs from those hospitals covered under the inpatient hospital prospective payment system. These data were then edited to remove outliers and ensure that the hospital participated in the Medicare program and had Medicare costs. However, we were unable to measure only those operating costs attributable to the inpatient portion of the hospital, because many cost centers are utilized by both inpatients and outpatients in the hospital. Health Economics Research (HER), under contract with CMS, is currently in the process of researching the possibility of constructing a separate outpatient market basket for CMS' outpatient hospital prospective payment system. This research may provide some insight and guidance for separating inpatient and outpatient costs. We excluded hospital-based subprovider cost centers (for example, skilled nursing, nursing, hospice, psychiatric, rehabilitation, intermediate care/mental retardation, and other long-term care) as well as the portion of overhead and ancillary costs incurred by these subproviders.

Second, the weight for professional liability insurance was calculated using data from a survey conducted by ANASYS under contract to CMS. This survey, called the National Hospital Malpractice Insurance Survey (NHMIS), was conducted to estimate hospital malpractice insurance costs over time at the national level. A more detailed description of this survey is found later in this preamble.

Third, data from the 1997 Business Expenditure Survey (BES) was used to develop a weight for the utilities and telephone services categories. Like most other data sources, the BES includes data for all hospitals and does not break out data by payer. However, we believe the overall data from the BES does not produce results that are inconsistent with the prospective payment system hospitals, particularly at the detailed

cost category level with which we are working.

Fourth, the sum of the weights for wages and salaries, employee benefits, contract labor, professional liability insurance, utilities, pharmaceuticals, blood and blood products, and telephone services was subtracted from other operating expenses to obtain a portion for all other expenses.

Finally, the remainder of the weight for all other expenses was divided into subcategories using relative cost shares from the 1997 Annual Input-Output Table for the hospital industry, produced by the Bureau of Economic Analysis, U.S. Department of Commerce. The 1997 Benchmark Input-Output data will be available, at the earliest, in late 2002, so we will be unable to incorporate these data in the final rule.

Below, we further describe the sources of the six main category weights and their subcategories in the proposed FY 1997-based market basket. We note the differences between the methodologies used to develop the FY 1992-based and the FY 1997-based market baskets.

- *Wages and Salaries:* The cost weight for the wages and salaries category was derived using Worksheet S-3 from the FY 1997 Medicare cost reports. Contract labor, which is also derived from the FY 1997 Medicare cost reports, is split between the wages and salaries and employee benefits cost categories, using the relationship for employed workers. An example of contract labor is registered nurses who are employed and paid by firms that contract for their work with the hospital. The wages and salaries category in the FY 1992-based market basket was developed from the FY 1992 Medicare cost reports. In addition, we used the 1992 Current Population Survey to break out more detailed occupational subcategories. These subcategories were not broken out for the proposed FY 1997-based market basket.

- *Employee Benefits:* The cost weight for the employee benefits category was derived from Worksheet S-3 of the FY 1997 Medicare cost reports. The employee benefits category in the FY 1992-based market basket was developed from FY 1992 Medicare cost reports and used the 1992 Current Population Survey to break out various occupational subcategories. These subcategories were not broken out for the proposed FY 1997-based market basket.

- *Nonmedical Professional Fees:* This category refers to various types of nonmedical professional fees such as

legal, accounting, engineering and management and consulting fees. Management and consulting and legal fees make up the majority of professional fees in the hospital sector. The cost weight for the nonmedical professional fees category was derived from the Bureau of Economic Analysis Input-Output data for 1997. The FY 1992-based index used a combination of data from the American Hospital Association (AHA) and the Medicare cost reports to arrive at a weight. However, because the AHA survey data for professional fees are no longer published, we were unable to duplicate this method. Had we used the proposed methodology to calculate the FY 1992 nonmedical professional fees component, the proportion would have been similar to the FY 1997 share.

- *Professional Liability Insurance:* The proposed FY 1997-based market basket uses a weight for professional liability insurance derived from a survey conducted by ANASYS under contract to CMS (Contract Number 500-98-005). This survey attempted to estimate hospital malpractice insurance costs over time at the national level for years 1996 and 1997. The population universe of the survey was defined as all non-Federal short-term, acute care prospective payment system hospitals. A statistical sample of hospitals was drawn from this universe and data collected from those hospitals. This sample of hospitals was then matched to the appropriate cost report data so that a malpractice cost weight could be calculated. The questions used in the survey were based on a 1986 General Accounting Office (GAO) malpractice survey questionnaire that was modified so data could be collected to calculate a malpractice cost weight and the rate of change for a constant level of malpractice coverage at a national level. The 1997 proportion as calculated by ANASYS was compared to limited data for FYs 1998 and 1999 contained in the Medicare Health Care System Cost Report Information System (HCRIS). The percentages are relatively comparable. However, since this field was virtually incomplete in the FY 1997 cost report file, we were unable to use this cost report data.

In contrast, the FY 1992-based market basket professional liability insurance weight was determined using the cost report data for PPS-6 (cost reporting periods beginning in FY 1989), the last year these costs had to be treated separately from all other administrative and general costs, trended forward to FY 1992 based on the relative importance of malpractice costs found in the previous market basket.

- *Utilities:* For the proposed FY 1997-based market baskets, the cost weight for utilities was derived from the Bureau of the Census' Business Expenditures Survey. For the FY 1992-based market baskets, the cost weight for utilities was derived from the Bureau of the Census' Asset and Expenditures Survey. The Business Expenditure Survey replaced the Asset and Expenditure Survey and the categories and results are similar.

- *All Other Products and Services:* The all other products and services category includes the remainder of products and services that hospitals purchase in providing care. Products found in this category include: direct service food, contract service food, pharmaceuticals, blood and blood products, chemicals, medical instruments, photo supplies, rubber and plastics, paper products, apparel, machinery and equipment, and miscellaneous products. Services found in this category include: telephone, postage, other labor-intensive services, and other nonlabor-intensive services. Labor-intensive services include those services for which local labor markets would likely influence prices. A complete discussion of the labor-related share is presented later in this preamble. The shares for pharmaceuticals and blood and blood products were derived from the FY 1997 Medicare cost reports, while the share for telephone services was derived from the BES. Relative shares for the other subcategories were derived from the 1997 Bureau of Economic Analysis Annual Input-Output Table for the hospital industry.

The calculation of these subcategories involved calculating a residual from the Input/Output Table using categories similar to those not yet accounted for in the market basket. Subcategory weights were then calculated as a proportion of this residual and applied to the similar residual in the market basket.

- *Blood and blood products:* When the market basket was last revised and rebased to FY 1992, the component for blood services was discontinued because of the lack of appropriate data to determine a weight. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) required that CMS consider the prices of blood and blood products purchased by hospitals and determine whether those prices are adequately reflected in the market basket. In accordance with this requirement, CMS has done considerable research to determine if a component for blood and blood products should be added to the market basket and, if so, how the weight should be determined. CMS has studied four alternative data sources to possibly

determine a weight for blood in the market basket. If none of these data sources was deemed acceptable, we could conclude that a component for blood should not be reintroduced in the hospital market basket. In a December 2001 report by the MedPAC entitled "Blood Safety in Hospitals and Medicare Inpatient Payment," MedPAC recommended that the market basket should explicitly account for the cost of blood and blood products by reintroducing a separate component for their prices.

The first alternative data source studied was using data from the Medicare cost reports. The cost reports have two cost centers where the costs of blood can be recorded: (1) whole blood and packed red blood cells (nonsalary); and (2) blood storing, processing, and transfusion (nonsalary). Although all prospective payment system hospitals submit a cost report, less than half of these hospitals reported data in either of the two blood cost centers. However, if we can determine that the hospitals reporting blood are representative of all prospective payment system hospitals, then a cost share can be computed using the cost reports.

The second alternative involves constructing weights from the Input-Output Table from the BEA, Department of Commerce. These data were used to construct the weight when the market basket was revised before FY 1992. Unfortunately, BEA stopped reporting blood separately in their Input-Output Table in 1987. One possible use of these data would be to calculate a weight by updating the prior weight by the relative price change for blood between the last data point available and 1997. However, by using this method, only the escalation in prices, not the changes in quantity or intensity of use of blood products, would be captured.

The third alternative was using data from the MedPAR files. This option was discussed in MedPAC's December 2001 report, and involves using claims data or data on hospital charges. In order to construct a weight for the market basket, the underlying costs of blood must be

calculated from the claims data. An analysis of cost-to-charge ratios of hospitals can determine if this is feasible.

The final alternative data source is the Bureau of the Census' quinquennial Business Expenditure Survey and the Economic Census. A weight can be obtained indirectly by taking the ratio of receipts of nonprofit blood collectors to total operating expenses of hospitals. Some adjustments would be needed in order for the weight calculated in this way to be completely valid. In addition, this method assumes that all blood used by hospitals comes from nonprofit sources. However, in 1999, hospitals collected 7 percent of the donated units.

After a thorough analysis, CMS has determined that the Medicare cost reports, after minor adjustments, are the best option. The data from the Input-Output Table are not optimal because they are not current and would have to be aged using only price data, which do not reflect quantity and intensity changes over this period. Although the MedPAR data could be adjusted to compute a cost share, using claims data is not the preferred alternative. Census data would be an attractive option if the cost reports were not available.

The main weakness of the Medicare cost reports is the inconsistent reporting of hospitals in the two blood cost centers. In 1997, only 48.0 percent of all hospitals reported blood in one or both cost centers. However, these hospitals accounted for 62.2 percent of the operating costs of all hospitals. In order for the calculation of the blood cost share weight to be acceptable, the hospitals that reported blood would need to be adjusted to be representative of all hospitals, including those that did not report blood on the cost reports.

Because of the similarity of data in the two blood cost centers, the assumption was made that if a hospital reported blood in only one of the two cost centers, all of its blood costs were reported in that cost center. In the FY 1997 cost reports, of the hospitals that reported blood, 41.3 percent reported only in the blood cells cost center, 58.2

percent reported only in the blood storing cost center, and only 0.5 percent reported in both blood cost centers. To calculate a weight, the numerator was the summation of the data in both blood cost centers. The denominator was the summation of the operating costs of each hospital that reported blood in each cost center minus the operating costs of the few hospitals that reported blood in both cost centers to avoid double counting.

The blood cost share calculated from these data was then adjusted so that the hospitals reporting blood had the same characteristics of all other hospitals. Adjustments were necessary because the hospitals that reported blood were more likely to be urban and teaching hospitals than those hospitals that did not report blood. The adjustments made less than a 0.1 percent difference in the cost share.

The weight produced using the cost report for FY 1997 was 0.875 percent. We also looked at cost report data from FYs 1996 and 1998. The weights calculated in these years were similar to the FY 1997 weight. The calculation of the blood cost share using the alternative data sources cited above was similar to the results using the cost reports. Given the consistency with these other sources, the representativeness of our estimate, and the stability of the cost share, we are proposing to use the Medicare cost reports to determine a weight for blood and blood products in the proposed hospital market basket.

Overall, our work resulted in the identification of 23 separate cost categories that represent the rebased weights in the proposed rebased and revised hospital market basket. There is one more category than was included in the FY 1992-based market basket (FY 1992-based had 22). The differences between the weights of the major categories determined from the Medicare cost reports for the proposed FY 1997-based index and the previous FY 1992-based index are summarized in Table 1.

TABLE 1.—FY 1992-BASED AND PROPOSED FY 1997-BASED PROSPECTIVE PAYMENT HOSPITAL OPERATING MAJOR COST CATEGORIES AND WEIGHTS AS DETERMINED FROM THE MEDICARE COST REPORTS

Expense categories	Proposed rebased FY 1997 hospital market basket	FY 1992-based hospital market basket
Wages and Salaries	50.686	50.244
Employee Benefits	10.970	11.146
Pharmaceuticals	5.416	4.162
Blood and Blood Products	0.875

TABLE 1.—FY 1992-BASED AND PROPOSED FY 1997-BASED PROSPECTIVE PAYMENT HOSPITAL OPERATING MAJOR COST CATEGORIES AND WEIGHTS AS DETERMINED FROM THE MEDICARE COST REPORTS—Continued

Expense categories	Proposed rebased FY 1997 hospital market basket	FY 1992-based hospital market basket
All Other	32.053	34.448
Total	100.000	100.000

Table 2 sets forth all of the proposed market basket cost categories and weights. For comparison purposes, the 1992-based cost categories and weights are included in the table.

TABLE 2.—FY 1992-BASED AND PROPOSED FY 1997-BASED PROSPECTIVE PAYMENT HOSPITAL OPERATING COST CATEGORIES AND WEIGHTS

Expense categories	Proposed rebased FY 1997 hospital market basket weights	FY 1992-based hospital market basket weights
1. Compensation	61.656	61.390
A. Wages and Salaries*	50.686	50.244
B. Employee Benefits*	10.970	11.146
2. Professional Fees*	5.401	2.127
3. Utilities	1.353	1.542
A. Fuel, Oil, and Gasoline	0.284	0.369
B. Electricity	0.833	0.927
C. Water and Sewerage	0.236	0.246
4. Professional Liability Insurance	0.840	1.189
5. All Other	30.749	33.752
A. All Other Products	19.537	24.825
(1.) Pharmaceuticals	5.416	4.162
(2.) Direct Purchase Food	1.370	2.314
(3.) Contract Service Food	1.274	1.072
(4.) Chemicals	2.604	3.666
(5.) Blood and Blood Products	0.875
(6.) Medical Instruments	2.192	3.080
(7.) Photographic Supplies	0.204	0.391
(8.) Rubber and Plastics	1.668	4.750
(9.) Paper Products	1.355	2.078
(10.) Apparel	0.583	0.869
(11.) Machinery and Equipment	1.040	0.207
(12.) Miscellaneous Products	0.956	2.236
B. All Other Services	11.212	8.927
(1.) Telephone Services	0.398	0.581
(2.) Postage	0.857	0.272
(3.) All Other: Labor Intensive*	5.438	7.277
(4.) All Other: Non-Labor Intensive	4.519	0.796
Total	100.000	100.000

* Labor-related.

Note: Due to rounding, weights may not sum to total.

3. Selection of Price Proxies

After computing the FY 1997 cost weights for the proposed rebased hospital market basket, it is necessary to select appropriate wage and price proxies to monitor the rate of change for each expenditure category. Most of the indicators are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- Producer Price Indexes—Producer Price Indexes (PPIs) measure price changes for goods sold in other than

retail markets. PPIs are preferable price proxies for goods that hospitals purchase as inputs in producing their outputs because a PPI would better reflect the prices faced by hospitals. For example, we used the PPI for ethical (prescription) drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because hospitals generally purchase drugs directly from the wholesaler. The PPIs that we use measure price change at the final stage of production.

- Consumer Price Indexes—Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Because they may not represent the price faced by a producer, the consumer price indexes were used only if an appropriate PPI was not available, or if the expenditure was more similar to that of retail consumers in general rather than a purchase at the wholesale level. For example, the CPI for food purchased away from home was

used as a proxy for contracted food services.

- Employment Cost Indexes—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked.

These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. They are appropriately not affected by shifts in employment mix. Table 3 sets forth the complete proposed hospital market basket

including cost categories, weights, and price proxies. For comparison purposes, the respective FY 1992-based market basket price proxies are listed as well. A summary outlining the choice of the various proxies follows the table.

TABLE 3.—PROPOSED FY 1997-BASED PROSPECTIVE PAYMENT HOSPITAL OPERATING COST CATEGORIES, AND WEIGHTS, AND FY 1992-BASED AND PROPOSED FY 1997-BASED PRICE PROXIES

Expense categories	Proposed rebased FY 1997 hospital market basket weights	Proposed rebased FY 1997 hospital market basket price proxy	FY 1992 hospital market basket price proxy
1. Compensation	61.656		
A. Wages and salaries *	50.686	ECI-wages and salaries, civilian hospital workers.	CMS occupational wage proxy.
B. Employee benefits *	10.970	ECI—benefits, civilian hospital workers ...	CMS occupational benefit proxy.
2. Professional fees *	5.401	ECI—compensation for professional specialty & technical.	ECI—compensation for professional, specialty & technical.
3. Utilities	1.353		
A. Fuel, oil, and gasoline	0.284	PPI refined petroleum products	PPI refined petroleum products.
B. Electricity	0.833	PPI commercial electric power	PPI commercial electric power.
C. Water and sewerage	0.236	CPI—U water & sewerage maintenance ...	CPI—U water & sewerage maintenance.
4. Professional liability insurance	0.840	CMS professional liability insurance premium index.	CMS professional liability insurance premium index.
5. All other products	30.749		
A. All other products	19.537		
(1.) Pharmaceuticals	5.416	PPI ethical (prescription) drugs	PPI ethical (prescription) drugs.
(2.) Direct purchase food	1.370	PPI processed foods and feeds	PPI processed foods and feeds.
(3.) Contract service food	1.274	CPI—U food away from home	CPI—U food away from home.
(4.) Chemicals	2.604	PPI industrial chemicals	PPI industrial chemicals.
(5.) Blood and blood products	0.875	PPI blood and blood derivatives, human use.	N/A.
(6.) Medical instruments	2.192	PPI medical instruments & equipment	PPI medical instruments and equipment.
(7.) Photographic supplies	0.204	PPI photographic supplies	PPI photographic supplies.
(8.) Rubber and plastics	1.668	PPI rubber & plastic products	PPI rubber and plastic products.
(9.) Paper products	1.355	PPI converted paper and paperboard products.	PPI converted paper and paperboard products.
(10.) Apparel	0.583	PPI apparel	PPI apparel.
(11.) Machinery and equipment	1.040	PPI machinery and equipment	PPI machinery and equipment.
(12.) Miscellaneous products	0.956	PPI finished goods less food and energy	PPI finished goods.
B. All other services	11.212		
(1.) Telephone services	0.398	CPI—U telephone services	CPI—U telephone services.
(2.) Postage	0.857	CPI—U postage	CPI—U postage.
(3.) All other: labor intensive *	5.438	ECI—Compensation for private service occupations.	ECI—compensation for private service occupations.
(4.) All other: non-labor intensive	4.519	CPI—U all items	CPI—U all items.
Total	100.000		

* Labor related.

a. Wages and Salaries

For measuring the price growth of wages in the FY 1997-based market basket, we are proposing to use the ECI for civilian hospitals. This differs from the proxy used in the FY 1992-based index in which a blended occupational wage index was used. The blended occupational wage proxy used in the FY 1992-based index and the ECI for wages and salaries for hospitals both reflect a fixed distribution of occupations within the hospital. The major difference between the two proxies is in the treatment of professional and technical

wages. In the blended occupational wage proxy, the professional and technical category is blended evenly between the ECI for wages and salaries for hospitals and the ECI for wages and salaries for professional and technical occupations in the overall economy, instead of hospital-specific occupations as reflected in the ECI for hospitals. This blend was done to create a normative price index that did not reflect the market imperfections in the hospital labor markets that existed for much of the 1980s and early 1990s.

Between 1987 (the first year the ECI for hospitals was available, although the

pattern existed before then using other measures of hospital wages) and 1994, the ECI for wages and salaries for hospital workers grew faster than the blended occupational wage proxy. This trend then reversed for the 1995 through 2000 period when the ECI grew slower than the blended occupational wage proxy each year. This is the apparent result of the shift of private insurance enrollees from fee-for-service plans to managed care plans and the tighter controls these plans exhibited over hospital utilization and incentives to shift care out of the inpatient hospital setting. More recently, the ECI for wages

and salaries for hospital workers is again growing faster than the blended occupational wage proxy, raising the question of whether the relationship between hospital wages and the occupational wage blend from 1994 through 2000 was the signaling of a new era in the competitiveness of the hospital labor market, or simply the temporary reversal of the long-term pattern of labor market imperfections in hospitals.

In order to answer this question, we researched the historical determinants of this relationship and estimated what the future market conditions are likely to be. Our analysis indicated that the driving force behind the long-term differential between hospital wages and the blended occupational wage proxy was the increased demand for hospital services and the subsequent increase in hospital utilization, particularly in outpatient settings. However, during the 1994–2000 period, the major force behind the reversal of the differential was the shift of enrollees to managed care plans that had tighter restrictions on hospital utilization and encouraged the shift of care out of the hospital setting. To a lesser extent, the robust economic growth and tight economy-wide labor markets that accompanied this period helped to reverse the differential as well. Over the last year or two, there has been a move back towards less restrictive plans, and a subsequent increase in the utilization of medical services. This recent surge appears to reflect the true underlying fundamentals of health care demand. This concept is reinforced by the similar patterns being observed for nursing homes and other health sectors as well. This is an important development, specifically when compared to the ECI for wages and salaries for nursing homes, which reflect less skilled occupations, yet still experienced a similar acceleration in wage growth. Thus, we would expect that this recent surge in hospital wages is reflective of competitive labor market conditions, and would likely persist only as long as the underlying demand for health care was accelerating.

While the shift to managed care plans had a noticeable one-time effect, we do feel that the hospital labor market is more competitive than prior to this period and that the expected shift towards more restrictive insurance plans over the coming decade will act to create a wage differential that reflects the underlying increases in demand for hospital services. As shown in Table 5, using the ECI has only a minor overall impact (0.1 percentage point per year) from FY 1995 through FY 2001 on the

hospital market basket. For FY 2003, the proposed hospital market basket is forecast to increase 0.2 percentage points faster (3.3 vs. 3.1) than it would have if the occupational blend had been used. Based on this, we are proposing to use the ECI for wages and salaries for hospitals and the ECI for benefits for hospitals as the proxies in the hospital market basket for wages and benefits, respectively. The ECI met our criteria of relevance, reliability, availability, and timeliness. Relevance means that the proxy is applicable and representative of the cost category that it proxies. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Availability means that the proxy is publicly available. Timeliness implies that the proxy is published regularly, at least once a quarter.

b. Employee Benefits

The proposed FY 1997-based hospital market basket uses the ECI for employee benefits for civilian hospitals. This differs from the FY 1992-based index in which a blended occupational index was used. Our conclusions were based on a similar analysis that was done for the wages and salaries proxy described above.

c. Nonmedical Professional Fees

The ECI for compensation for professional and technical workers in private industry is applied to this category since it includes occupations such as management and consulting, legal, accounting and engineering services. The same price measure was used in the FY 1992-based market basket.

d. Fuel, Oil, and Gasoline

The percentage change in the price of gas fuels as measured by the PPI (Commodity Code #0552) was applied to this component. The same price measure was used in the FY 1992-based market basket.

e. Electricity

The percentage change in the price of commercial electric power as measured by the PPI (Commodity Code #0542) was applied to this component. The same price measure was used in the FY 1992-based market basket.

f. Water and Sewerage

The percentage change in the price of water and sewerage maintenance as measured by the Consumer Price Index (CPI) for all urban consumers (CPI Code # CUUR0000SEHG01) was applied to this component. The same price

measure was used in the FY 1992-based market basket.

g. Professional Liability Insurance

The percentage change in the hospital professional liability insurance price as estimated by the CMS Hospital Malpractice Index was applied. In the FY 1992-based market basket, the same proxy was used.

We are currently conducting research into improving our proxy for professional liability insurance. This research includes subcontracting with ANASYS through a contract with DRI-WEFA to extend the results of its NHMIS survey to set up a sample of hospitals from which malpractice insurance premium data will be directly collected. This new information, which would include liability estimates for hospitals that self-insure, would be combined with our current proxy data to obtain a more accurate price measure. Depending on the timing of this new information, the proxy for professional liability insurance in the market basket may be modified for the final rule. In addition, we are researching a BLS PPI for malpractice premiums that may be a more appropriate proxy for this cost category.

h. Pharmaceuticals

The percentage change in the price of prescription drugs as measured by the PPI (Commodity Code # PPI283D#RX) was applied to this variable. This is a special index produced by BLS. The previous price proxy used in the FY 1992-based index (Commodity Code #0635) was discontinued after BLS revised its indexes.

i. Food, Direct Purchases

The percentage change in the price of processed foods and foods as measured by the PPI (Commodity Code #02) was applied to this component. The same price measure was used in the FY 1992-based market basket.

j. Food, Contract Services

The percentage change in the price of food purchased away from home as measured by the CPI for all urban consumers (CPI Code # CUUR0000SEFV) was applied to this component. The same price measure was used in the FY 1992-based market basket.

k. Chemicals

The percentage change in the price of industrial chemical products as measured by the PPI (Commodity Code #061) was applied to this component. While the chemicals in this category include industrial as well as other types

of chemicals, the industrial chemicals component constitutes the largest proportion by far. Thus, Commodity Code #061 is the appropriate proxy. The same price measure was used in the FY 1992-based market basket.

l. Blood and Blood Products

The percentage change in the price of blood and derivatives for human use as measured by the PPI (Commodity Code #063711) was applied to this component. As discussed earlier in this preamble, a comparable cost category was not available in the FY 1992-based market basket.

We are proposing that the blood and blood products cost category use the PPI for blood and blood derivatives as its price proxy. This proxy is relevant, reliable, available, and timely. We considered placing the blood weight in the Chemicals or Pharmaceuticals cost category, but found this made only minor changes to the total index. We also considered constructing an index based on blood cost data received from the American Red Cross, America's Blood Centers, and Zeman and Company. However, these data are collected annually and not widely available. The PPI for blood and blood derivatives was the only index we found that met all of our criteria.

m. Surgical and Medical Equipment

The percentage change in the price of medical and surgical instruments as measured by the PPI (Commodity Code #1562) was applied to this component. The same price measure was used in the FY 1992-based market basket.

n. Photographic Supplies

The percentage change in the price of photographic supplies as measured by the PPI (Commodity Code #1542) was

applied to this component. The same price measure was used in the FY 1992-based market basket.

o. Rubber and Plastics

The percentage change in the price of rubber and plastic products as measured by the PPI (Commodity Code #07) was applied to this component. The same price measure was used in the FY 1992-based market basket.

p. Paper Products

The percentage change in the price of converted paper and paperboard products as measured by the PPI (Commodity Code #0915) was used. The same price measure was used in the FY 1992-based market basket.

q. Apparel

The percentage change in the price of apparel as measured by the PPI (Commodity Code #381) was applied to this component. The same price measure was used in the FY 1992-based market basket.

r. Machinery and Equipment

The percentage change in the price of machinery and equipment as measured by the PPI (Commodity Code #11) was applied to this component. The same price measure was used in the FY 1992-based market basket.

s. Miscellaneous Products

The percentage change in the price of all finished goods less food and energy as measured by the PPI (Commodity Code #SOP3500) was applied to this component. The percentage change in the price of all finished goods was used in the FY 1992-based market basket. This change was made to remove the effect of food and energy prices, which are already captured elsewhere in the market basket.

t. Telephone

The percentage change in the price of telephone services as measured by the CPI for all urban consumers (CPI Code # CUUR0000SEED) was applied to this component. The same price measure was used in the FY 1992-based market basket.

u. Postage

The percentage change in the price of postage as measured by the CPI for all urban consumers (CPI Code # CUUR0000SEEC01) was applied to this component. The same price measure was used in the FY 1992-based market basket.

v. All Other Services, Labor Intensive

The percentage change in the ECI for compensation paid to service workers employed in private industry was applied to this component. The same price measure was used in the FY 1992-based market basket.

w. All Other Services, Nonlabor Intensive

The percentage change in the all-items component of the CPI for all urban consumers (CPI Code # CUUR0000SA0) was applied to this component. The same price measure was used in the FY 1992-based market basket.

For further discussion of the rationale for choosing many of the specific price proxies, we reference the August 30, 1996 final rule (61 FR 46326). Table 4 shows the historical and forecasted updates under both the proposed FY 1997-based and the FY 1992-based market baskets. For comparison purposes, the FY 1997-based index incorporating different wage and benefit proxies is included in Table 5.

TABLE 4.—FY 1992-BASED AND PROPOSED FY 1997-BASED PROSPECTIVE PAYMENT HOSPITAL OPERATING INDEX PERCENT CHANGE, 1995–2004

Fiscal year (FY)	Prospective rebased 1997 hospital market basket	FY 1992-based market basket
Historical data:		
FY 1995	2.8	3.1
FY 1996	2.3	2.4
FY 1997	1.6	2.1
FY 1998	2.7	2.9
FY 1999	2.7	2.5
FY 2000	3.3	3.6
FY 2001	4.2	4.1
Average FYs 1995–2001	2.8	3.0
Forecast:		
FY 2002	3.7	2.8
FY 2003	3.3	3.0
FY 2004	2.9	3.2

TABLE 4.—FY 1992-BASED AND PROPOSED FY 1997-BASED PROSPECTIVE PAYMENT HOSPITAL OPERATING INDEX PERCENT CHANGE, 1995–2004—Continued

Fiscal year (FY)	Prospective rebased 1997 hospital market basket	FY 1992-based market basket
Average FYs 2002–2004	3.3	3.0

Source: Global Insights, Inc, DRI-WEFA, 1st Qtr. 2002; @USMACRO/MODTREND @CISSIM/TRENDLONG0202.

Table 5 indicates that switching the proxy for wages and benefits to the ECI for Civilian Hospitals has a minimal effect on the FY 2003 update and a minimal effect over time. However, we believe that it is a more appropriate measure of price change in hospital wages and benefit prices given the current labor market conditions facing hospitals.

TABLE 5.—PROPOSED 1997-BASED PROSPECTIVE PAYMENT HOSPITAL OPERATING INDEX PERCENT CHANGE, USING DIFFERENT WAGE AND BENEFIT PROXIES, 1995–2004

Fiscal year (FY)	Proposed rebased 1997 hospital market basket using ECIs for wages and benefits	Proposed rebased 1997 market basket using occupational wage and benefit proxies
Historical data:		
FY 1995	2.8	2.9
FY 1996	2.3	2.5
FY 1997	1.6	2.3
FY 1998	2.7	3.2
FY 1999	2.7	2.9
FY 2000	3.3	3.5
FY 2001	4.2	4.0
Average FYs 1995–2001	2.8	3.0
Forecast:		
FY 2002	3.7	3.0
FY 2003	3.3	3.1
FY 2004	2.9	3.1
Average FYs 2002–2004	3.3	3.0

Source: Global Insights, Inc, DRI-WEFA, 1st Qtr. 2002; @USMACRO/MODTREND @CISSIM/TRENDLONG0202.

The reintroduction of a cost component for blood and blood products in the market basket also does not make a noticeable impact on the market basket. Table 6 shows the proposed FY 1997-based market basket percentage change with blood broken out separately compared to market baskets with blood included in either chemicals or drugs.

TABLE 6.—PROPOSED 1997-BASED PROSPECTIVE PAYMENT HOSPITAL OPERATING INDEX PERCENT CHANGE, USING COST CATEGORIES FOR BLOOD AND BLOOD PRODUCTS, 1995–2004

Fiscal year (FY)	Proposed FY 1997-based market basket		
	With blood as a separate category	With blood included in chemicals	With blood included in drugs
Historical data:			
FY 1995	2.8	2.9	2.8
FY 1996	2.3	2.3	2.4
FY 1997	1.6	1.6	1.6
FY 1998	2.7	2.7	2.8
FY 1999	2.7	2.5	2.7
FY 2000	3.3	3.4	3.3
FY 2001	4.2	4.2	4.2
Average FYs 1995–2001	2.8	2.8	2.8
Forecast:			
FY 2002	3.7	3.6	3.7
FY 2003	3.3	3.3	3.3
FY 2004	2.9	3.0	3.0
Average FYs 2002–2004	3.3	3.3	3.3

Source: Global Insights, Inc, DRI-WEFA, 1st Qtr. 2002; @USMACRO/MODTREND @CISSIM/TRENDLONG0202.

4. Labor-Related Share

Sections 1886(d)(2)(H) and (d)(3)(E) of the Act direct the Secretary to estimate from time to time the proportion of payments that are labor-related: "The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates * * *".

In its June 2001 Report to Congress, MedPAC recommended that "To ensure accurate input-price adjustments in Medicare's prospective payment systems, the Secretary should reevaluate current assumptions about the proportions of providers' costs that reflect resources purchased in local and national markets." (Report to the Congress: Medicare in Rural America, p. 80, Recommendation 4D.) MedPAC believes that the labor-related share is an estimate of the national average proportion of providers' costs associated with inputs that are *only* affected by local market wage levels. MedPAC recommended the labor-related share include the weights for wages and salaries, fringe benefits, contract labor, and other labor-related costs for locally purchased inputs only. By changing the definition, and thereby lowering the labor-related share, funds would be transferred from urban to rural hospitals, which generally have wage index values less than 1.0.

Given the recommendation by MedPAC and our proposal to rebase and revise the hospital market basket, we have reviewed the definition and methodology of the labor-related share.

In addition, we reviewed the differences between urban and rural hospitals, updated regression results, and began reviewing possible alternative methodologies for calculating the labor-related share.

The labor-related share is used to determine the proportion of the national prospective payment system base payment rate to which the area wage index is applied. In the past we have defined the labor-related share for prospective payment system acute care hospitals as the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share for the acute care hospital inpatient prospective payment system market basket has been the sum of the weights for wages and salaries, fringe benefits, professional fees, contract labor, postage, business services, and labor-intensive services.

The difference between the CMS definition of the labor-related share and MedPAC's recommendation is that MedPAC includes inputs that can only be purchased in the local labor market, while CMS' includes inputs that are related to, influenced by, or vary with the local labor market, even if those services may be purchased at the national level. We believe our measure of the labor-related share reflects the cost of those inputs that are likely purchased in the local market, and is consistent with the requirements under sections 1886(d)(2)(H) and (d)(3)(E) of the Act described at the beginning of section IV.A.4. of this proposed rule.

In connection with the rebasing and revising of the prospective payment

system hospital market basket to 1997 data, we are proposing to recalculate the labor-related share of the standardized amounts. Our methodology is consistent with that used in the past to determine the labor-related share, which is the summation of the cost categories from the market basket deemed to vary with the local labor market. Based on the relative weights listed in Table 7, the proposed labor-related portion (wages and salaries, employee benefits, professional fees, and all other labor-intensive services) of the prospective payment system hospital market basket is 72.5 percent, and the nonlabor-related portion is 27.5 percent. By capturing more than just the direct labor costs that are available from the Medicare cost reports, our definition captures the "buy-versus-hire" decisions hospitals make in the purchase of their inputs. Accordingly, effective with discharges occurring on or after October 1, 2002, we are proposing to use these revised labor-related and nonlabor-related shares of the large urban and other areas' standardized amounts used to establish the prospective payment rates. Table 7 compares the FY 1992-based labor-related share with the proposed FY 1997-based labor-related share. As shown in Table 7, we have removed postage costs from the proposed FY 1997-based labor-related share because we do not believe these costs are likely to vary with the local labor market. Also, by changing the data source used to determine professional fees, the weight for that category has increased significantly.

TABLE 7.—LABOR-RELATED SHARE

Cost category	FY 1992-based weight	Proposed 1997-based weight	Difference
Wages and salaries	50.244	50.686	0.442
Fringe benefits	11.146	10.970	-0.176
Nonmedical professional fees	2.127	5.401	3.274
Postal services*	0.272	-0.272
Other labor-intensive services**	7.277	5.438	-1.839
Total labor-related	71.066	72.495	1.429
Total nonlabor-related	28.934	27.505	-1.429

* No longer considered to be labor-related.

** Other labor-intensive services includes landscaping services, services to buildings, detective and protective services, repair services, insurance services, laundry services, auto parking and repairs, physical fitness facilities, other medical services, colleges and professional schools, and other government enterprises.

We are concerned that the result of this methodology could have negative impacts that would fall predominantly on rural hospitals and are interested in public comments on alternative methodologies. While we are not

proposing to change the methodology for calculating the labor-related share in this proposed rule, we have begun the research necessary to reevaluate the current assumptions used in determining this share. This

reevaluation is consistent with the MedPAC recommendation in MedPAC's June 2001 report. Our research involves analyzing the compensation share separately for urban and rural hospitals, using regression analysis to determine

the proportion of costs influenced by the area wage index, and exploring alternative methodologies to determine whether all or just a portion of professional fees and nonlabor intensive services should be considered labor-related. Although we have not completed our research into this issue, we are summarizing some of our preliminary findings below. We encourage comments on this research and any information that is available to help determine the most appropriate measure.

The compensation share of costs for hospitals in rural areas was higher on average than the compensation share for hospitals in urban areas. Using FY 1997 Medicare cost report data, rural areas had an average compensation share of 62.7 percent, while urban areas had a share of 61.5 percent. This compares to a share of 61.7 percent for all hospitals. These findings were validated consistently through our regression analysis, described in more detail below, as the coefficient on the wage index was higher when the regressions were run only for rural hospitals compared to when the regressions were run only for urban hospitals. Based on these findings, it does not appear that using a national average labor share for all hospitals to adjust the national payment rate by the area wage index disadvantages rural hospitals that tend to have a wage index value below 1.0.

Our research attempted to validate our national average labor share by conducting regression analysis to determine the proportion of hospital's costs that varied with the area wage index. We have conducted this type of regression analysis before in helping to determine the labor-related share, most recently for the SNF prospective payment system (66 FR 39585). Our first step was to edit the data, which had significant outliers in some of the variables we used in the regressions. We originally began with an edit that excluded the top and bottom 5 percent of reports based on average Medicare cost per discharge and number of discharges. We also used edits to exclude reports that did not meet basic criteria for use, such as having costs greater than 0 for total, operating, and capital for the overall facility and for only the Medicare proportion. We also required that the hospital occupancy rate, length of stay, number of beds, full-time equivalents (FTEs), and overall and Medicare discharges be greater than 0. Finally, we excluded reports with occupancy rates greater than 1.

Our initial regression specification (in log form) was the Medicare operating cost per Medicare discharge as the

dependent variable and the independent variables being the area wage index, the case mix index, the ratio of interns and residents per bed (as proxy for IME status), and a dummy for large urban hospitals. This regression produced a coefficient for all hospitals for the area wage index of 0.638 (which is equivalent to the labor share and can be interpreted as an elasticity because of the log specification) with an adjusted R-squared of 64.3. While on the surface this would appear to be a reasonable result, this same specification for urban hospitals had a coefficient of 0.532 (adjusted R-squared = 53.2) and a coefficient of 0.709 (adjusted R-squared = 36.4) for rural hospitals. This highlighted some apparent problems with the specification because the overall regression results appear to be masking underlying problems. It would not seem reasonable that urban hospitals would have a labor share below their actual compensation share or that the discrepancy between urban and rural hospitals would be this large. The other major problem with the regression was that the coefficient on the case-mix index was significantly below 1.0 for each specification. When we standardized the Medicare operating cost per Medicare discharge for case mix, the fit fell dramatically and the urban/rural discrepancy became even larger.

Based on this initial result, we tried two modifications to the regressions to correct for the underlying problems. First, we edited the data differently to determine if a few reports were causing the inconsistent results. We found that when we tightened the edits, the wage index coefficient was lower and the fit was worse. When we loosened the edits, we found higher wage index coefficients and still a worse fit. Second, we added variables to the regression equation to attempt to explain some of the variation that was not being captured. We found the best fit occurred when the following variables were added: the occupancy rate, the number of hospital beds, a dummy for control status, the Medicare length of stay, the number of FTEs per bed, and the age of fixed assets. The result of this specification was a wage index coefficient of 0.620 (adjusted R-squared = 68.7), with the regression on rural hospitals having a coefficient of 0.772 (adjusted R-squared = 45.0) and the regression on urban hospitals having a coefficient of 0.474 (adjusted R-squared = 60.9). Neither of these alternatives seemed to help the underlying difficulties with the regression analysis.

Because the market basket method determines the proportion of labor-

related costs for the entire hospital, not just Medicare costs (due to the unavailability of Medicare specific data for such detailed cost categories) we also ran the regressions on overall hospital operating cost per discharge. The initial specification (only 4 independent variables) produced similar results to those discussed above, that is, what appeared to be a reasonable overall share but with major problems underlying the data. The more detailed specification also did not improve the results over the previous runs.

Because of these problems, we did not believe the regression analysis was producing enough sound evidence at this point for us to make the decision to change from the current method for calculating the labor-related share using market basket categories. We plan to continue to analyze these data and work on alternative specifications, including working with MedPAC, which has done a similar analysis in its studies of payment adequacy in the past. We welcome comments on this approach, given the difficulties we have encountered.

We also have been examining ways to refine our market basket approach to more accurately account for the proportion of costs influenced by the local labor market. Specifically, we have been looking at the professional fees and labor intensive cost categories to determine if only a proportion of the costs in these categories should be considered labor-related, not the entire cost category. Professional fees include management and consulting fees, legal services, accounting services, and engineering services. Labor-intensive services are mostly building services, but also include other maintenance and repair and insurance services. While we have identified some possible approaches for accomplishing this, we do not believe at this point that we have completely validated them and thus are not proposing to change from our current method. Below we briefly describe the possible approaches and some of the issues surrounding these approaches.

One possible option would be to only include in the labor-related share the compensation portion of the cost category for each industry included in professional fees and labor-intensive services. This could be done using data from the 1997 BES, which reports detailed cost categories by industry (SIC) code. For example, management and consulting fees (SIC 874) is one of the major pieces of professional fees. The BES indicates that compensation accounts for 59.2 percent of operating costs in management and consulting

fees. If we only considered for inclusion in the labor-related share the portion that is compensation, this would result in a lower labor share. However, at this point, there does not appear to be enough information available from the BES to do this for every industry code. It is also not clear that at least some proportion of noncompensation costs of these inputs for hospitals would not vary with the local labor market. We are still researching the appropriateness of this option and whether it could be used to assist in determining the labor-related share.

Another possible option would be to use data from the Bureau of the Census' 1992 Enterprise Statistics to attempt to determine the proportion of costs for professional fees and labor-intensive services associated with centrally located overhead. That is, could we identify the proportion of costs that are borne in a central location such that they would not be related to the local labor market? The Enterprise Statistics include payroll data for both auxiliary establishments of a multiestablishment company and the entire company. Since auxiliary establishments primarily manage, administer, service, and support the activities of other establishments of the company, we were considering using this information to estimate the proportion of professional fees and labor-intensive services associated with central locations instead of with the location of the hospital. The Enterprise Statistics data are available for specific enterprise industry codes (EIC) that could seemingly be matched to the industry codes from the I-O used to determine professional fees and labor-intensive services. The methodology would consist of determining the auxiliary establishments payroll share of the total establishment, and subtracting that portion from the compensation portion of expenses for each I-O industry code. The initial research into this method is pointing out some difficulties in matching industry and EIC codes since the Enterprise Statistics do not contain as much detail as the I-O. In addition, it is not clear yet that this method would remove the appropriate amount of central office labor costs. We will continue to research this option, but at this time we are not proposing to use it in the calculation of the labor-related share.

We plan to continue researching whether an alternative methodology for determining the labor-related share would be more appropriate than our current methodology, including working with MedPAC. We plan to complete this research prior to August 1 and would make the appropriate changes in the final rule if we found another methodology to be superior to our current methodology. At this time, we are proposing to continue to use our existing methodology in determining the labor-related share.

5. Separate Market Basket for Hospitals and Hospital Units Excluded From the Acute Care Hospital Inpatient Prospective Payment System

In its March 1, 1990 report, ProPAC recommended that we establish a separate market basket for hospitals and hospital units excluded from the acute care hospital inpatient prospective payment system. Effective with FY 1991, we adopted ProPAC's recommendation to implement separate market baskets. (See the September 4, 1990 final rule (55 FR 36049).) Prospective payment system hospitals and excluded hospitals and units tend to have different case mixes, practice patterns, and composition of inputs. The fact that excluded hospitals are not included under the acute care hospital inpatient prospective payment system in part reflects these differences. Studies completed by CMS, ProPAC, and the hospital industry have documented different weights for excluded hospitals and units and prospective payment system hospitals.

The excluded hospital market basket is a composite set of weights for Medicare-participating psychiatric hospitals and units, rehabilitation hospitals and units, long-term care hospitals, children's hospitals, and cancer hospitals. We are proposing to use cost report data for excluded freestanding hospitals whose Medicare average length of stay is within 15 percent (that is, 15 percent higher or lower) of the total facility average length of stay for excluded hospitals, except psychiatric hospitals. A tighter measure of Medicare length of stay within 8 percent (that is, 8 percent higher or lower) of the total facility average length of stay is proposed for freestanding psychiatric hospitals. This was done because psychiatric hospitals have a relatively small proportion of costs from

Medicare and a relatively small share of Medicare psychiatric cases. While the 15 percent length of stay edit was used for the FY 1992-based index, the tighter, 8 percent edit for psychiatric hospitals was not. We believe that limiting our sample to hospitals with a Medicare average length of stay within a comparable range to the total facility average length of stay provides a more accurate reflection of the structure of costs for treating Medicare patients.

Table 8 compares major weights in the proposed rebased FY 1997 market basket for excluded hospitals with weights in the proposed rebased FY 1997 market basket for acute care prospective payment system hospitals. Wages and salaries are 51.998 percent of total operating costs for excluded hospitals compared to 50.686 percent for acute care prospective payment hospitals. Employee benefits are 11.253 percent for excluded hospitals compared to 10.970 percent for acute care prospective payment hospitals. As a result, compensation costs (wages and salaries plus employee benefits) for excluded hospitals are 63.251 percent of costs compared to 61.656 percent for acute care prospective payment hospitals, reflecting the more labor-intensive services conducted in excluded hospitals.

A significant difference in the category weights also occurs in pharmaceuticals. Pharmaceuticals represent 5.416 percent of costs for acute care prospective payment hospitals and 6.940 percent for excluded hospitals. The weights for the excluded hospital market basket were derived using the same data sources and methods as for the acute care prospective payment market basket as outlined previously. Differences in weights between the proposed excluded hospital and acute care prospective payment hospital market baskets do not necessarily lead to significant differences in the rate of price growth for the two market baskets. If individual wages and prices move at approximately the same annual rate, both market baskets may have about the same overall price growth, even though the weights may differ substantially, because both market baskets use the same wage and price proxies. Also, offsetting price increases for various cost components can result in similar composite price growth in both market baskets.

TABLE 8.—PROPOSED FY 1997-BASED EXCLUDED HOSPITAL AND PROSPECTIVE PAYMENT HOSPITAL MARKET BASKETS, COMPARISON OF SIGNIFICANT WEIGHTS

Category	Proposed rebased 1997 excluded hospital market basket	Proposed rebased 1997 Prospective Payment System hospital basket
Wages and salaries	51.998	50.686
Employee benefits	11.253	10.970
Professional fees	4.859	5.401
Pharmaceuticals	6.940	5.416
All other	24.950	25.527
Total	100.000	100.000

Table 9 lists the cost categories, weights, and proxies for the proposed FY 1997-based excluded hospital market basket. For comparison, the FY 1992-based cost category weights are included. The proxies are the same used in the proposed FY 1997-based acute care hospital inpatient prospective payment system market basket discussed above.

TABLE 9.—FY 1992-BASED AND PROPOSED FY 1997-BASED EXCLUDED HOSPITAL OPERATING COST CATEGORIES, WEIGHTS, AND PRICE PROXIES

Expense categories	Proposed rebased 1997 excluded hospital market basket weights	FY 1992-based excluded hospital market basket weights	FY 1997-based price proxy
1. Compensation	63.251	63.721	
A. Wages and salaries*	51.998	52.152	ECI-wages and salaries, civilian hospitals.
B. Employee benefits*	11.253	11.569	ECI-benefits, civilian hospitals.
2. Professional fees*	4.859	2.098	ECI-compensation for professional, specialty & technical.
3. Utilities	1.296	1.675	—
A. Fuel, oil, and gasoline	0.272	0.401	PPI commercial natural gas.
B. Electricity	0.798	1.007	PPI commercial electric power.
C. Water and sewerage	0.226	0.267	CPI-U water and sewerage maintenance.
4. Professional liability insurance	0.805	1.081	CMS professional liability insurance premiums index.
5. All other	29.790	31.425	—
A. All other products	19.680	24.227	—
(1) Pharmaceuticals	6.940	3.070	PPI ethical (prescription) drugs.
(2) Direct purchase food	1.233	2.370	PPI processed foods & feeds.
(3) Contract service food	1.146	1.098	CPI-U food away from home.
(4) Chemicals	2.343	3.754	PPI industrial chemicals.
(5) Blood and blood products	0.821	N/A	PPI blood and blood derivatives, human use.
(6) Medical instruments	1.972	3.154	PPI medical instruments & equipment.
(7) Photographic supplies	0.184	0.400	PPI photographic supplies.
(8) Rubber and plastics	1.501	4.865	PPI rubber & plastic products.
(9) Paper products	1.219	2.182	PPI converted paper & paperboard products.
(10) Apparel	0.525	0.890	PPI apparel.
(11) Machinery and equipment	0.936	0.212	PPI machinery & equipment.
(12) Miscellaneous products	0.860	2.232	PPI finished goods less food and energy.
B. All other services	10.110	7.198	—
(1) Telephone services	0.382	0.631	CPI-U telephone services.
(2) Postage	0.771	0.295	CPI-U postage.
(3) All other: labor intensive*	4.892	5.439	ECI-compensation for private service occupations.
(4) All other: Non-labor intensive	4.065	0.833	CPI-U all items.
Total	100.000	100.000	—

*Labor-related.

Note: Due to rounding, weights may not sum to total.

Table 10 shows the historical and forecasted updates under both the proposed FY 1997-based and the FY 1992-based excluded hospital market baskets.

TABLE 10.—FY 1992-BASED AND PROPOSED FY 1997-BASED EXCLUDED HOSPITAL OPERATING INDEX PERCENT CHANGE, 1995–2004

Fiscal year (FY)	Proposed rebased 1997 excluded hospital market basket	FY 1992-based excluded hospital market basket
Historical data:		
FY 1995	2.7	3.2
FY 1996	2.4	2.5
FY 1997	1.7	2.0
FY 1998	3.0	2.7
FY 1999	2.9	2.4
FY 2000	3.3	3.6
FY 2001	4.3	4.1
Average FYs 1995–2001	2.9	2.9
Forecast:		
FY 2002	3.7	2.8
FY 2003	3.4	3.0
FY 2004	3.0	3.1
Average FYs 2002–2004	3.4	3.0

Source: Global Insights, Inc, DRI-WEFA, 1st Qtr. 2002; @USMACRO/MODTREND @CISSIM/TRENDLONG0202.

A comparison of the proposed FY 1997-based index incorporating the new wage and benefits proxies (ECIs) and updated occupational wage proxies is included in Table 11.

TABLE 11.—PROPOSED FY 1997-BASED EXCLUDED HOSPITAL OPERATING INDEX PERCENT CHANGE, USING DIFFERENT WAGE AND BENEFIT PROXIES, 1995–2004

Fiscal year (FY)	Proposed rebased 1997 excluded hospital market basket	
	Using ECIs for hospital wages and benefits	Using occupational wage and benefit proxies
Historical data:		
FY 1995	2.7	2.9
FY 1996	2.4	2.5
FY 1997	1.7	2.3
FY 1998	3.0	3.4
FY 1999	2.9	3.1
FY 2000	3.3	3.5
FY 2001	4.3	4.0
Average FYs 1995–2001	2.9	3.1
Forecast:		
FY 2002	3.7	3.1
FY 2003	3.4	3.2
FY 2004	3.0	3.2
Average FYs 2002–2004	3.4	3.2

Source: Global Insights, Inc, DRI-WEFA, 1st Qtr. 2002; @USMACRO/MODTREND @CISSIM/TRENDLONG0202.

Like the proposed FY 1997-based prospective payment hospital index showed, there is little difference in the index over time when different compensation proxies are used. Table 12 shows the labor-related share for excluded hospitals.

TABLE 12.—LABOR-RELATED SHARE, EXCLUDED HOSPITALS

Cost category	FY 1992-based weight	Proposed FY 1997-based weight	Difference
Wages and salaries	52.152	51.998	-0.154
Fringe benefits	11.569	11.253	-0.316
Nonmedical professional fees	2.098	4.859	2.761
Postal services*	0.295	-0.295
Other labor intensive services**	5.439	4.892	-0.547
Total labor-related	71.553	73.002	1.449

TABLE 12.—LABOR-RELATED SHARE, EXCLUDED HOSPITALS—Continued

Cost category	FY 1992-based weight	Proposed FY 1997-based weight	Difference
Total nonlabor-related	28.447	26.998	- 1.449

* No longer considered to be labor-related.

** Other labor-intensive services includes landscaping services, services to buildings, detective and protective services, repair services, insurance services, laundry services, auto parking and repairs, physical fitness facilities, other medical services, colleges and professional schools, and other government enterprises.

B. Capital Input Price Index

The Capital Input Price Index (CIPI) was originally detailed in the September 1, 1992 **Federal Register** (57 FR 40016). There have been subsequent discussions of the CIPI presented in the May 26, 1993 (58 FR 30448), September 1, 1993 (58 FR 46490), May 27, 1994 (59 FR 27876), September 1, 1994 (59 FR 45517), June 2, 1995 (60 FR 29229), September 1, 1995 (60 FR 45815), May 31, 1996 (61 FR 27466), and August 30, 1996 (61 FR 46196) rules in the **Federal Register**. The August 30, 1996 rule discussed the most recent revision and rebasing of the CIPI to a FY 1992 base year, which reflects the capital cost structure facing hospitals in that year.

We are proposing to revise and rebase the CIPI to a FY 1997 base year to reflect the more recent structure of capital costs. To do this, we reviewed hospital expenditure data for the capital cost categories of depreciation, interest, and other capital expenses. As with the FY 1992-based index, we have developed two sets of proposed weights in order to calculate the proposed FY 1997-based CIPI. The first set of proposed weights identifies the proportion of hospital

capital expenditures attributable to each capital expenditure category, while the second set of proposed weights is a set of relative vintage weights for depreciation and interest. The set of vintage weights is used to identify the proportion of capital expenditures within a cost category that is attributable to each year over the useful life of capital assets in that category. A more thorough discussion of vintage weights is provided later in this section.

Both sets of weights are developed using the best data sources available. In reviewing source data, we determined that the Medicare cost reports provided accurate data for all capital expenditure cost categories. We are proposing to use the FY 1997 Medicare cost reports for acute care prospective payment system hospitals, excluding expenses from hospital-based subproviders, to determine weights for all three cost categories: Depreciation, interest, and other capital expenses. We compared the weights determined from the Medicare cost reports to other data sources for 1997, specifically the Bureau of the Census' BES and the AHA Annual Survey, and found the weights to be consistent with those data sources.

Lease expenses are not a separate cost category in the CIPI, but are distributed among the cost categories of depreciation, interest, and other, reflecting the assumption that the underlying cost structure of leases is similar to capital costs in general. We assumed 10 percent of lease expenses are overhead and assigned them to the other capital expenses cost category as overhead, as was done in previous capital market baskets. The remaining lease expenses were distributed to the three cost categories based on the weights of depreciation, interest, and other capital expenses not including lease expenses.

Depreciation contains two subcategories: Building and fixed equipment and movable equipment. The split between building and fixed equipment and movable equipment was determined using the Medicare cost reports. This methodology was also used to compute the FY 1992-based index.

Table 13 presents a comparison of the proposed rebased FY 1997 capital cost weights and the FY 1992 capital cost weights.

TABLE 13.—COMPARISON OF FY 1992 AND PROPOSED REBASED FY 1997 COST CATEGORY WEIGHTS

Expense categories	FY 1992 weights	Proposed rebased FY 1997 weights	Price proxy
Total	1.0000	1.0000	
Total depreciation	0.6484	0.7135	
Building and fixed equipment depreciation	0.3009	0.3422	Boeckh Institutional Construction Index—vintage weighted (23 years).
Movable equipment depreciation	0.3475	0.3713	PPI for machinery and equipment—vintage weighted (11 years).
Total interest	0.3184	0.2346	
Government/nonprofit interest	0.2706	0.1994	Average yield on domestic municipal bonds (Bond Buyer 20 bonds)—vintage weighted (23 years).
For-profit interest	0.0478	0.0352	Average yield on Moody's Aaa bonds—vintage weighted (23 years).
Other	0.0332	0.0519	CPI—Residential Rent.

Because capital is acquired and paid for over time, capital expenses in any given year are determined by past and present purchases of physical and

financial capital. The vintage-weighted CIPI is intended to capture the long-term consumption of capital, using vintage weights for depreciation

(physical capital) and interest (financial capital). These vintage weights reflect the purchase patterns of building and fixed equipment and movable