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 (MGCRB).
- Requests for wage data corrections, including clarification of our policies on mid-year corrections.

3. Revision and Rebasing 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 MGCRB.
- 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 l 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 retitle 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 II.B.13. of this preamble for a discussion of ICD–9–CM changes.) These proposed changes are being made in accordance with the principles established when we created the CC Exclusions List in 1987.

Tables 6G and 6H in the Addendum to this proposed rule contain the revisions to the CC Exclusions List that would be effective for discharges occurring on or after October 1, 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 2216l; or by calling (800) 553–6847.

Users should be aware of the fact that all revisions to the CC Exclusions List (FYs 1989, 1990, 1991, 1992, 1993, 1994, 1995, 1996, 1997, 1998, 1999, 2000, 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 Multiveasel 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, 200l 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 *a*cute *p*hysiology *a*nd *c*hronic *h*ealth *e*valuation). 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 autogeneous 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 Rebasing 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.

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 market 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 nenefits	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

equipment over time. Because depreciation and interest expenses are determined by the amount of past and current capital purchases, we used the vintage weights to compute vintage-weighted price changes associated with depreciation and interest expense.

Vintage weights are an integral part of the CIPI. Capital costs are inherently complicated and are determined by complex capital purchasing decisions over time, based on such factors as interest rates and debt financing. Capital is depreciated over time instead of being consumed in the same period it is purchased. The CIPI accurately reflects the annual price changes associated with capital costs, and is a useful simplification of the actual capital accumulation process. By accounting for the vintage nature of capital, we are able to provide an accurate, stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes. These unstable annual price changes do not reflect the actual annual price changes for Medicare capital-related costs. CMS's CIPI reflects the underlying stability of the capital acquisition process and provides hospitals with the ability to plan for changes in capital payments.

To calculate the vintage weights for depreciation and interest expenses, we used a time series of capital purchases for building and fixed equipment and movable equipment. We found no single source that provides the best time series of capital purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital data to meet this need. While the AHA Panel Survey provided a consistent database back to 1963, it did not provide annual capital purchases. The AHA Panel Survey did provide time series of depreciation and interest expenses that could be used to infer capital purchases over time. Although the AHA Panel Survey was discontinued after September 1997, we were able to use all of the available historical data from this survey since our proposed base year is FY 1997.

In order to estimate capital purchases from AHA data on depreciation and interest expenses, the expected life for each cost category (building and fixed equipment, movable equipment, debt instruments) is needed. The expected life is used in the calculation of vintage weights. We used FY 1997 Medicare cost reports to determine the expected life of building and fixed equipment and movable equipment. The expected life of any piece of equipment can be determined by dividing the value of the fixed asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated useful life of an asset if depreciation were to continue at current year levels, assuming straight-line depreciation. From the FY 1997 cost reports, we determined the expected life of building and fixed equipment to be 23 years, and the expected life of movable equipment to be 11 years. By comparison, the FY 1992-based index showed that the expected life for building and fixed equipment was 22 years, while that for movable equipment was 10 years. Our analysis of data for FYs 1996, 1998, and 1999 indicates very little change in these measures over time.

We used the fixed and movable weights derived from the FY 1997 Medicare cost reports to separate the AHA Panel Survey depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation. By multiplying the annual depreciation amounts by the expected life calculations from the FY 1997 Medicare cost reports, we determined year-end asset costs for building and fixed equipment and movable equipment. We subtracted the previous year asset costs from the current year asset costs and estimated annual purchases of building and fixed equipment and movable equipment back to 1963. From this capital purchase time series, we were able to calculate the vintage weights for building and fixed equipment, movable equipment, and debt instruments. Each of these sets of vintage weights is explained in detail below.

For building and fixed equipment vintage weights, we used the real annual capital purchase amounts for building and fixed equipment derived from the AHA Panel Survey. The real annual purchase amount was used to capture the actual amount of the physical acquisition, net of the effect of price inflation. This real annual purchase amount for building and fixed equipment was produced by deflating the nominal annual purchase amount by the building and fixed equipment price proxy, the Boeckh institutional construction index. Because building and fixed equipment has an expected life of 23 years, the vintage weights for building and fixed equipment are deemed to represent the average purchase pattern of building and fixed equipment over 23-year periods.

Vintage weights for each 23-year period are calculated by dividing the real building and fixed capital purchase amount in any given year by the total amount of purchases in the 23-year period. This calculation is done for each year in the 23-year period, and for each of the twelve 23-year periods from 1963 to 1997. The average of the twelve 23-year periods is used to determine the 1997 average building and fixed equipment vintage weights.

For movable equipment vintage weights, we used the real annual capital purchase amounts for movable equipment derived from the AHA Panel Survey. The real annual purchase amount was used to capture the actual amount of the physical acquisition, net of price inflation. This real annual purchase amount for movable equipment was calculated by deflating the nominal annual purchase amount by the movable equipment price proxy, the PPI for machinery and equipment. Because movable equipment has an expected life of 11 years, the vintage weights for movable equipment are deemed to represent the average purchase pattern of movable equipment over 11-year periods.

Vintage weights for each 11-year period are calculated by dividing the real movable capital purchase amount for any given year by the total amount of purchases in the 11-year period. This calculation is done for each year in the 11-year period, and for each of the twenty-four 11-year periods from 1963 to 1997. The average of the twenty-four 11-year periods is used to determine the FY 1997 average movable equipment vintage weights.

For interest vintage weights, we used the nominal annual capital purchase amounts for total equipment (building and fixed, and movable) derived from the AHA Panel Survey. Nominal annual purchase amounts were used to capture the value of the debt instrument. Because debt instruments have an expected life of 23 years, the vintage weights for interest are deemed to represent the average purchase pattern of total equipment over 23-year periods.

Vintage weights for each 23-year period are calculated by dividing the nominal total capital purchase amount for any given year by the total amount of purchases in the 23-year period. This calculation is done for each year in the 23-year period and for each of the twelve 23-year periods from 1963 to 1997. The average of the twelve 23-year periods is used to determine the FY 1997 average interest vintage weights. The vintage weights for the FY 1992 CIPI and the proposed FY 1997 CIPI are presented in Table 14.

TABLE 14.—CURRENT AND PROPOSED VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year (from farthest to most recent)	Building and fixed equipment		Movable equipment		Interest	
	FY 1992 22 years	Proposed FY 1997 23 years	FY 1992 10 years	Proposed FY 1997 11 years	FY 1992 22 years	Proposed FY 1992 23 years
1	0.019	0.018	0.069	0.063	0.007	0.007
2	0.020	0.021	0.075	0.068	0.008	0.009
3	0.023	0.023	0.083	0.074	0.010	0.011
4	0.026	0.025	0.091	0.080	0.012	0.012
5	0.028	0.026	0.097	0.085	0.014	0.014
6	0.030	0.028	0.103	0.091	0.016	0.016
7	0.031	0.030	0.109	0.096	0.018	0.019
8	0.032	0.032	0.115	0.101	0.021	0.022
9	0.036	0.035	0.124	0.108	0.024	0.026
10	0.039	0.039	0.133	0.114	0.029	0.030
11	0.043	0.042	.....	0.119	0.035	0.035
12	0.047	0.044	.....	.....	0.041	0.039
13	0.050	0.047	.....	.....	0.047	0.045
14	0.052	0.049	.....	.....	0.052	0.049
15	0.055	0.051	.....	.....	0.059	0.053
16	0.059	0.053	.....	.....	0.067	0.059
17	0.062	0.057	.....	.....	0.074	0.065
18	0.065	0.060	.....	.....	0.081	0.072
19	0.067	0.062	.....	.....	0.088	0.077
20	0.069	0.063	.....	.....	0.093	0.081
21	0.072	0.065	.....	.....	0.099	0.085
22	0.073	0.064	.....	.....	0.103	0.087
23	.....	0.065	.....	.....	.....	0.090
Total	1.000	1.000	1.000	1.000	1.000	1.000

After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate of increase for each expenditure category. Our proposed price proxies for the FY 1997-based CIPI are the same as those for the FY 1992-based CIPI. We still believe these are the most appropriate proxies for hospital capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability. We ran the proposed FY 1997-based index using the Moody's Aaa bonds average yield and using the Moody's Baa bonds average yield as proxy for the for-profit interest cost category. There was no difference in the two sets of index percent changes either historically or forecasted. The rationale for selecting the price proxies is explained more fully in the August 30, 1996 final rule (61 FR 46196). The proposed proxies are presented in Table 13.

Global Insights, Inc., DRI–WEFA forecasts a 0.7 percent increase in the proposed rebased FY 1997 CIPI for FY 2003, as shown in Table 15.

TABLE 15.—FY 1992 AND PROPOSED FY 1997-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, 1995–2004

Federal fiscal year	CIPI, FY 1992-based	Proposed CIPI, FY 1997-based
1995	1.2	1.5
1996	1.0	1.3
1997	0.9	1.2
1998	0.7	0.9
1999	0.7	0.9
2000	0.9	1.1
2001	0.7	0.9
Average: FYs 1995–2001	0.9	1.1
Forecast:		
2002	0.6	0.8
2003	0.5	0.7
2004	0.6	0.7
Average: FYs 2002–2004	0.6	0.7

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

This 0.7 percent increase is the result of a 1.3 percent increase in projected vintage-weighted depreciation prices (building and fixed equipment, and movable equipment) and a 2.7 percent increase in other capital expense prices, partially offset by a 2.2 percent decrease in vintage-weighted interest rates in FY 2003, as indicated in Table 16.

TABLE 16.—CMS PROPOSED CAPITAL INPUT PRICE INDEX PERCENT CHANGES, TOTAL AND COMPONENTS, FISCAL YEARS 1985–2005

Fiscal year	Total	Total depreciation	Depreciation, building and fixed equipment	Depreciation, movable equipment	Interest	Other
Wgts FY 1997	1.000	0.7135	0.3422	0.3713	0.2346	0.0519
Vintage-Weighted Price Changes						
1995	1.5	2.7	4.0	1.6	−1.8	2.5
1996	1.3	2.5	3.8	1.4	−2.3	2.6
1997	1.2	2.3	3.6	1.2	−2.4	2.8
1998	0.9	2.1	3.3	0.9	−3.0	3.2
1999	0.9	1.9	3.2	0.7	−2.8	3.2
2000	1.1	1.7	3.1	0.4	−1.6	3.4
2001	0.9	1.5	2.9	0.1	−2.2	4.3
Forecast:						
2002	0.8	1.4	2.8	0.0	−2.2	4.0
2003	0.7	1.3	2.7	−0.1	−2.2	2.7
2004	0.7	1.3	2.5	−0.1	−2.1	2.8
2005	0.7	1.3	2.5	−0.1	−2.0	2.8

Rebasing the CIPI from FY 1992 to FY 1997 increased the percent change in the FY 2003 forecast by 0.2 percentage points, from 0.5 to 0.7 as shown in Table 15. The difference is caused mostly by changes in cost category weights, particularly the smaller weight for interest and larger weight for depreciation. Because the interest component has a negative price change associated with it for FY 2003, the smaller share it accounts for in the FY 1997-based index means it has less of an impact than in the FY 1992-based index. The changes in the expected life and vintage weights have only a minor impact on the overall percent change in the index.

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

A. Transfer Payment Policy

1. Expanding the Postacute Care Transfer Policy to Additional DRGs (§ 412.4)

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

Under section 1886(d)(5)(J) of the Act, which was added by section 4407 of Public Law 105–33, a ''qualified discharge'' from one of 10 DRGs selected by the Secretary to a postacute care provider is treated as a transfer case beginning with discharges on or after October 1, 1998. This section requires the Secretary to define and pay as transfers all cases assigned to one of 10 DRGs selected by the Secretary if the individuals are discharged to one of the following postacute care settings:

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

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

The Conference Agreement that accompanied Public Law 105–33 noted that ''(t)he Conferees are concerned that Medicare may in some cases be overpaying hospitals for patients who are transferred to a postacute care setting after a very short acute care hospital stay. The conferees believe that Medicare's payment system should continue to provide hospitals with strong incentives to treat patients in the most effective and efficient manner, while at the same time, adjust PPS [prospective payment system] payments in a manner that accounts for reduced hospital lengths of stay because of a discharge to another setting.'' (H.R. Report No. 105–217, 105th Cong., 1st Sess., 740 (1997).)

In the July 31, 1998 final rule (63 FR 40975), we implemented section 1886(d)(5)(J) of the Act, which directed the Secretary to select 10 DRGs based upon a high volume of discharges to postacute care and a disproportionate use of postacute care services. As discussed in the July 31, 1998 final rule, these 10 DRGs were selected in 1998 based on the MedPAR data from FY 1996. Using that information, we identified and selected the first 20 DRGs that had the largest proportion of discharges to postacute care (and at least 14,000 such transfer cases). In order to select 10 DRGs from the 20 DRGs on our list, we considered the volume and percentage of discharges to postacute care that occurred before the mean length of stay and whether the discharges occurring early in the stay were more likely to receive postacute care. We identified the following DRGs

to be subject to the special 10 DRG transfer rule:

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

Similar to our existing policy for transfers between two acute care hospitals, the transferring hospital in a postacute transfer for 7 of the 10 DRGs receives twice the per diem rate the first day and the per diem rate for each following day of the stay prior to the transfer, up to the full DRG payment. However, 3 of the 10 DRGs exhibit a disproportionate share of costs very early in the hospital stay in postacute transfer situations. For these 3 DRGs, hospitals receive 50 percent of the full DRG payment for the first day of the stay and 50 percent of the per diem for the remaining days of the stay, up to the full DRG payment. This is consistent with section 1886(d)(5)(J)(i) of the Act, which recognizes that in some cases ''a substantial portion of the costs of care are incurred in the early days of the inpatient stay.''

The statute provides that, after FY 2000, the Secretary is authorized to expand this policy to additional DRGs. In July 1999, the previous Administration committed to not expanding the number of DRGs included in the policy until FY 2003. Therefore, CMS did not propose any change to the postacute care settings or the 10 DRGs in FY 2001 or FY 2002.

Under contract with CMS (Contract No. 500–95–0006), Health Economics Research, Inc. (HER) conducted an analysis of the impact on hospitals and hospital payments of the postacute care transfer provision. We included in the August 1, 2000 final rule (65 FR 47079) a summary of that analysis. Among other issues, the analysis sought to evaluate the reasonableness of expanding the transfer payment policy beyond the current 10 selected DRGs.

The analysis supported the initial 10 DRGs selected as being consistent with the nature of the Congressional mandate. According to HER, ''[t]he top 10 DRGs chosen initially by HCFA exhibit very large PAC [postacute care] levels and PAC discharge rates (except for DRG 264, Skin Graft and/or Debridement for Skin Ulcer or Cellulitis without CC, which was paired with DRG 263). All 10 appear to be excellent choices based on the other criteria as well. Most have fairly high short-stay PAC rates (except possibly for Strokes, DRG 14, and Mental Retardation, DRG 429).''

The HER report discussed the issues related to potentially expanding the postacute care transfer policy to all DRGs. In favor of this expansion, HER pointed to the following benefits:

- A simple, uniform, formula-driven policy;
- The same policy rationale exists for all DRGs;
- DRGs with little utilization of short-stay postacute care would not be harmed by the policy;
- Less confusion in discharge destination coding; and
- Hospitals that happen to be disproportionately treating the current 10 DRGs may be harmed more than hospitals with an aggressive, short-stay, postacute care transfer policy for other DRGs.

The complete HER report may be obtained at: *http://www.cms.gov/medicare/ippsmain.htm.*

Consistent with HER's findings, we believe expanding the postacute care transfer policy to all DRGs may be the most equitable approach at this time, since a policy that is limited to certain DRGs may result in disparate payment treatment across hospitals, depending on the types of cases treated. We are considering implementing this expansion of the postacute transfer policy in the final rule. For example, a hospital specializing in some of the types of cases included in the current 10 DRG transfer policy would receive reduced payments for those cases transferred for postacute care after a brief acute inpatient stay, while a hospital specializing in cases not included in the current 10 DRGs may be just as aggressive in transferring its patients for postacute care, but it would receive full payment for those cases.

Another aspect of the issue is that some hospitals have fewer postacute care options available for their patients. In its June 2001 Report to Congress: Medicare in Rural America, MedPAC wrote: ''[a] shortage of ambulatory and post-acute care resources may prevent rural hospitals from discharging patients as early in the episode of care as urban hospitals would'' (page 68). MedPAC went on to note that the decline in length of stay for urban hospitals since 1989 was greater for urban hospitals than for rural hospitals (34 percent compared with 25 percent through 1999), presumably due to earlier discharges to postacute care settings. Although MedPAC contemplated returning money saved by expanding the policy to the base payment rate, thereby increasing payments for nontransfer cases, currently section 1886(d)(5)(I)(ii) of the Act provides that any expansion to the postacute transfer policy would not be budget neutral. (Budget neutrality refers to adjusting the base payment rates to ensure total aggregate payments are the same after implementing a policy change as they were prior to the change.) Nevertheless, over the long run, reducing the Medicare Trust Fund expenditures for patients who are transferred to a postacute care setting after a very short acute care hospital stay will improve the program's overall financial stability. Our analysis indicates that expanding the postacute care transfer policy to all DRGs would reduce program payments for these cases by approximately $1.9 billion for FY 2002.

If we were to expand the transfer policy to all DRGs, we would expand the list of those DRGs where a disproportionate share of the costs of the entire stay occurs early in the stay. We conducted analysis to identify those DRGs that would be eligible for the special transfer payment methodology specified in § 412.4(f)(2). As stated above, currently, three DRGs (DRGs 209, 210, and 211) are paid under a special transfer payment calculation whereby they receive 50 percent of the full DRG payment amount on the first day of the stay for cases transferred to a postacute care provider.

We identified cases that were transferred to home health care, SNFs, or long-term care, matching records by beneficiary identification numbers and discharge and admission dates. We standardized charges to account for differences in area wage levels, indirect medical education costs, and disproportionate share payments, and we reduced charges to costs using the available cost-to-charge ratios.

We then grouped the costs by DRG and length of stay. The average costs for transfer cases with a length of stay of 1 day were compared to the costs of transfer cases whose length of stay

approximated the geometric mean length of stay for that particular DRG. The average costs for the transfer cases with a length of stay of 1 day were also compared to costs for all cases with a length of stay approximating the geometric mean length of stay across the DRG. Based on this analysis, we identified the following DRGs that, if the postacute care transfer policy were to be expanded, would qualify for the special postacute care transfer payment policy of 50 percent of the full DRG payment for the first day of the stay:

- DRG 7 (Peripheral and Cranial Nerve and Other Nervous System Procedures with CC);
- DRG 159 (Hernia Procedures Except Inguinal and Femoral Age >17 with CC);
- DRG 218 (Lower Extremity and Humerus Procedure Except Hip, Foot, Femur Age >17 with CC);
- DRG 226 (Soft Tissue Procedures with CC);
- DRG 263 (Skin Graft and/or Debridement for Skin Ulcer or Cellulitis with CC);
- DRG 264 (Skin Graft and/or Debridement for Skin Ulcer or Cellulitis without CC);
- DRG 306 (Prostatectomy with CC);
- DRG 308 (Minor Bladder Procedures with CC);
- DRG 315 (Other Kidney and Urinary Tract O.R. Procedures);
- DRG 493 (Laparoscopic Cholecystectomy without C.D.E. with CC); and
- DRG 497 (Spinal Fusion Except Cervical with CC).

This list contains DRGs not currently paid under the special formula (DRGs 209, 210, and 211 will continue to receive the special payment). All of the DRGs in the list meet the following criteria: The average costs of transfer cases on the first day equals the average costs of cases staying the geometric mean length of stay; the geometric mean length of stay is 4 days or greater; and there were at least 50 transfer cases occurring on the first day of the stay.

We also note that DRGs 263 and 264 (which are included in the current list of 10 DRGs subject to the postacute care transfer policy) would qualify for special payment, even though both DRGs have not previously received payment under the special payment provision. However, DRG 264 does qualify under the criteria described above for identifying cases for the potential expanded postacute care transfer policy. Because DRGs 263 and 264 are paired DRGs (that is, the only difference in the cases assigned to DRG 263 as opposed to DRG 264 is that the patient has a complicating or comorbid condition), we would include both DRGs under this expanded policy. If we were to include only DRG 264, there would be an incentive not to include a code identifying a complicating or comorbid condition, so that a transfer case would be assigned to DRG 264 instead of DRG 263 due to the higher per diem payment for DRG 264.

Rather than expand the postacute care transfer policy to all DRGs, another option that we are considering for the final rule is expanding the postacute care transfer policy only to additional DRGs that have high rates of transfers, similar to the initial implementation of only 10 DRGs. For example, an incremental expansion would be to add another 10 DRGs to the policy. Using the same criteria to identify DRGs with high postacute care transfer rates, we identified additional DRGs to include in the postacute care transfer policy. We note that three of the DRGs we identified are paired DRGs (that is, they contain a CC/no-CC split). For the same reason given above for treating paired DRGS consistently, we would include the pairs for the 10 DRGs identified. We estimate the impact of this approach would be to reduce payments to hospitals by approximately $916 million for FY 2002. Under this approach, discharges from the following 13 DRGs (in addition to the 10 DRGs already subject to the postacute care transfer policy) could be considered to be subject to an alternative postacute care transfer policy:

- DRG 12 (Degenerative Nervous System Disorders);
- DRG 79 (Respiratory Infections and Inflammations Age >17 with CC);
- DRG 80 (Respiratory Infections and Inflammations Age >17 without CC);
- DRG 107 (Coronary Bypass with Cardiac Catheterization);
- DRG 109 (Coronary Bypass with PTCA or Cardiac Catheterization);
- DRG 148 (Major Small and Large Bowel Procedures with CC);
- DRG 149 (Major Small and Large Bowel Procedures without CC);
- DRG 239 (Pathological Fractures and Musculoskeletal System and Connective Tissue Malignancy);
- DRG 243 (Medical Back Problems);
- DRG 320 (Kidney and Urinary Tract Diagnoses Age >17 with CC);
- DRG 321 (Kidney and Urinary Tract Diagnoses Age >17 without CC);
- DRG 415 (O.R. Procedure for Infections and Parasitic Diseases); and
- DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis).

Expanding the postacute care transfer policy in this limited manner, however, would retain many of the potential inequities of the current system. Although we are concerned about the potential for a large impact of implementing any expansion of the postacute care transfer payment policy, we believe that the current policy may create payment inequities across patients and across hospitals. By expanding the postacute transfer policy, we would expect to reduce or eliminate these possible inequities. Therefore, we are soliciting comments on the two options we have identified and discussed in this proposed rule. In the final rule, we could adopt one of the approaches discussed above, or some other approach based on comments received on this proposal for addressing this issue. If commenters submit comments on alternate approaches, we are asking them to also provide useful data relating to alternative DRGs to which the expansion should or should not apply and detailed supporting explanations.

If we adopt either of the proposals discussed above or a variation based on comments submitted, we would follow procedures similar to those that are currently followed for treating cases identified as transfers in the DRG recalibration process. That is, as described in the discussion of DRG recalibration in section II.C. of this proposed rule, additional transfer cases would be counted as a fraction of a case based on the ratio of a hospital's transfer payment under the per diem payment methodology to the full DRG payment for nontransfer cases.

2. Technical Correction

When we revised our regulations on payments for discharges and transfers under § 412.4 in the July 31, 1998 final rule (63 FR 41003), we inadvertently did not exclude discharges from one hospital area or unit to another inpatient area or unit of the hospital that is paid under the acute care hospital inpatient prospective payment system (§ 412.4(b)(2)) from the types of cases paid under the general rule for transfer cases. We are proposing to correct the regulation text to reflect our policy (as reflected in prior preamble language) that transfers from one area or unit within a hospital to another are not paid as transfers (except as described under the special 10 DRG rule at § 412.4(c)). We are proposing to correct this error by revising § 412.4(f)(1) to provide that only the circumstances described in paragraph (b)(1) and (c) of § 412.4 are paid as transfers under the general transfer rule. This proposed correction

would reflect the fact that transfers under § 412.4(b)(2) are to be paid as discharges and not transfers.

B. Sole Community Hospitals (SCHs) (§§ 412.77 and 412.92)

1. Phase-In of FY 1996 Hospital-Specific Rates

Under the acute care hospital inpatient prospective payment system, special payment protections are provided to a sole community hospital (SCH). Section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that, by reason of factors such as isolated location, weather conditions, travel conditions, absence of other like hospitals (as determined by the Secretary), or historical designation by the Secretary as an essential access community hospital, is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations that set forth the criteria that a hospital must meet to be classified as an SCH are located in § 412.92.

To be classified as an SCH, a hospital either must have been designated as an SCH prior to the beginning of the hospital inpatient prospective payment system on October 1, 1983, or must be located more than 35 miles from other like hospitals, or the hospital must be located in a rural area and meet one of the following requirements:

- It is located between 25 and 35 miles from other like hospitals, and it—
  —Serves at least 75 percent of all inpatients, or at least 75 percent of Medicare beneficiary inpatients, within a 35-mile radius or, if larger, within its service area; or
  —Has fewer than 50 beds and would qualify on the basis of serving at least 75 percent of its area's inpatients except that some patients seek specialized care unavailable at the hospital.
- It is located between 15 and 35 miles from other like hospitals, and because of local topography or extreme weather conditions, the other like hospitals are inaccessible for at least 30 days in each of 2 out of 3 years.
- The travel time between the hospital and the nearest like hospital is at least 45 minutes because of distance, posted speed limits, and predictable weather conditions.

Effective with hospital cost reporting periods beginning on or after April 1, 1990, section 1886(d)(5)(D)(i) of the Act, as amended by section 6003(e) of Public Law 101–239, provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment to the hospital for the cost reporting period:

- The Federal rate applicable to the hospital;
- The updated hospital-specific rate based on FY 1982 costs per discharge; or
- The updated hospital-specific rate based on FY 1987 costs per discharge.

Section 405 of Public Law 106–113 added section 1886(b)(3)(I) to the Act, and section 213 of Public Law 106–554 made further amendments to that section of the Act extending to all SCHs the ability to rebase their hospital-specific rates using their FY 1996 operating costs, effective for cost reporting periods beginning on or after October 1, 2000. The provisions of section 1886(b)(3)(I) of the Act were addressed in the June 13, 2001 interim final rule with comment period (66 FR 32177) and were finalized in the August 1, 2001 final rule (66 FR 39872).

In the June 13, 2001 interim final rule, we correctly described the provisions of section 1886(b)(3)(I) of the Act, as amended, and their implementation. However, in the August 1, 2001 final rule, in summarizing the numerous legislative provisions that had affected payments to SCHs, we incorrectly described the application of the statutory provisions in the background section of the preamble on SCHs (66 FR 39872). (We wish to point out that the Addendum to the August 1, 2001 final rule accurately describes the calculation of the hospital-specific rate (66 FR 39944).) Specifically, the payment options that we described in the August 1, 2001 preamble language on SCHs were incorrect in that we did not include the Federal rate in the blends. Therefore, we are providing below a correct description of the provisions of section 1886(b)(3)(I) of the Act and clarifying their application in determining which of the payment options will yield the highest rate of payment for SCHs.

For purposes of payment to SCHs for which the FY 1996 hospital-specific rate yields the greatest aggregate payment, the Federal rate is included in the blend, as set forth below:

- For discharges during FY 2001, 75 percent of the greater of the Federal amount or the updated FY 1982 or FY 1987 hospital-specific rates (identified in the statute as the subsection (d)(5)(D)(i) amount), plus 25 percent of the updated FY 1996 hospital-specific rate (identified in the statute as the ''rebased target amount'').
- For discharges during FY 2002, 50 percent of the greater of the Federal amount or the updated FY 1982 or FY 1987 hospital-specific rates, plus 50 percent of the updated FY 1996 hospital-specific rate.
- For discharges during FY 2003, 25 percent of the greater of the Federal amount or the updated FY 1982 or FY 1987 hospital-specific rates, plus 75 percent of the updated FY 1996 hospital-specific rate.
- For discharges during FY 2004 and subsequent fiscal years, the hospital-specific rate would be determined based on 100 percent of the updated FY 1996 hospital-specific rate.

For each cost reporting period, the fiscal intermediary determines which of the payment options will yield the highest rate of payment. Payments are automatically made at the highest rate using the best data available at the time the fiscal intermediary makes the determination. However, it may not be possible for the fiscal intermediary to determine in advance precisely which of the rates will yield the highest payment by year's end. In many instances, it is not possible to forecast the outlier payments, the amount of the disproportionate share hospital (DSH) adjustment, or the indirect medical education (IME) adjustment, all of which are applicable only to payments based on the Federal rate. The fiscal intermediary makes a final adjustment at the close of the cost reporting period to determine precisely which of the payment rates would yield the highest payment to the hospital.

If a hospital disagrees with the fiscal intermediary's determination regarding the final amount of program payment to which it is entitled, it has the right to appeal the fiscal intermediary's decision in accordance with the procedures set forth in Subpart R of Part 405, which concern provider payment determinations and appeals.

The regulation text of § 412.77 and § 412.92(d) that was revised to incorporate the provisions of section 1886(b)(3)(I) of the Act, as amended, and published in the June 13, 2001 interim final rule with comment period (66 FR 32192 through 32193) and finalized in the August 1, 2001 final rule (66 FR 39932), is accurate.

2. SCH Like Hospitals

Section 1886(d)(5)(D)(iii) of the Act provides that, to qualify as a SCH, a hospital must be not more than 35 road miles from another hospital. There are several other conditions under which a hospital may qualify as a SCH, including if it is the ''* * * sole source of inpatient hospital services reasonably available to individuals in a geographic area * * *'' because of factors such as the ''* * * absence of other like hospitals * * *'' We have defined a ''like hospital'' in regulations as a hospital furnishing short-term, acute

care (§ 412.92(c)(2)). Like hospitals refers to hospitals paid under the acute care hospital inpatient prospective payment system.

We have become aware that, in some cases, new specialty hospitals that offer a very limited range of services have opened within the service area of a SCH and may be threatening the special status of the SCH. For example, a hospital that offers only a select type of surgery on an inpatient basis would qualify under our existing rules as an SCH ''like hospital'' if it met the hospital conditions of participation and was otherwise eligible for payment under the acute care hospital inpatient prospective payment system. Under our existing regulations, a SCH could lose its special status due to the opening of such a specialty hospital, even though there is little, if any, overlap in the types of services offered by the SCH and the specialty hospital.

We believe that limiting eligibility for SCH status to hospitals without SCH like hospitals in their service area is a way to identify those hospitals that truly are the sole source of short-term acute-care inpatient services in the community. A limited-service, specialty hospital, by definition, would not offer an alternate source of care in the community for most inpatient services and therefore, we believe, should not be considered a ''like'' hospital with the effect of negating SCH status of a hospital that is the sole source of short-term acute care inpatient services in the community. Therefore, we are proposing to amend the definition of SCH like hospitals under § 412.92(c)(2), effective with cost reporting periods beginning on or after October 1, 2002, to exclude any hospital that provides no more than a very small percent of the services furnished by the limited-service facility that overlap with the services provided by the SCH. We believe the percentage of overlapping services should be sufficiently small so that we can ensure that only hospitals that truly are the sole source of short-term acute-care in their community qualify for SCH status. Therefore, we are proposing that this percentage be set at 3 percent. However, we are soliciting public comments on alternate appropriate levels of service overlap, as well as on the overall proposed change to the definition of like hospitals.

C. Outlier Payments: Technical Change (§ 412.80)

Sections 1886(d)(5)(A) and (d)(5)(K) of the Act provide for payments, in addition to the basic prospective payments, for ''outlier'' cases; that is, cases involving extraordinarily high costs. Cases qualify for outlier payments by demonstrating costs that exceed a fixed loss cost outlier threshold equal to the prospective payment rate for the DRG plus any IME (§ 412.105) and DSH (§ 412.106) payments for the case and, for discharges on or after October 1, 2001, additional payments for new technologies or services.

Implementing regulations for outlier payments are located in subpart F of part 412. Paragraph (a) of § 412.80 specifies the basic rules for making the additional outlier payments, broken down into three applicable effective periods. We have become aware that in paragraph (a)(2), which relates to outlier payments for discharges occurring on or after October 1, 1997, and before October 1, 2001, we did not include language to specify that the additional costs of outlier cases must exceed the standard DRG payment and any additional payment the hospital would receive for IME and for DSH, plus a fixed loss dollar threshold. Therefore, we are proposing to make a technical change by revising § 412.80(a)(2), applicable for discharges occurring during the period between October 1, 1997 and October 1, 2001, to include the appropriate language regarding additional payments for IME and payments for DSH. (We note that when we amended § 412.80 to incorporate the provisions on the additional payments for new technology under paragraph (a)(3) (66 FR 46924, September 7, 2001), effective October 1, 2001, we did include this language.)

D. Rural Referral Centers (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the prospective payment system as a rural referral center. For discharges occurring before October 1, 1994, rural referral centers received the benefit of payment based on the other urban amount rather than the rural standardized amount. Although the other urban and rural standardized amounts were the same for discharges beginning with that date, rural referral centers continue to receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 1886(d)(8)(E) of the Act, as amended, creates a mechanism, separate and apart from the MGCRB, permitting an urban hospital to apply to the Secretary to be treated as being located in the rural area of the State in which the hospital is located. The statute directs the Secretary to treat a qualifying hospital as being located in the rural area for purposes of provisions under section 1886(d) of the Act. One of the criteria under section 1886(d)(8)(E) of the Act is that the hospital would qualify as an SCH or a rural referral center if it were located in a rural area. An SCH would be eligible to be paid on the basis of the higher of its hospital-specific rate or the Federal rate. On the other hand, a primary benefit under section 1886(d) of the Act for an urban hospital to become a rural referral center would be waiver of the proximity requirements that are otherwise applicable under the MGCRB process, as set forth in § 412.230(a)(3)(i).

Although hospitals that are reclassified as rural under section 1886(d)(8)(E) of the Act are not permitted to reclassify through the MGCRB, effective October 1, 2000, hospitals located in what is now an urban area if they were ever a rural referral center, were reinstated to rural referral center status. These hospitals may then take advantage of the waiver from the proximity requirements for reclassification.

In addition, as discussed in 62 FR 45999 and 63 FR 26317, under section 4202 of Public Law 105–33, a hospital that was classified as a rural referral center for FY 1991 is to be classified as a rural referral center for FY 1998 and later years so long as that hospital continued to be located in a rural area and did not voluntarily terminate its rural referral center status. Otherwise, a hospital seeking rural referral center status must satisfy applicable criteria. One of the criteria under which a hospital may qualify as a rural referral center is to have 275 or more beds available for use. A rural hospital that does not meet the bed size requirement can qualify as a rural referral center if the hospital meets two mandatory prerequisites (specifying a minimum case-mix index and a minimum number of discharges) and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). With respect to the two mandatory prerequisites, a hospital may be classified as a rural referral center if—

- The hospital's case-mix index is at least equal to the lower of the median case-mix index for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median case-mix index for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. (The number of discharges criterion for an osteopathic

hospital is at least 3,000 discharges per year.)

1. Case-Mix Index

Section 412.96(c)(1) provides that CMS will establish updated national and regional case-mix index values in each year's annual notice of prospective payment rates for purposes of determining rural referral center status. The methodology we use to determine the proposed national and regional case-mix index values is set forth in regulations at § 412.96(c)(1)(ii). The proposed national mean case-mix index value includes all urban hospitals nationwide, and the proposed regional values are the median values of urban hospitals within each census region, excluding those with approved teaching programs (that is, those hospitals receiving indirect medical education payments as provided in § 412.105). These values are based on discharges occurring during FY 2001 (October 1, 2000 through September 30, 2001) and include bills posted to CMS's records through December 2001.

We are proposing that, in addition to meeting other criteria, hospitals with fewer than 275 beds, if they are to qualify for initial rural referral center status for cost reporting periods beginning on or after October 1, 2002, must have a case-mix index value for FY 2001 that is at least—

- 1.3229; or
- The median case-mix index value for urban hospitals (excluding hospitals with approved teaching programs as identified in § 412.105) calculated by CMS for the census region in which the hospital is located.

The median case-mix index values by region are set forth in the following table:

Region	Case-Mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.2089
2. Middle Atlantic (PA, NJ, NY)	1.2235
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.2985
4. East North Central (IL, IN, MI, OH, WI)	1.2377
5. East South Central (AL, KY, MS, TN)	1.2459
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.1616
7. West South Central (AR, LA, OK, TX)	1.2641
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.3255
9. Pacific (AK, CA, HI, OR, WA)	1.2779

The preceding numbers will be revised in the final rule to the extent required to reflect the updated FY 2001 MedPAR file, which will contain data from additional bills received through March 31, 2002.

Hospitals seeking to qualify as rural referral centers or those wishing to know how their case-mix index value compares to the criteria should obtain hospital-specific case-mix index values from their fiscal intermediaries. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, these case-mix index values are computed based on all Medicare patient discharges subject to DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS will set forth the national and regional numbers of discharges in each year's annual notice of prospective payment rates for purposes of determining rural referral center status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. We are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2001 (that is, October 1, 2000 through September 30, 2001). That is the latest year for which we have complete discharge data available.

Therefore, we are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial rural referral center status for cost reporting periods beginning on or after October 1, 2002, must have as the number of discharges for its cost reporting period that began during FY 2001 a figure that is at least—

- 5,000; or
- The median number of discharges for urban hospitals in the census region in which the hospital is located, as indicated in the following table:

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	6,905
2. Middle Atlantic (PA, NJ, NY)	8,648
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	8,914
4. East North Central (IL, IN, MI, OH, WI)	8,040
5. East South Central (AL, KY, MS, TN)	6,748
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	5,696
7. West South Central (AR, LA, OK, TX)	6,220
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	9,167
9. Pacific (AK, CA, HI, OR, WA)	7,053

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, 5,000 discharges is the minimum criterion for all hospitals. These numbers will be revised in the final rule based on the latest FY 2001 cost report data.

We reiterate that an osteopathic hospital, if it is to qualify for rural referral center status for cost reporting periods beginning on or after October 1, 2002, must have at least 3,000 discharges for its cost reporting period that began during FY 2001.

E. Indirect Medical Education (IME) Adjustment (§ 412.105)

1. Background

Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals that have residents in an approved graduate medical education (GME) program receive an additional payment for a Medicare discharge to reflect the higher indirect operating costs of teaching hospitals relative to nonteaching hospitals. The existing regulations regarding the calculation of this additional payment, known as the indirect medical education (IME) adjustment, are located at § 412.105. The additional payment is based on the IME adjustment factor. The IME adjustment factor is calculated using a hospital's ratio of residents to beds, which is represented as r, and a multiplier, which is represented as c, in the following equation: $c \times [(1 + r)^{.405} - 1]$. The formula is traditionally described in terms of a certain percentage increase in payment for every 10-percent increase in the resident-to-bed ratio. Section 1886(d)(5)(B)(ii)(VII) of the Act provides that, for discharges occurring during FY 2003 and thereafter, the ''c'' variable, or formula multiplier, is 1.35. The formula multiplier of 1.35 represents a 5.5-percent increase in IME payment for every 10-percent increase in the resident-to-bed ratio.

2. Temporary Adjustments to the FTE Cap To Reflect Residents Affected by Residency Program Closure: Resident-to-Bed Ratio for Displaced Residents (§§ 412.105(a) and (f)(1)(ix))

In the August 1, 2001 hospital inpatient prospective payment system final rule (66 FR 39899), we expanded the policy at existing § 413.86(g)(8) (proposed to be redesignated as § 413.86(g)(9) in this proposed rule), which allows a temporary adjustment to a hospital's FTE cap when a hospital trains additional residents because of another hospital's closure, to also allow a temporary adjustment when a hospital trains residents displaced by the closure of another hospital's residency program (but the hospital itself remains open). We revised regulations at existing § 413.86(g)(8) to state that, if a hospital that closes its residency training program agrees to temporarily reduce its FTE cap, another hospital(s) may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of the former hospital's residency training program. We defined ''closure of a hospital residency training program'' as when the hospital ceases to offer training for residents in a particular approved medical residency training program. The methodology for adjusting the caps for the ''receiving'' hospital and the ''hospital that closed its program'' as they apply to the IME adjustment and direct GME payments is set forth in the regulations at existing §§ 412.105(f)(1)(ix) and 413.86(g)(8)(iii), respectively.

In the August 1, 2001 rule, we noted a commenter who requested that CMS further revise the regulations to grant temporary relief to hospitals in calculating the IME adjustment with regard to application of the resident-to-bed ratio cap (66 FR 39900). The commenter believed that while the cap on the number of residents has been temporarily adjusted, if the receiving hospital is not allowed to also adjust its resident-to-bed ratio in the prior year, the lower resident-to-bed ratio from the prior year would act to reduce the IME payments to the receiving hospital. The commenter suggested that, similar to the exception for residents in hospitals that begin new programs under § 412.105(a)(1), an adjustment should be made to the prior year's FTE residents equal to the increase in the current year's FTEs that is attributable to the transferred residents. In response to the commenter, we stated that we had decided not to allow the exclusion of these displaced residents in applying the resident-to-bed ratio cap. We explained that, while we believed that the receiving hospital may be held to a lower cap in the first year of training the displaced residents, the receiving hospital would benefit from the higher cap in the subsequent years as the displaced residents complete their training and leave that hospital. However, we indicated that we would consider suggestions for possible future changes to this policy.

We have revisited this policy and now realize that our rationale for not allowing the adjustment for displaced residents to the resident-to-bed ratio cap may have been faulty. We initially believed that, in the year following the last year in which displaced residents trained at the receiving hospital, the receiving hospital would benefit from the higher resident-to-bed ratio cap. However, we have determined that, while it is correct that the hospital will have a higher resident-to-bed ratio cap because of the higher number of displaced residents in the prior year, the receiving hospital's FTE count decreases as the displaced residents finish their training. Therefore, the receiving hospital would not need a higher resident-to-bed ratio cap to accommodate the remaining FTEs. Consequently, the higher resident-to-bed ratio cap in fact would not benefit the receiving hospital. Thus, we are now proposing to allow the exclusion of residents displaced by either the closure of another hospital's program or another hospital's closure in applying the resident-to-bed ratio cap. Specifically, assuming a hospital is eligible to receive a temporary adjustment to its FTE cap as described in existing § 413.86(g)(8), we are proposing that, solely for purposes of applying the resident-to-bed ratio cap in the *first* year in which the receiving hospital is training the displaced residents, the receiving hospital may adjust the numerator of the prior year's resident-to-bed ratio by the number of FTE residents that has caused the receiving hospital to exceed its FTE cap. (We note that this adjustment to the resident-to-bed ratio cap does not apply to changes in bed size). In the years subsequent to the first year in which the receiving hospital takes in the displaced residents, we believe an adjustment to the numerator of the prior year's resident-to-bed ratio is unnecessary because the receiving hospital's actual FTE count in those years would either stay the same or, as the displaced residents complete their training or leave that hospital, decrease each year. If all other variables remain constant, an increase in the current year's resident-to-bed ratio will establish a higher cap for the following year. In the second and subsequent years of training the displaced residents, the receiving hospital's resident-to-bed ratio for the current year would not be higher than the prior year's ratio and thus would not be limited by the resident-to-bed ratio cap.

In the cost reporting period following the departure of the last displaced residents, when the temporary FTE cap adjustment is no longer applicable, we are proposing that, solely for purposes of applying the resident-to-bed ratio cap, the resident-to-bed ratio be calculated *as if* the displaced residents had not trained at the receiving hospital in the prior year. In other words, in the year that the hospital is no longer training displaced residents, the attendant FTEs should be removed from the numerator of the resident-to-bed ratio from the prior year (that is, the resident-to-bed ratio cap). We believe that because we are proposing to allow the adjustment to the resident-to-bed ratio cap in the first year in which the receiving hospital trains displaced residents, it is equitable to remove those FTEs when calculating the resident-to-bed ratio cap after all the displaced

residents have completed their training at the receiving hospital.

The following is an example of how the receiving hospital's IME resident-to-bed ratio cap would be adjusted for displaced residents coming from either a closed hospital or a closed program:

Example: Hospital A has a family practice program with 3 residents. On June 30, 2002, Hospital A closes. Hospital B, which also has a family practice program, agrees to continue the training of Hospital A's residents beginning July 1, 2002. Its fiscal year end is June 30. As of July 1, 2002, the 3 residents displaced by the closure of Hospital A include 1 PGY1 resident, 1 PGY2 resident, and 1 PGY3 resident. In addition, Hospital B has 5 of its own residents, an IME FTE resident cap of 5, and 100 beds. Subject to the criteria under existing § 413.86(g)(8), Hospital B's FTE cap is temporarily increased to 8 FTEs. According to the proposed policy stated above, Hospital B's resident-to-bed ratio and resident-to-bed ratio cap would be determined as follows:

July 1, 2002 through June 30, 2003

• Resident-to-bed ratio: 5 FTEs + 3 displaced FTEs / 100 beds = .08 (line 3.18 of Worksheet E, Part A of the Medicare cost report, Form CMS 2552–96).

(Note: For purposes of applying the rolling average calculation at § 412.105(f)(1)(v) to this example, it is assumed that Hospital B had 5 FTE residents in both the prior and the penultimate cost reporting periods. Therefore, 5 FTEs are used in the numerator of the resident-to-bed ratio. Under § 412.105(f)(1)(v), displaced residents are added to the receiving hospital's rolling average FTE count in each year that the displaced residents are training at the receiving hospital.)

• Resident-to-bed ratio cap: 5 FTEs (from fiscal year end June 30, 2002) + *3 displaced FTEs (from fiscal year end June 30, 2003)* / 100 beds = .08 (line 3.19 of Worksheet E, Part A of Form CMS 2552–96).

• The lower of the resident-to-bed ratio from the current year (.08) or the resident-to-bed ratio cap from the prior year (.08) is used to calculate the IME adjustment. Therefore, Hospital B would use a resident-to-bed ratio of .08 (line 3.20 of Worksheet E, Part A of Form CMS 2552–96).

July 1, 2003 through June 30, 2004

The PGY3 displaced resident has completed his or her family practice training on June 30, 2003 and has left Hospital B. Hospital B continues to train a displaced (now) PGY2 resident, and a displaced (now) PGY3 resident.

• Resident-to-bed ratio: 5 FTEs + 2 displaced FTEs / 100 beds = .07 (line 3.18 of Worksheet E, Part A of Form CMS 2552–96).

• Resident-to-bed ratio cap: 5 FTEs (from fiscal year end June 30, 2003) + 3 displaced FTEs (from fiscal year end June 30, 2003) / 100 beds = .08 (line 3.19 of Worksheet E, Part A of Form CMS 2552–96).

• The lower of the resident-to-bed ratio from the current year (.07) or the resident-to-bed ratio cap from the prior year (.08) is used to calculate the IME adjustment. Hospital B would use a resident-to-bed ratio of .07 (line 3.20 of Worksheet E, Part A of Form CMS 2552–96).

July 1, 2004 through June 30, 2005

Another of the remaining displaced residents has completed his or her family practice training on June 30, 2004 and has left Hospital B. Hospital B continues to train one displaced (now) PGY3 resident.

• Resident-to-bed ratio: 5 FTEs + 1 displaced FTE / 100 beds = .06 (line 3.18 of Worksheet E, Part A of Form CMS 2552–96).

• Resident-to-bed ratio cap: 5 FTEs (from fiscal year end June 30, 2004) + 2 displaced FTEs (from fiscal year end June 30, 2004) / 100 beds = .07 (line 3.19 of Worksheet E, Part A of Form CMS 2552–96).

• The lower of the resident-to-bed ratio from the current year (.06) or the resident-to-bed ratio cap from the prior year (.07) is used to calculate the IME adjustment. Hospital B would use a resident-to-bed ratio of .06 (line 3.20 of Worksheet E, Part A of Form CMS 2552–96).

July 1, 2005 through June 30, 2006

The last displaced resident has completed his or her family practice training on June 30, 2005 and has left Hospital B. Hospital B no longer trains any displaced residents, and, therefore, the last displaced resident is *removed* from the numerator of the resident-to-bed ratio cap.

• Resident-to-bed ratio: 5 FTEs + 0 displaced FTEs / 100 beds = .05

• Resident-to-bed ratio cap: 5 FTEs (from fiscal year end June 30, 2005) + *0 displaced FTEs (subtract 1 displaced FTE from FYE June 30, 2005)* / 100 beds = .05

• The lower of the resident-to-bed ratio from the current year (.05) or the resident-to-bed ratio cap from the prior year (.05) is used to calculate the IME adjustment. Hospital B would use a resident-to-bed ratio of .05.

We are proposing that this exception to the resident-to-bed ratio cap for residents coming from a closed hospital or a closed program would be effective for cost reporting periods beginning on or after October 1, 2002. We are proposing to revise § 412.105(a)(1) accordingly.

3. Counting Beds for the IME and DSH Adjustments (§ 412.105(b) and § 412.106(a)(l)(i))

As discussed under section V.E.2. of this proposed rule, the regulations for determining the number of beds to be used in calculating the resident-to-bed ratio for the IME adjustment are located at § 412.105(b). These regulations also are used to determine the number of beds for other purposes, including calculating the DSH adjustment at § 412.106(a)(l)(i). Section 412.105(b) specifies that the number of beds in a hospital is determined by counting the number of available bed days during the cost reporting period and dividing that number by the number of days in the cost reporting period. The number of available bed days does not include beds or bassinets in the healthy newborn nursery, custodial care beds, or beds in excluded distinct part hospital units.

Section 2405.3G of Part I of the Medicare Provider Reimbursement Manual (PRM) further defines ''available'' beds. Specifically, section 2405.3G states that an available bed is a bed that is permanently maintained and is available for use to lodge inpatients. However, there has been some uncertainty concerning the application of this definition of ''available.'' For example, a question arises as to whether beds in rooms or entire units that are unoccupied for extended periods of time should continue to be counted on the basis that, if there would ever be a need, they could be put into use.

Counting the number of beds in a hospital is intended to measure the size of a hospital's routine acute care inpatient operations. While hospitals necessarily maintain some excess capacity, we believe there is a point where excess capacity may distort the bed count. Therefore, we are proposing to revise our policy concerning the determination of a hospital's bed size to exclude beds that represent an excessive level of unused capacity. We believe this proposed refinement of our bed counting policy would better capture the size of a hospital's inpatient operations as described above.

We analyzed Medicare hospital data and found that, among hospitals that have between 100 and 130 beds, hospitals receiving DSH payments have lower occupancy rates than similar hospitals not receiving DSH payments. Because DSH payments are higher for urban hospitals with more than 100

beds, there may be an incentive for these hospitals to maintain excess capacity in order to qualify for those higher payments. Among 189 urban hospitals in this bed-size range that did not receive DSH payments during FY 1999, the average occupancy rate was 55 percent. However, among 294 urban hospitals in this bed-size range that did receive DSH payments during FY 1999, the average occupancy rate was 47 percent. Twenty-five percent of this group of hospitals (those receiving DSH payments) had occupancy rates below 35 percent. Among the hospitals not receiving DSH payments, 25 percent had occupancy rates below 43 percent. We believe this is indicative of a tendency among some small urban hospitals to maintain excess capacity in order to qualify for higher DSH payments. Therefore, we are proposing that if a hospital's reported bed count results in an occupancy rate (average daily census of patients divided by number of beds) below 35 percent, the applicable bed count, for purposes of establishing the number of available beds for that hospital, would exclude beds that would result in an average annual occupancy rate below 35 percent (proposed § 412.105(b)(3)).

For example, if a hospital reports 105 beds for a cost reporting period, but has an average daily census of 26 patients for that same cost reporting period, its occupancy rate equals 24.8 percent (that is, 26/105). Because its occupancy rate is below the proposed minimum threshold of 35 percent, its maximum available bed count would be 74, which is the number of beds that would result in an occupancy rate of 35 percent, given an average daily census of 26 patients (that is, 26/.35).

We would otherwise continue to determine a hospital's bed size using existing regulations and program manual instructions, including the application of the available bed policy.

Following are the steps a hospital would undertake in determining its number of beds in a cost reporting period under our proposed policy:

Step 1: Determine the number of available beds using the existing regulations at § 412.105(b) and PRM instructions.

Step 2: Determine the average daily census by dividing the total number of inpatient acute care days in the hospital by the number of days in the cost reporting period.

Step 3: Divide the average daily census determined in step 2 by 35 percent.

Step 4: Use the *lower* of the number of beds as determined under step 1, or the result of step 3 for purposes of the IME and DSH calculations.

We believe that this proposed policy more accurately indicates the size of a hospital's operations. We are proposing to specify under proposed § 412.105(b)(3) that if a hospital's reported bed count results in an occupancy rate below 35 percent, the applicable bed count for that hospital would be the number of beds that would result in an occupancy rate of 35 percent. We are proposing to make this proposed policy effective for discharges occurring on or after October 1, 2002.

F. Medicare-Dependent, Small Rural Hospitals: Ongoing Review of Eligibility Criteria (§ 412.108(b))

Section 6003(f) of the Omnibus Budget Reconciliation Act of 1989 (Public Law 101–239) added section 1886(d)(5)(G) to the Act and created the category of Medicare-dependent, small rural hospitals (MDHs). MDHs are eligible for a special payment adjustment under the acute care hospital inpatient prospective payment system. Initially, in order to be classified as an MDH, a hospital must have met all of the following criteria:

- The hospital is located in a rural area (as defined in § 412.63(b);
- The hospital has 100 or fewer beds (as defined at § 412.105(b)) during the cost reporting period;
- The hospital is not classified as an SCH (as defined at § 412.92); and
- The hospital has no less than 60 percent of its inpatient days or discharges attributable to inpatients receiving Medicare Part A benefits during its cost reporting period beginning in FY 1987.

MDHs were eligible for a special payment adjustment under the acute care hospital inpatient prospective payment system, effective for cost reporting periods beginning on or after April 1, 1990, and ending on or before March 31, 1993. Hospitals classified as MDHs were paid using the same methodology applicable to SCHs, that is, based on whichever of the following rates yielded the greatest aggregate payment for the cost reporting period:

- The national Federal rate applicable to the hospital.
- The updated hospital-specific rate based on FY 1982 costs per discharge.
- The updated hospital-specific rate based on FY 1987 costs per discharge.

Section 13501(e)(1) of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66) extended the MDH provision through FY 1994 and provided that, after the hospital's first three 12-month cost reporting periods beginning on or after April 1, 1990, the additional payment to an MDH whose applicable hospital-specific rate exceeded the Federal rate was limited to 50 percent of the amount by which the hospital-specific rate exceeded the Federal rate. The MDH provision expired effective with cost reporting periods beginning on or after October 1, 1994.

Section 4204(a)(3) of Public Law 105–33 reinstated the MDH special payment for discharges occurring on or after October 1, 1997 and before October 1, 2001, but did not revise the qualifying criteria for these hospitals or the payment methodology.

Section 404(a) of Public Law 106–113 extended the MDH provision to discharges occurring before October 1, 2006.

As specified in the June 13, 2001 interim final rule with comment period (66 FR 32172) and finalized in the August 1, 2001 final rule (66 FR 39883), section 212 of Public Law 106–554 provided that, effective with cost reporting periods beginning on or after April 1, 2001, a hospital has the option to base MDH eligibility on two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report, rather than on the cost reporting period that began during FY 1987 (section 1886(d)(5)(G)(iv)(IV) of the Act). According to section 1886(d)(5)(G)(iv)(IV) of the Act, the criteria for at least 60 percent Medicare utilization will be met if, in at least ''2 of the 3 most recently audited cost reporting periods for which the Secretary has a settled cost report'', at least 60 percent of the hospital's inpatient days or discharges were attributable to individuals receiving Medicare Part A benefits.

We would like to point out that cost reports undergo different levels of review. For example, some cost reports are settled with a desk review; others, through a full field audit. We believe the intention of the law is to provide hospitals the ability to qualify for MDH status based on their most recent settled cost reporting periods, each of which undergoes a level of audit in its settlement.

Hospitals that qualify under section 1886(d)(5)(G)(iv)(IV) of the Act are subject to the other provisions already in place for MDHs. That is, all MDHs are paid using the payment methodology as defined in § 412.108(c) and may be eligible for the volume decrease provision as defined in § 412.108(d).

Under existing classification procedures at § 412.108(b), a hospital must submit a written request to its fiscal intermediary to be considered for

MDH status based on at least two of its three most recently audited cost reporting periods for which the Secretary has a settled cost report (as specified in § 412.108(a)(1)(iii)(c)). The fiscal intermediary will make its determination and notify the hospital within 90 days from the date it receives the hospital's request and all of the required documentation. The intermediary's determination is subject to review under 42 CFR Part 405, Subpart R. MDH status is effective 30 days after the date of written notification of approval.

We are proposing to clarify and to codify in the regulations (proposed § 412.108(b)(4)) that an approved classification as an MDH remains in effect unless there is a change in the circumstances under which the classification was approved. That is, in order to maintain its eligibility for MDH status, a hospital must continue to be a small (100 or fewer beds), rural hospital, with no less than 60 percent Medicare inpatient days or discharges during either its cost reporting period beginning in FY 1987 or during at least two of its three most recently settled cost reporting periods.

We also are proposing to clarify and to codify in the regulations (proposed § 412.108(b)(5)) that the fiscal intermediary will evaluate on an ongoing basis whether or not a hospital continues to qualify for MDH status. This proposed clarification would include evaluating whether or not a hospital that qualified for MDH status under section 1886(d)(5)(G)(iv)(IV) of the Act continues to qualify for MDH status based on at least two of its three most recently settled cost reporting periods.

In addition, we are proposing, (proposed § 412.108(b)(6)) that if a hospital loses its MDH status, that change in status would become effective 30 days after the fiscal intermediary provides written notification to the hospital that it no longer meets the MDH criteria. If the hospital would like to be considered for MDH status after another cost reporting period has been audited and settled, we are proposing to require that the hospital must reapply by submitting a written request to its fiscal intermediary (proposed § 412.108(b)(7)). An MDH that continues to meet the criteria would not have to reapply.

G. Eligibility Criteria for Reasonable Cost Payments to Rural Hospitals for Nonphysician Anesthetists (§ 412.113(c))

Currently, a rural hospital can qualify and be paid on a reasonable cost basis for qualified nonphysician anesthetists (certified registered nurse anesthetists (CRNAs) and anesthesiologist assistants) services for a calendar year beyond 1990 and subsequent years as long as it can establish before January 1 of that year that it did not provide more than 500 surgical procedures requiring anesthesia services, both inpatient and outpatient.

In the September 1, 1983 interim final rule with comment period that implemented the acute care hospital inpatient prospective payment system, we established the general policy to include, under that prospective payment system, inpatient hospital services furnished incident to a physician's service, with a time-limited exception for the inpatient hospital services of anesthetists (48 FR 39794). The purpose of this exception, which originally was for cost reporting periods beginning before October 1, 1986, was that the practice of physician-employer and anesthetist-employee was so widespread that we believed ''it would be disruptive of medical practice and adverse to the quality of patient care to require all such contracts to be renegotiated in the limited time available before the implementation of the prospective payment system.''

Section 2312 of Public Law 98–369 provided for reimbursement to hospitals on a reasonable cost basis as a pass-through for the costs that hospitals incur in connection with 27 the services of CRNAs. [3] Section 2312(c) provided that the amendment was effective for cost reporting periods beginning on or after October 1, 1984, and before October 1, 1987.

Section 9320 of Public Law 99–509 (which established a fee schedule for the services of nurse anesthetists) amended section 2312(c) of Public Law 98–369 by extending the pass-through provision for cost reporting periods beginning before January 1, 1989. Section 608 of Public Law 100–485 limited the pass-through provision effective during 1989, 1990, and 1991, to hospitals meeting the following criteria:

- As of January 1, 1988, the hospital employed or contracted with a certified nonphysician anesthetist;
- In 1987, the hospital had a volume of surgical procedures (including inpatient and outpatient procedures) requiring anesthesia services that did not exceed 250 (or such higher number as the Secretary determines to be appropriate); and
- Each certified nonphysician anesthetist employed by, or under contract with, the hospital has agreed not to bill under Part B of Medicare for professional services furnished by the anesthetist at the hospital.

Subsequently, section 6132 of Public Law 101–239 amended section 608 of Public Law 100–458 by raising the established 250-procedure threshold to 500 procedures (effective for anesthesia services furnished on or after January 1, 1990), and extended the cost pass-through indefinitely. However, section 6132 of Public Law 101–239 left intact the requirement that the hospital must have not exceeded a maximum number of surgical procedures (effectively raised to 500), both inpatient and outpatient, requiring anesthesia services during 1987. Also, the statutory authority for the Secretary to adopt such other appropriate maximum threshold volume of procedures as determined appropriate was not affected by section 6132.

In light of the age of this provision, we undertook to reexamine the appropriateness of the current 500-procedure threshold. Nonphysician anesthetists who are not employed by or have a contractual relationship with a hospital paid under this provision may receive payments under a fee schedule. Payments under the fee schedule are generally somewhat lower than those made on a reasonable cost basis. Therefore, hospitals that exceed 500 procedures may have difficulty retaining access to nonphysician anesthetists' services because cost reimbursement is unavailable. According to data from the American Association of Nurse Anesthetists (AANA), the average total annual compensation for a CRNA in 2001 was approximately $155,000. The AANA estimates that, based on payments under the Medicare fee schedule, a CRNA would have to provide at least 800 anesthesia procedures to reach this average level of compensation.

The statute provides the Secretary with the authority to determine the appropriateness of the volume threshold, in part, so that changes necessary to meet the needs of rural hospitals can be made. As we have found that hospitals that exceed the 500 surgical procedures may have difficulty in retaining access to nonphysician anesthetists' services, we believe that the appropriate maximum threshold for surgical procedures should be raised in order for the payment exception to apply to those hospitals most in need of this payment treatment. Based upon the data available to us concerning the best

[3] We noted in the August 31, 1984 final rule that section 2312 and the Conference Report used the term ''CRNA'' throughout. However, we believed it was Congressional intent to apply this pass-through payment amount to the services of all qualified hospital-employed nonphysician anesthetists (49 FR 34748).

estimates of average total compensation to a CRNA, we believe that the maximum volume threshold for surgical procedures requiring anesthesia services should be raised to 800. Therefore, to ensure continued access to nonphysician anesthetists' services in rural hospitals, we are proposing to revise §§ 412.113(c)(2)(ii) and (c)(2)(iii) to raise the 500-procedure threshold to 800 procedures.

H. Medicare Geographic Classification Review Board (MGCRB) Reclassification Process (§§ 412.230, 412.232, and 412.273)

With the creation of the MGCRB, beginning in FY 1991, under section 1886(d)(10) of the Act, hospitals could request reclassification from one geographic location to another for the purpose of using the other area's standardized amount for inpatient operating costs or the wage index value, or both (September 6, 1990 interim final rule with comment period (55 FR 36754), June 4, 1991 final rule with comment period (56 FR 25458), and June 4, 1992 proposed rule (57 FR 23631)). Implementing regulations in Subpart L of Part 412 (§§ 412.230 *et seq.*) set forth criteria and conditions for redesignations from rural to urban, rural to rural, or from an urban area to another urban area, with special rules for SCHs and rural referral centers.

1. Withdrawals, Teminations, and Cancellations

Under § 412.273(a) of our regulations, a hospital, or group of hospitals, may withdraw its application for reclassification at any time before the MGCRB issues its decision or, if after the MGCRB issues its decision, within 45 days of publication of our annual notice of proposed rulemaking concerning changes to the acute care hospital inpatient prospective payment system for the upcoming fiscal year (for example, this proposed rule for FY 2003). In the August 1, 2001 final rule, we specified that, for purposes of implementing section 304 of Public Law 106–554, the withdrawal procedures and the applicable timeframes in the existing regulations would apply to hospitals that receive 3-year reclassification for wage index purposes (66 FR 39886). Once effective, a withdrawal means that the hospital would not be reclassified for purposes of the wage index for FY 2003 (and would not receive continued reclassification for FYs 2004 and 2005), unless the hospital subsequently cancels its withdrawal.

Consistent with section 1886(d)(10)(D)(v) of the Act, a hospital may terminate its approved 3-year reclassification during the second or third years (§ 412.273(b)). This is a separate action from a reclassification withdrawal that occurs in accordance with the timeframes described above. Currently, in order to terminate an approved 3-year reclassification, we require the hospital to notify the MGCRB in writing within 45 days of the publication date of the annual proposed rule for changes to the hospital inpatient prospective payment system (§ 412.273(b)(1)(i)). A termination, unless subsequently cancelled, is effective for the full fiscal years remaining in the 3-year period.

We also provided that a hospital may apply for reclassification to a different area for the year corresponding to the second or third year of the reclassification (that is, an area different from the one to which it was originally reclassified) and, if successful, the reclassification would be for 3 years. Since the publication of the final rule, we received an inquiry regarding a situation where a hospital with an existing 3-year wage index reclassification successfully reclassifies to a different area, then withdraws from that second reclassification within the allowable timeframe for withdrawals. This scenario raises several issues not specifically addressed in the August 1, 2001 final rule, which we are proposing to clarify in this proposed rule.

For example, the question arises, at what point does a hospital's termination of a 3-year reclassification become effective when a hospital applies for reclassification to another area? As noted above, the August 1, 2001 final rule specified that a hospital must file a written request with the MGCRB within 45 days of publication of the annual proposed rule to terminate the reclassification. However, the rules do not specify at what point a previous 3-year reclassification is terminated when a hospital applies for reclassification to another area in subsequent years. One might conclude that an application for a wage index reclassification to another area constitutes a written notification of a hospital's intent to terminate an existing 3-year reclassification. Under this scenario, however, if the application to the second area were denied, it would then be necessary for the hospital to formally cancel the termination of its reclassification to the first area within 45 days of publication of the proposed rule to avoid a lapse in reclassification status the following year. Therefore, we are proposing to clarify, in § 412.273(b)(2)(iii), that, in a situation where a hospital with an existing 3-year wage index reclassification applies to be reclassified to another area, its existing 3-year reclassification will be terminated when a second 3-year wage index reclassification goes into effect for payments for discharges on or after the following October 1. In such a case, it will not be necessary for the hospital to submit a separate written notice of its intent to terminate its existing 3-year reclassification. Of course, a hospital also may still terminate an existing 3-year reclassification through written notice to the MGCRB, regardless of whether it successfully reclassifies to a different area.

The scenario of a hospital with an existing 3-year reclassification seeking reclassification to a second area raises another issue. If the hospital's request is approved by the MGCRB, but the hospital withdraws from that successful reclassification and ''falls back'' to its original 3-year reclassification, does the hospital retain the right to cancel that withdrawal the next year? In this way, a hospital could accumulate multiple reclassifications from which it could choose in any given year through canceling prior withdrawals or terminations to one area and withdrawing or terminating reclassifications to other areas.

We do not believe section 304 of Public Law 106–554 was intended to be used in such a manner. Therefore, we are proposing to clarify existing policy that a previous 3-year reclassification may not be reinstated after a subsequent 3-year reclassification to another area takes effect. This would mean that a hospital that is reclassified to an area for purposes of the wage index may have only one active 3-year reclassification at a time. Once a 3-year reclassification to a second area becomes effective, a previously terminated 3-year reclassification may not be reinstated by terminating or withdrawing the reclassification to the second area and then canceling the termination or withdrawal of the reclassification to the first area.

As we stated in the August 1, 2001 final rule, we believe the 3-year wage index reclassification policy was intended to provide consistency and predictability in hospital reclassifications and the wage index data. Allowing hospitals multiple reclassification options to choose from would create a situation where many hospitals move in unpredictable ways between the proposed and final rules based on their calculation of which of several areas would yield the highest wage index. This would reduce the predictability of the system, hampering the ability of the majority of hospitals to

adequately project their future revenues. Therefore, we are proposing to amend § 412.273(b)(2)(ii) to provide that, once a 3-year reclassification becomes effective, a hospital may no longer cancel a withdrawal or termination of another 3-year reclassification, even within 3 years from the date of such withdrawal or termination. We are also proposing a technical correction to § 412.273(b)(2)(i) to correct the terminology regarding canceling (rather than terminating) a withdrawal.

Finally, the August 1, 2001 final rule did not specifically describe the process to cancel a withdrawal or termination. Therefore, we are proposing to add a new § 412.273(d) (existing paragraph (d) would be redesignated as paragraph (e)) to describe the process whereby a hospital may cancel a previous withdrawal or termination of a 3-year wage index reclassification. Specifically, a hospital may cancel a previous withdrawal or termination by submitting written notice of its intent to the MGCRB no later than the deadline for submitting reclassification applications for reclassifications effective at the start of the following fiscal year (§ 412.256(a)(2)).

2. Effect of Change of Ownership on Hospital Reclassifications

Sections 412.230(e)(2)(ii) and 412.232(d)(2)(ii) provide that, for reclassifications effective beginning FY 2003, a hospital must provide a 3-year average of its average hourly wages using wage survey data from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes.

As discussed in the August 1, 2001 final rule, we received a comment suggesting that, for purposes of calculating the 3-year average hourly wages, we permit a hospital that has changed ownership the option of excluding prior years' wage data submitted by a previous owner in order for the new hospital to qualify for reclassification. Although we responded to the comment (66 FR 39890), we have now determined that there is a need to further clarify our policy regarding change of ownership and hospitals that do not accept assignment of the previous owner's provider agreement.

In our response to the comment, we stated that, where a hospital has simply changed ownership and the new owners have acquired the financial assets and liabilities of the previous owners, all of the applicable wage data associated with that hospital are included in the calculation of its 3-year average hourly wage. Where this is not the case and there is no obligation on the part of the new hospital to claim the financial assets or assume the liabilities of a predecessor hospital, the wage data associated with the previous hospital's provider number would not be used in calculating the new hospital's 3-year average hourly wage.

Section 489.18(c) provides that, when there is a change of ownership, the existing provider agreement will automatically be assigned to the new owner. Our regulations at § 412.230(e)(2) do not specifically address the situation of new hospitals seeking to reclassify for wage index purposes, in light of the requirement that reclassification is based on a 3-year average hourly wage. Therefore, we are proposing to revise § 412.230(e)(2), by adding a new paragraph (e)(2)(iii), to clarify our existing policy to specify that, in situations where a hospital does not accept assignment of the existing hospital's provider agreement under § 489.18, the hospital would be treated as a new hospital with a new provider number. In that case, the wage data associated with the previous hospital's provider number would not be used in calculating the new hospital's 3-year average hourly wage. As we stated in the August 1, 2001 final rule, we believe this policy clarification is consistent with how we treat hospitals whose ownership has changed for other Medicare payment purposes. We are proposing to revise § 412.230 to clarify, under proposed new paragraph (e)(2)(iii), that once a new hospital has accumulated at least 1 year of wage data using survey data from the CMS hospital wage survey used to determine the wage index, it is eligible to apply for reclassification on the basis of those data.

I. Payment for Direct Costs of Graduate Medical Education (§ 413.86)

1. Background

Under section 1886(h) of the Act, Medicare pays hospitals for the direct costs of graduate medical education (GME). The payments are based in part on the number of residents trained by the hospital. Section 1886(h) of the Act caps the number of residents that hospitals may count for direct GME.

Section 1886(h)(2) of the Act, as amended by section 9202 of the Consolidated Omnibus Reconciliation Act (COBRA) of 1985 (Public Law 99–272), and implemented in regulations at § 413.86(e), establishes a methodology for determining payments to hospitals for the costs of approved GME programs. Section 1886(h)(2) of the Act, as amended by COBRA, sets forth a payment methodology for the determination of a hospital-specific, base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable costs of GME for a base period by its number of residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, the period of October 1, 1983 through September 30, 1984). The PRA is multiplied by the weighted number of full-time equivalent (FTE) residents working in all areas of the hospital complex (or nonhospital sites, when applicable), and the hospital's Medicare share of total inpatient days to determine Medicare's direct GME payments. In addition, as specified in section 1886(h)(2)(D)(ii) of the Act, for cost reporting periods beginning on or after October 1, 1993, through September 30, 1995, each hospital's PRA for the previous cost reporting period is not updated for inflation for any FTE residents who are not either a primary care or an obstetrics and gynecology resident. As a result, hospitals with both primary care and obstetrics and gynecology residents and nonprimary care residents in FY 1994 or FY 1995 have two separate PRAs: one for primary care and obstetrics and gynecology and one for nonprimary care.

Section 1886(h)(2) of the Act was further amended by section 311 of Public Law 106–113 to establish a methodology for the use of a national average PRA in computing direct GME payments for cost reporting periods beginning on or after October 1, 2000, and on or before September 30, 2005. Generally, section 1886(h)(2)(D) of the Act establishes a ''floor'' and a ''ceiling'' based on a locality-adjusted, updated, weighted average PRA. Each hospital's PRA is compared to the floor and ceiling to determine whether its PRA should be revised. For cost reporting periods beginning on or after October 1, 2000, and before October 1, 2001, the floor PRA is 70 percent of the locality-adjusted, updated, weighted average PRA. For cost reporting periods beginning on or after October 1, 2001, and before October 1, 2002, section 511 of Public Law 106–554 amended the floor PRA to equal 85 percent of the locality-adjusted, updated, weighted average PRA. PRAs that are below the applicable floor PRA for a particular cost reporting period would be adjusted to equal the floor PRA. PRAs that exceed the ceiling, that is, 140 percent of the locality-adjusted, updated, weighted average PRA, would, depending on the fiscal year, either be frozen and not increased for inflation, or

increased by a reduced inflation factor. Existing regulations at § 413.86(e)(4) specify the methodology for calculating each hospital's weighted average PRA and the steps for determining whether a hospital's PRA will be revised.

2. Determining the Weighted Average PRAs for Newly Participating Hospitals (§ 413.86(e)(5))

As stated earlier, under section 1886(h) of the Act and implementing regulations, in most cases Medicare pays hospitals for the direct costs of GME on the basis of per resident costs in a 1984 base year. However, under existing § 413.86(e)(5), if a hospital did not have residents in an approved residency training program, or did not participate in Medicare during the base period, the hospital's base period for its PRA is its first cost reporting period during which the hospital participates in Medicare and the residents are on duty during the first month of that period. If there are at least three existing teaching hospitals with PRAs in the same geographic wage area (MSA), as that term is used in 42 CFR Part 412, the fiscal intermediary will calculate a PRA based on the lower of the new teaching hospital's actual cost per resident in its base period or a weighted average of all the PRAs of existing teaching hospitals in the same MSA. There must be at least three existing teaching hospitals with PRAs in the MSA for this calculation. If there are less than three existing teaching hospitals with PRAs within the new teaching hospital's MSA, effective for cost reporting periods beginning on or after October 1, 1997, the fiscal intermediary uses the updated regional weighted average PRA (determined for each of the nine census regions established by the Bureau of Census for statistical and reporting purposes) for the new teaching hospital's MSA (see 62 FR 46004, August 29, 1997). A new teaching hospital is assigned a PRA equal to the lower of its actual allowable direct GME costs per resident or the weighted average PRA as calculated by the fiscal intermediary. Using a methodology based on a weighted average ensures that a new teaching hospital receives a PRA that is representative of the costs of training residents within its specific geographic wage area.

Under existing policy, to calculate the weighted average PRA of teaching hospitals within a particular MSA, the fiscal intermediary begins by determining the base year PRA and the base year FTE count of each respective teaching hospital within that MSA. The weighted average PRA is (a) the sum of the products of each existing teaching hospital's base year PRA in the MSA and its base year FTEs, (b) divided by the sum of the base year FTEs from each of those hospitals. While a methodology using base year PRAs and FTEs was appropriate and workable in the years closely following the implementation of hospital-specific PRAs, it has become administratively burdensome for both CMS and the fiscal intermediaries to recreate base year information in calculating a weighted average. The methodology is particularly problematic in instances where there are large numbers of teaching hospitals in an MSA.

In addition, as discussed in section V.I.1. of this proposed rule, hospitals that were training nonprimary care residents during FYs 1994 and 1995 have a distinct nonprimary care PRA, because there was no update in the inflation factor for these years (§ 413.86(e)(3)(ii)). Thus, most teaching hospitals currently have two PRAs: one for primary care and obstetrics and gynecology; and one for all other residents. (Hospitals that first train residents after FY 1995 only have a single PRA, regardless of whether they train primary care or other residents.) However, since the current methodology for calculating weighted average PRAs is based on data from FY 1984, which was prior to the years during which the PRAs were not adjusted for inflation to reflect nonprimary care residents, the methodology does not account for *all* PRAs (both primary care and obstetrics and gynecology and nonprimary care) within an MSA.

Accordingly, we are proposing to simplify and revise the weighted average PRA methodology under § 413.86(e)(5)(i)(B) to reflect the average of all PRAs in an MSA, both primary care and obstetrics and gynecology, and nonprimary care. We would continue to calculate a weighted average PRA. However, rather than using 1984 base year data, we are proposing to use PRAs (both primary care and obstetrics and gynecology and nonprimary care) and FTE data from the most recently settled cost reports of teaching hospitals in an MSA. We are proposing that the intermediary would calculate the weighted average PRA using the following steps:

Step 1: Identify *all* teaching hospitals (including those serviced by another intermediary(ies)) in the same MSA as the new teaching hospital.

Step 2: Identify the respective primary care and obstetrics and gynecology FTE counts, the nonprimary care FTE counts, or the total FTE count (for hospitals with a single PRA) of each teaching hospital in step 1 from the most recently settled cost reports. (Use the FTE counts from line 3.07 and line 3.08 of the Medicare cost report, CMS–2552–96, Worksheet E–3, Part IV.)

Step 3: Identify the PRAs (either a hospital's primary care and obstetrics and gynecology PRA and nonprimary care PRA, or a hospital's single PRA) from the most recently settled cost reports of the hospitals in step 1, and update the PRAs using the CPI–U inflation factor to coincide with the fiscal year end of the new teaching hospital's base year cost reporting period. For example, if the base year fiscal year end of a new teaching hospital is December 31, 2003, and the most recently settled cost reports of the teaching hospitals within the MSA are from the fiscal year ending June 30, 2000, September 30, 2000, or December 31, 2000, the PRAs from these cost reports would be updated for inflation to December 31, 2003.

Step 4: Calculate the weighted average PRA using the PRAs and FTE counts from steps 2 and 3. For each hospital in the calculation:

(a) Multiply the primary care PRA by the primary care and obstetrics and gynecology FTEs.

(b) Multiply the nonprimary care PRA by the nonprimary care FTEs.

(c) For hospitals with a single PRA, multiply the single PRA by the hospital's total number of FTEs.

(d) Add the products from steps (a), (b), and (c) for all hospitals.

(e) Add the FTEs from step 3 for all hospitals.

(f) Divide the sum from step (d) by the sum from step (e). The result is the weighted average PRA for hospitals within an MSA.

The following is an example of how to calculate a weighted average PRA under the proposed methodology:

Example

Assume that new Hospital A has a June 30 fiscal year end and begins training residents for the first time on July 1, 2003. Thus, new Hospital A's base year for purposes of establishing a PRA is the fiscal year ending June 30, 2004. New Hospital A is located in MSA 1234, in which three other teaching hospitals exist, Hospital B, Hospital C, and Hospital D. These three hospitals also have a fiscal year end of June 30 and their most recently settled cost reports are for the fiscal year ending June 30, 2000. For fiscal year ending June 30, 2000, Hospital B has 200 primary care and obstetrics and gynecology FTEs, 150 nonprimary care FTEs, and 150 nonprimary care FTEs. Hospital C has 50 primary care and obstetrics and gynecology FTEs and 60

nonprimary care FTEs. Hospital D has 25 FTEs. After updating the PRAs for inflation by the CPI–U to June 30, 2004, Hospital B has a primary care and obstetrics and gynecology PRA of $120,000 and a nonprimary care PRA of $115,000, Hospital C has a primary care and obstetrics and gynecology PRA of $100,000 and a nonprimary care PRA of $97,000, and Hospital D has a single PRA of $90,000.

(a) Primary care:
Hospital B: $120,000 × 200 FTEs = $24,000,000
Hospital C: $100,000 × 50 FTEs = $5,000,000
(b) Nonprimary care:
Hospital B: $115,000 × 150 FTEs = $17,250,000
Hospital C: $97,000 × 60 FTEs = $5,820,000
(c) Single PRA:
Hospital D: $90,000 × 25 FTEs = $2,250,000
(d) $24,000,000 + 5,000,000 + $17,250,000 + $5,820,000 + $2,250,000 = $54,320,000.
(e) 200 + 50 + 150 + 60 + 25 = 485 total FTEs.
(f) $54,320,000/485 FTEs = $112,000, the weighted average PRA for MSA1234 for fiscal year ending June 30, 2004.

New Hospital A's PRA would be the lower of $112,000 or its actual base year GME costs per resident.

We are proposing that this new weighted average calculation would be effective for hospitals with direct GME base years that begin on or after October 1, 2002.

In addition, we are taking the opportunity to clarify the language under existing § 413.86(e)(5)(i)(B), which relates to calculating the weighted average under existing policy. Specifically, existing § 413.86(e)(5)(i)(B) states: ''The weighted mean value of per resident amounts of all hospitals located in the same geographic wage area, as that term is used in the prospective payment system under part 412 of this chapter, *for cost reporting periods beginning in the same fiscal years* [emphasis added].'' We believe this language could be misinterpreted to imply that only those PRAs of hospitals in the same geographic wage area (MSA) *that have the same fiscal year end as the new teaching hospital* should be used in the weighted average calculation. However, the PRAs of *all* hospitals within the MSA of the new teaching hospital should be used, not just the PRAs of hospitals with the same fiscal year end as the new teaching hospital. The proposed revision appears under a proposed new § 413.86(e)(5)(i)(c).

3. Aggregate FTE Limit for Affiliated Groups (§§ 413.86 (b) and (g)(7))

Section 1886(h)(4)(H)(ii) of the Act permits, but does not require, the Secretary to prescribe rules that allow institutions that are member of the same affiliated group (as defined by the Secretary) to elect to apply the FTE resident limit on an aggregate basis. This provision allows the Secretary to permit hospitals flexibility in structuring rotations within a combined cap when they share residents' time. In accordance with the broad authority conferred by the statute, we created criteria for defining ''affiliated group'' and ''affiliation agreements'' in both the August 29, 1997 final rule (62 FR 45965) and the May 12, 1998 final rule (63 FR 26317). Because we have received many inquiries from the hospital industry on this policy, we are proposing to clarify in regulations the requirements for participating in an affiliated group. These requirements are explicitly derived from the policy explained in the August 29, 1997 and May 12, 1998 final rules.

Specifically, we are proposing to add under § 413.86(b) a new definition of ''Affiliation agreement.'' This new proposed definition would state that an affiliation agreement is a written, signed, and dated agreement by responsible representatives of each respective hospital in an affiliated group (as defined in § 413.86(b)), that specifies—

- The term of the agreement, which, at a minimum must be one year, beginning on July 1 of a year.
- Each participating hospital's direct and indirect FTE cap.
- The annual adjustment to each hospital's FTE caps, for both direct GME and IME. This adjustment must reflect the fact that any positive adjustment to one hospital's direct and indirect FTE caps must be offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect FTE caps of at least the same amount.
- The names of the participating hospitals and their Medicare provider numbers.

In addition, we are proposing to add a new § 413.86(g)(5)(iv) and a new § 413.86(g)(7) to clarify the requirements for a hospital to receive a temporary adjustment to its FTE cap through an affiliation agreement. (Existing § 413.86(g)(5)(iv) through (vi) are proposed to be redesignated as § 413.86(g)(5)(v) through (vii), respectively; and existing §§ 413.86(g)(7) through (g)(12) are proposed to be redesignated as §§ 413.86(g)(8) through (g)(13), respectively, to accommodate these additions.) Specifically, we are proposing that a hospital may receive a temporary adjustment to its FTE cap, which is subject to the averaging rules, to reflect residents added or subtracted because the hospital is participating in an affiliated group (as that term is defined under § 413.86(b)). Under this proposed provision—

- Each hospital in the affiliated group must submit the affiliation agreement (as that term is proposed to be defined under § 413.86(b)), to the CMS fiscal intermediary servicing the hospital and send a copy to CMS's Central Office no later than July 1 of the residency program year during which the affiliation agreement will be in effect.
- There must be a rotation of a resident(s) among the hospitals participating in the affiliated group during the term of the affiliation agreement, such that more than one of the hospitals counts the proportionate amount of the time spent by the resident(s) in their FTE resident counts. (However, no resident may be counted in the aggregate as more than one FTE.) This requirement is intended to ensure that the participating hospitals maintain a ''cross-training'' relationship during the term of the affiliation agreement.
- The net effect of the adjustments (positive or negative) on the affiliated hospitals' aggregate FTE cap for each affiliation agreement must not exceed zero.
- If the affiliation agreement terminates for any reason, the FTE cap for each hospital in the affiliated group will revert to the individual hospital's pre-affiliation FTE cap.

Except for the proposed new § 413.86(g)(7)(iv) regarding the treatment of FTE caps after termination of the affiliation agreement, each provision of proposed new § 413.86(g)(7) is explicitly derived from policy stated in the May 12, 1998 final rule (63 FR 26336). We are proposing to incorporate in regulations policy that was previously established under the formal rulemaking process.

We are proposing a change in policy concerning what happens to each participating affiliated hospital's FTE cap when an affiliation agreement terminates (proposed new § 413.86(g)(7)(iv)). In the preamble of the May 12, 1998 final rule (63 FR 26339), we stated: ''Each agreement must also specify the adjustment to each respective hospital cap in the event the agreement terminates, dissolves, or, if the agreement is for a specified time period, for residency training years and cost reporting periods subsequent to the

period of the agreement for purposes of applying the FTE cap on an aggregate basis. In the absence of an agreement on the FTE caps for each respective institution following the end of the agreement, each hospital's FTE cap will be the indirect and direct medical education FTE count from each hospital's cost reporting period ending in 1996 and the cap will not be applied on an aggregate basis.'' Our purpose for allowing hospitals to redistribute their FTE caps (within the limits of the aggregate FTE caps) upon the termination of an affiliation was to enable hospitals by agreement to more closely reflect the realities of the residency rotational arrangement. However, in practice, very few hospitals have altered their FTE caps following termination of affiliation agreements. Rather, the vast majority of hospitals opted to revert to their respective 1996 FTE caps upon the termination of an affiliation. In addition, we have found that our existing policy is susceptible to the following abusive practice that does not comport with our original purpose for allowing redistribution of FTE caps among hospitals following termination of an affiliation agreement. We have learned of a number of instances in which one hospital (Hospital A) affiliated with another hospital (Hospital B) in anticipation of Hospital B's closure at some point during the residency program year. In these instances, the affiliation agreement was made solely for the purpose of obtaining a permanent adjustment to Hospital A's FTE cap through the terms of the termination clause. We do not believe these permanent FTE cap adjustments that result from hospital closures (or any other circumstances) were intended when Congress passed the provision on affiliation agreements. As stated above, we believe affiliations were meant to provide flexibility for hospitals in the rotations of residents where, in the normal course of an affiliation between two or more hospitals, the actual number of residents training at each hospital may vary somewhat from year to year. Affiliations were *not* intended to be used as a vehicle for circumventing the statutory FTE cap on the number of residents. In addition, we have separately addressed issues that arise when residents are displaced because of a pending hospital closure. We have in place a policy at existing § 413.86(g)(8) (proposed to be redesignated as § 413.86(g)(9) in this proposed rule) that permits *temporary* FTE cap adjustments for hospitals that take on the training of residents displaced by the closure of another hospital.

Therefore, we are proposing that, effective October 1, 2002, for hospitals with affiliation agreements that terminate (for any reason) on or after that date, the direct and indirect FTE caps for each hospital in the affiliated group will revert back to each individual hospital's original FTE cap prior to the affiliation (proposed new § 413.86(g)(7)(iv)). This policy would not preclude the participating hospitals from entering into additional affiliation agreements for later residency years.

Since this proposed policy would be effective for agreements that terminate on or after October 1, 2002, hospitals that have already received a permanent FTE cap adjustment from their fiscal intermediaries through the existing termination clause policy would retain those cap adjustments.

We also are proposing to make a conforming clarification at § 412.105(f)(1)(vi) for purposes of IME payments.

4. Rotating Residents to Other Hospitals

At existing § 413.86(f), we state, in part, that a hospital may count residents training in all areas of the hospital complex; no individual may be counted as more than one FTE; and, if a resident spends time in more than one hospital or in a nonprovider setting, the resident counts as a partial FTE based on the proportion of *time worked at the hospital* to the total time worked (emphasis added). A similar policy exists at §§ 412.105(f)(1)(ii) and (iii) for purposes of counting resident FTEs for IME payment. Although these policies concerning the counting of the number of FTE residents for IME and direct GME payment purposes have been in effect since October 1985, we continue to receive questions about whether residents can be counted by a hospital for the time during which the resident is rotated to other hospitals.

We would like to clarify that it is longstanding Medicare policy, based on language in both the regulations and the statute, to prohibit one hospital from claiming the FTEs training at another hospital for IME and direct GME payment. This policy applies even when the hospital that proposes to count the FTE resident(s) actually incurs the costs of training the residents(s) (such as salary and other training costs) at another hospital.

First, section 1886(h)(4)(B) of the Act states that the rules governing the direct GME count of the number of FTE residents ''shall take into account individuals who serve as residents for only a portion of a period with a hospital or simultaneously with more than one hospital.'' In the September 4, 1990 **Federal Register** (55 FR 36064), we stated that '' * * * regardless of which teaching hospital employs a resident who rotates among hospitals, each hospital would count the resident in proportion to the amount of time spent at its facility.'' Therefore, another hospital *cannot* count the time spent by residents training at another hospital. Only the hospital where the residents are actually training can count those FTEs for that portion of time. For example, if, during a cost reporting year, a resident spends 3 months training at Hospital A and 9 months training at Hospital B, Hospital A can only claim .25 FTE and Hospital B can only claim .75 FTE. Over the course of the entire cost reporting year, the resident would add up to 1.0 FTE.

We have been made aware of some instances where an urban hospital may incur all the training costs of residents while those residents train at a rural hospital, because the rural hospital may not have the resources or infrastructure to claim those costs and FTEs on a Medicare cost report. However, even in this scenario, the urban hospital is precluded from claiming any FTEs for the proportion of time spent in training at that rural hospital, or at any other hospital.

We note, however, that, consistent with the statutory provisions of section 1886(d)(5)(B)(iv) of the Act for IME payment and section 1886(h)(4)(E) of the Act for direct GME payment, a hospital may count the time residents spend training in a *nonhospital* setting if the hospital complies with the regulatory criteria at § 413.86(f)(4).

J. Responsibilities of Medicare-Participating Hospitals in Emergency Cases (EMTALA)

1. Background

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Act impose specific obligations on Medicare-participating hospitals that offer emergency services. These obligations concern individuals who come to a hospital emergency department and request examination or treatment for medical conditions, and apply to all of these patients, regardless of whether or not they are beneficiaries of any program under the Act. Section 1867 of the Act sets forth requirements for medical screening examinations for medical conditions, as well as necessary stabilizing treatment or appropriate transfer. In addition, section 1867 of the Act specifically prohibits a delay in providing required screening or stabilization services in order to inquire

about the individual's payment method or insurance status. Section 1867 of the Act also provides for the imposition of civil monetary penalties on hospitals and physicians responsible for the following: (a) Negligently failing to appropriately screen a patient seeking emergency medical care; (b) negligently failing to provide stabilizing treatment to an individual with an emergency medical condition; or (c) negligently transferring a patient in an inappropriate manner. (Section 1867(e)(4) of the Act defines ''transfer'' to include both transfers to other health care facilities and cases in which the patient is released from the care of the hospital without being moved to another health care facility.)

These provisions, taken together, are frequently referred to as the Emergency Medical Treatment and Labor Act (EMTALA), also known as the patient antidumping statute. EMTALA was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA). As a result, many people initially referred to EMTALA as ''COBRA'' or the ''COBRA antidumping'' statute. Congress enacted these antidumping provisions in the Social Security Act because of its concern with an ''increasing number of reports'' that hospital emergency rooms were refusing to accept or treat patients with emergency conditions if the patients did not have insurance:

''* * * The Committee is most concerned that medically unstable patients are not being treated appropriately. There have been reports of situations where treatment was simply not provided. In numerous other situations, patients in an unstable condition have been transferred improperly, sometimes without the consent of the receiving hospital.

''There is some belief that this situation has worsened since the prospective payment system for hospitals became effective. The Committee wants to provide a strong assurance that pressures for greater hospital efficiency are not to be construed as license to ignore traditional community responsibilities and loosen historic standards.

''[Under the statute] [a]ll participating hospitals with emergency departments would be required to provide an appropriate medical screening examination for any individual who requests it (or has a request made on his behalf) to determine whether an emergency medical condition exists or if the patient is in active labor.'' (H.R. Rept. No. 99–241, Part 1, 99th Cong., 1st Sess. (1985), p. 27.)

The regulations implementing section 1867 of the Act are found at 42 CFR 489.24, Special responsibilities of Medicare hospitals in emergency cases. Section 489.24 provides for the following:

- Paragraph (a) requires that when an individual presents to a hospital's emergency department and a request is made on the individual's behalf for examination or treatment of a medical condition, the hospital must provide for an appropriate medical screening examination to determine whether or not an emergency medical condition exists.
- Paragraph (b) provides the definitions of terms, including ''comes to the emergency department,'' ''emergency medical condition,'' ''stabilized,'' and ''to stabilize.''
- Paragraph (c) addresses procedures a hospital must follow when it determines that an emergency medical condition exists. If the hospital determines that an emergency medical condition exists, the hospital must provide for further medical examination and treatment as required to stabilize the patient. If the hospital does not have the capabilities to stabilize the patient, an appropriate transfer to another facility is permitted. A transfer is appropriate when the medical benefits of the transfer outweigh the medical risks of the transfer and other requirements, specified in the regulation at paragraph (d), are met. Also, the hospital may transfer an unstable patient who makes an informed written request. Paragraph (c) further states that a hospital may not delay an appropriate medical screening examination, or further examination or treatment, to inquire about the individual's payment method or insurance status.

In addition, § 489.24 addresses: (a) Restriction of a transfer until the individual is stabilized; (b) the responsibilities of the receiving hospital; (c) termination of the provider agreement for failure to comply with EMTALA requirements; and (d) matters concerning consultation with Peer Review Organizations (paragraphs (d) through (h), respectively).

Some EMTALA-related requirements are implemented under regulations at §§ 489.20(l), (m), (q), and (r)(1), (r)(2), and (r)(3). Those regulations deal with a hospital's obligations to report the receipt of patients that it has reason to believe may have been transferred inappropriately; to post signs in the emergency department describing a patient's rights to emergency treatment under section 1867 of the Act; and to maintain patient records, physician on-call lists, and emergency room logs. We are including this brief description for informational purposes but, because we are not proposing to change the regulations in § 489.20, they will not be discussed further in this document.

In promulgating these cited regulatory sections and in enforcing the provisions of EMTALA, we are aware of the necessary balance between the hospital's and a physician's legal duty to provide examination and treatment under the statute and the practical realities of the manner in which hospitals and medical staffs are organized and operated on a day-to-day basis, as well as proper mobilization of resources within hospitals in order to comply with these legal duties. Reports of overcrowding in hospital emergency departments are common in many parts of the country. Within the requirements of EMTALA, individuals should be treated at the appropriate site of care.

Hospitals and physicians have now had over 15 years of experience in organizing themselves to comply with the provisions of EMTALA. Throughout this section of this proposed rule relating to EMTALA, we solicit comments from hospitals, physicians, patients, and beneficiary groups on the proposed changes to the EMTALA policies.

2. Special Advisory Bulletin on EMTALA Obligations

On November 10, 1999, CMS (previously, HCFA) and the Office of the Inspector General (OIG) published jointly in the **Federal Register** a Special Advisory Bulletin addressing the requirements of the patient antidumping statute and the obligations of hospitals to medically screen all patients seeking emergency services and provide stabilizing medical treatment as necessary to all patients, including enrollees of managed care plans, whose conditions warrant it (64 FR 61353). The Special Advisory Bulletin addressed issues of dual staffing of hospital emergency rooms by managed care and nonmanaged care physicians, prior authorization requirements of some managed care plans, use of advance beneficiary notices (ABNs) or other financial responsibility forms, handling of individuals' inquiries about financial liability for emergency services, and voluntary withdrawal of a treatment request. Although it does not amend the Code of Federal Regulations, the Special Advisory Bulletin informs individuals of HHS policy regarding application of the patient antidumping statute and offers advice on the best practices to follow to avoid violation of the requirements imposed under that statute.

As discussed further in section V.J.4. of this preamble, we are now proposing to codify certain policies on prior authorization that are currently stated only in the Special Advisory Bulletin. We believe these changes in the regulations are needed to ensure uniform and consistent application of policy and to avoid any misunderstanding of EMTALA requirements by patients, physicians, or hospital employees.

3. EMTALA Provisions in This Proposed Rule

Recently, a number of questions have been raised about the applicability of § 489.24 to specific situations. These questions arise in the context of managed care plans' requirements for prior authorization, case experiences involving elective procedures, and situations when patients have been admitted as inpatients but are not stabilized, or later experience a deterioration in their medical condition. Some hospitals are uncertain whether various conditions of participation found in 42 CFR part 482 apply to these situations or whether the EMTALA requirements included in the provider agreement regulations at § 489.24 apply, or both. Some representatives of the provider community have asked us to reexamine CMS policy on the applicability of EMTALA to provider-based departments. Finally, there have also been questions concerning the applicability of EMTALA to physicians who are ''on call'' and to hospitals that own ambulances when those ambulances operate under communitywide emergency medical services (EMS) protocols. To help promote consistent application of the regulations concerning the special responsibilities of Medicare hospitals in emergency cases, we are proposing changes to § 489.24 to clarify its application to these situations and at the same time address concerns about EMTALA raised by the Secretary's Advisory Committee on Regulatory Reform. These changes are discussed more fully below and include the following:

- We are proposing to change the requirements relating to emergency patients presenting at those off-campus outpatient clinics that do not routinely provide emergency services. We believe these changes would enhance the quality and promptness of emergency care by permitting individuals to be referred to appropriately equipped emergency facilities close to such clinics.
- We are proposing to clarify when EMTALA applies to both inpatients and outpatients. We believe these clarifications would enhance overall patient access to emergency services by helping to relieve administrative burdens on frequently overcrowded emergency departments.
- We are proposing to clarify the circumstances in which physicians, particularly specialty physicians, must serve on hospital medical staff ''on-call'' lists. We expect these clarifications would help improve access to physician services for all hospital patients by permitting hospitals local flexibility to determine how best to maximize their available physician resources. We are currently aware of reports of physicians, particularly specialty physicians, severing their relationships with hospitals, especially when those physicians belong to more than one hospital medical staff. Physician attrition from these medical staffs could result in hospitals having no specialty physician service coverage for their patients. Our proposed clarification of the on-call list requirement would permit hospitals to continue to attract physicians to serve on their medical staffs and thereby continue to provide services to emergency room patients.
- We are proposing to clarify the responsibilities of hospital-owned ambulances so that these ambulances can be more fully integrated with citywide and local community EMS procedures for responding to medical emergencies and thus use these resources more efficiently for the benefit of these communities.

We solicit comments on all of these proposed changes.

4. Prior Authorization

Some managed care plans may seek to pay hospitals for services only if the hospitals obtain approval from the plan for the services before providing the services. Requirements for this approval are frequently referred to as ''prior authorization'' requirements. However, EMTALA (specifically, section 1867(h) of the Act and our regulation at § 489.24(c)(3)) explicitly prohibit hospitals from delaying screening or stabilization services in order to inquire about the individual's method of payment or insurance status. Thus, prior authorization requirements are a matter of concern because hospitals could, in seeking prior authorization from an insurer, present a barrier to or delay in the provision of services required by EMTALA.

After review of these considerations, we believe that our existing policy will best implement the intent of the statute by prohibiting a participating hospital from seeking authorization from the individual's insurance company for screening services or services required to stabilize an emergency medical condition until after the hospital has provided the appropriate medical screening examination required by EMTALA to the patient and has initiated any further medical examination and treatment that may be required to stabilize the patient's emergency medical condition.

We are soliciting comments as to whether the regulations should be further revised to state that the hospital may seek other information (apart from information about payment) from the insurer about the individual, and may seek authorization for all services concurrently with providing any stabilizing treatment, as long as doing so does not delay required screening and stabilization services.

In addition, we are proposing to specify that an emergency physician is not precluded from contacting the patient's physician at any time to seek advice regarding the patient's medical history and needs that may be relevant to the medical screening and treatment of the patient, as long as this consultation does not inappropriately delay required screening or stabilization services.

As explained earlier, this policy was stated in a Special Advisory Bulletin published jointly by CMS (then HCFA) and the OIG. However, we are now proposing to clarify existing language at § 489.24(c)(3) (proposed to be redesignated as paragraph (d)(4)) in this proposed rule to include this policy in the regulations.

5. Hospital Responsibility for Communication With Medicare+Choice Organizations Concerning Post-Stabilization Care Services

Section 422.113 of our existing regulations establishes rules concerning the responsibility of Medicare+Choice organizations for emergency and post-stabilization care services provided to Medicare+Choice enrollees (65 FR 40170, June 29, 2000). Under § 422.113(c)(2), a Medicare+Choice organization is financially responsible for post-stabilization care under certain circumstances, including situations in which the organization cannot be contacted or does not respond timely to a hospital's request for preapproval of this care.

It has come to our attention that, in some instances, hospitals may have failed to contact Medicare+Choice organizations on a timely basis to seek authorization for post-stabilization services. In such a case, the Medicare+Choice organization does not

have the opportunity provided for under the regulations to decide whether to approve the provision of post-stabilization services at the hospital where the emergency services were provided, or to require that the enrollee instead be transferred to another hospital for such services. Therefore, we are proposing to add a new paragraph (d)(6) under § 489.24 to specify that a hospital must promptly contact the Medicare+Choice organization after a Medicare+Choice enrollee who is treated for an emergency medical condition is stabilized.

6. Clarification of ''Comes to the Emergency Department''

Section 1867(a) of the Act and our regulations at § 489.24(a) provide, in part, that if any individual comes to the emergency department of a hospital and a request is made on that individual's behalf for examination or treatment of a medical condition, the hospital must provide an appropriate medical screening examination within the capability of the hospital's emergency department. If the hospital determines that such an individual has an emergency medical condition, the hospital is further obligated to provide either necessary stabilizing treatment or an appropriate transfer. Occasionally, questions have arisen as to whether these EMTALA requirements apply to situations in which a patient comes to a hospital, but does not present to the hospital's emergency department. We are proposing to clarify under what circumstances a hospital is obligated under EMTALA to screen, stabilize, or transfer an individual who comes to a hospital, presenting either at its dedicated emergency department, as proposed to be defined below, or elsewhere on hospital property, seeking examination or treatment.

Sometimes individuals come to hospitals seeking examination or treatment for medical conditions that could be emergency medical conditions, but present for examination or treatment at areas of the hospital other than the emergency department. For example, a woman in labor may go directly to the labor and delivery department of a hospital or a psychiatric outpatient experiencing a psychiatric crisis may present at the psychiatry department. In the June 22, 1994 final rule (59 FR 32098), we defined ''comes to the emergency department'' at § 489.24(b) to clarify that a hospital's EMTALA obligations are triggered whenever an individual presents on hospital property in this manner in an attempt to gain access to the hospital for emergency care and requests examination or treatment for an emergency medical condition. At the time we adopted this interpretation of ''comes to the emergency department,'' we explained:

''We believe that section 1867 of the Act also applies to all individuals who attempt to gain access to the hospital for emergency care. An individual may not be denied services simply because the person failed to actually enter the facility's designated emergency department.'' (59 FR 32098)

We repeated this standard for situations in which a hospital becomes bound to meet EMTALA's screening and stabilization or transfer requirements with respect to individuals who present on hospital property in an attempt to gain access to the hospital for emergency care, but outside of a hospital's emergency department, in interpretative guidelines published in the State Operations Manual:

''If an individual arrives at a hospital and is not technically in the emergency department, but is on the premises (including the parking lot, sidewalk and driveway) of the hospital and requests emergency care, he or she is entitled to a medical screening examination.'' (State Operations Manual Appendix V—Responsibilities of Medicare Participating Hospitals in Emergency Cases, V–16)

Thus, an individual can ''come to the emergency department,'' creating an EMTALA obligation on the part of the hospital, in one of two ways: The individual can present at a hospital's dedicated emergency department (as proposed to be defined below) and request examination or treatment for a medical condition; or the individual can present elsewhere on hospital property in an attempt to gain access to the hospital for emergency care (that is, at a location that is on hospital property but is not part of a dedicated emergency department), and request examination or treatment for what may be an emergency medical condition.

Because of the need to clarify the applicability of EMTALA to a particular individual depending on where he or she presents on hospital property in order to obtain emergency care, we are proposing to define ''dedicated emergency department.'' ''Dedicated emergency department'' would mean a specially equipped and staffed area of the hospital that is used a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical conditions, as defined in § 489.24(b), and is either located: (1) On the main hospital campus; or (2) off the main hospital campus and is treated by Medicare under § 413.65(b) as a department of the hospital. The EMTALA statute was intended to apply to individuals presenting to a hospital for emergency care services. Accordingly, we believe it is irrelevant whether the dedicated emergency department is located on or off the hospital main campus, as long as the individual is presenting to ''a hospital'' for those services. Therefore, we are proposing in our definition of ''dedicated emergency department'' that such a department may be located on the main hospital campus, or it may be a department of the hospital located off the main campus. (We note that this proposed definition would encompass not only what is generally thought of as a hospital's ''emergency room,'' but would also include other departments of hospitals, such as labor and delivery departments and psychiatric units of hospitals, that provide emergency or labor and delivery services, or both, or other departments that are held out to the public as an appropriate place to come for medical services on an urgent, nonappointment basis.)

We are soliciting public comment on whether this proposed definition should more explicitly define what is a ''dedicated emergency department.'' Specifically, we are seeking comment on whether a ''significant portion of the time'' should be defined more objectively; for example, in terms of some minimum number or minimum percentage of patients (20, 30, 40 percent or more of all patients seen) presenting for emergency care at a particular area of the hospital in order for it to qualify as a ''dedicated emergency department.'' As an alternative, we could also consider a qualifying criteria that is based on determining whether the facility is used ''regularly'' for the evaluation or treatment of emergency medical conditions. Similarly, we are seeking comments on how we could define ''regularly'' more objectively in our consideration of this alternative. We further seek comments from hospitals, physicians, and others on how hospitals currently organize themselves to react to situations in which individuals come to a hospital requesting a screening examination or medical treatment, or both.

This proposed rule would clarify for hospitals that they must provide at least a medical screening examination to all individuals who present to an area of a hospital meeting the definition of dedicated emergency department and request examination or treatment for a medical condition, or have such a request made on their behalf. As we explain in section V.J.7. of this preamble, individuals who present to an

area of a hospital other than a dedicated emergency department on hospital property must receive a medical screening examination under EMTALA, only when the individual requests examination or treatment for what may be an emergency medical condition, or has such a request made on his or her behalf, as provided in the proposed changes to § 489.24(b) in this proposed rule.

7. Applicability of EMTALA: Individual Comes to the Dedicated Emergency Department for Nonemergency Services

We sometimes receive questions as to whether EMTALA's requirements apply to situations in which an individual comes to a hospital's dedicated emergency department, but no request is made on the individual's behalf for emergency medical evaluation or treatment. In view of the specific language of section 1867 of the Act and the discussion in section V.J.6. of this proposed rule, which proposes to define a hospital's dedicated emergency department as a specially equipped and staffed area of the hospital that is used a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical conditions located on the main hospital campus or at an off-campus department of the hospital, we believe that a hospital must be seen as having an EMTALA obligation with respect to any individual who comes to the dedicated emergency department, if a request is made on the individual's behalf for examination or treatment for a medical condition, whether or not the treatment requested is explicitly for an emergency condition. A request on behalf of the individual would be considered to exist if a prudent layperson observer would believe, based on the individual's appearance or behavior, that the individual needs examination or treatment for a medical condition. This does not mean, of course, that all EMTALA screenings must be equally extensive. The statute plainly states that the objective of the appropriate medical screening examination is to determine whether or not an emergency medical condition exists. Therefore, hospitals are not obligated to provide screening services beyond those needed to determine that there is no emergency.

In general, a medical screening examination is the process required to reach, with reasonable clinical confidence, a determination about whether a medical emergency does or does not exist. We expect that in most cases in which a request is made for medical care that clearly is unlikely to involve an emergency condition, an individual's statement that he or she is not seeking emergency care, together with brief questioning by qualified medical personnel, would be sufficient to establish that there is no emergency condition and that the hospital's EMTALA obligation would thereby be satisfied.

To clarify our policy in this area, we are proposing to redesignate paragraphs (c) through (h) of § 489.24 as paragraphs (d) through (i) (we are proposing to remove existing paragraph (i), as explained in section V.J.10. of this preamble) and to add a new paragraph (c) to state that if an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an ''emergency medical condition'' as defined in paragraph (b). (See example 1 below.)

Example 1: A woman walks up to the front desk of a hospital's emergency room, a dedicated emergency department, and tells the hospital employee attending the front desk that she had a wound sutured several days earlier and was directed by her doctor to have the sutures removed that day. The front desk attendant registers the woman according to the hospital's normal registration procedure and directs the woman to the waiting area. An emergency nurse, who has been designated by the hospital as a ''qualified medical person'' (as provided for in existing § 489.24(a)), calls the woman into the examination area of the emergency room. The nurse asks the woman if she has experienced any discomfort or noticed any problems in the area sutured. The woman explains that she is feeling fine, and the wound is not causing her any discomfort, but that her doctor had directed her a week ago to have the sutures removed that day. The nurse physically inspects the sutures and determines that the wound is healing appropriately. The nurse explains to the woman that she does not have an emergency medical condition and may direct the woman to an outpatient clinic where nonemergency personnel will provide the services the woman has requested.

Application: In this case, the woman presented at the hospital's dedicated emergency department and requested examination or treatment for a medical condition—specifically, she asked that her sutures be removed. Therefore, the hospital is bound under section 1867(a) of the Act to provide her a medical screening examination in order to determine whether or not she has an emergency medical condition. The actions of the nurse, ''a qualified medical person,'' constitute an appropriate medical screening examination under EMTALA because the nurse has determined, with reasonable clinical confidence, that the woman has no emergency medical condition. This appropriate medical screening examination fully satisfies the hospital's EMTALA obligations as to that woman; because the screening examination revealed no emergency medical condition, the hospital properly referred the woman to an outpatient clinic for nonemergency care.

8. Applicability of EMTALA: Individual Presents at an Area of the Hospital on the Hospital's Main Campus Other Than the Dedicated Emergency Department

Routinely, individuals come to hospitals as outpatients for many nonemergency medical purposes, and if such an individual initially presents at an on-campus area of the hospital other than a dedicated emergency department, we would expect that the individual typically would not be seeking emergency care. Under most of these circumstances, EMTALA would therefore not apply (this concept is further discussed in section V.J.8. of this preamble). A hospital would, however, incur an EMTALA obligation with respect to an individual presenting at that area who requests examination or treatment for what may be an emergency medical condition, or had such a request made on his or her behalf. This policy would not require that an emergency medical condition be found, upon subsequent medical examination, to exist. Rather, EMTALA is triggered in on-campus areas of the hospital other than a dedicated emergency department where, in an attempt to gain access to the hospital for emergency care, an individual comes to a hospital and requests an examination or treatment for a medical condition that may be an emergency.

We are proposing to specify in the regulations that such a request would be considered to exist if the individual requests examination or treatment for what the individual believes to be an emergency medical condition. Where there is no actual request because, for example, the individual is unaccompanied and is physically incapable of making a request, the request from the individual would be considered to exist if a prudent layperson observer would believe, based upon the individual's appearance or behavior, that the individual needs emergency examination or treatment. We believe this proposed policy is appropriate because it would not be

consistent with the intent of section 1867 of the Act to deny its protections to those individuals whose need for emergency services arises upon arrival on hospital on-campus property at the hospital's main campus but have not been presented to the dedicated emergency department.

Under the proposed policies discussed above, a request for examination or treatment by an individual presenting for what may be an emergency medical condition at an on-campus area of the hospital other than the dedicated emergency department would not have to be expressed verbally in all cases, but in some cases should be inferred from what a prudent layperson observer would conclude from an individual's appearance or behavior. While there may be a request (either through the individual or a prudent layperson), thereby triggering an EMTALA obligation on the part of the hospital, this policy does not mean that the hospital must maintain emergency medical screening or treatment capabilities in each department or at each door of the hospital, nor anywhere else on hospital property other than the dedicated emergency department. If an individual presents at an on-campus area of the hospital other than the dedicated emergency department in an attempt to gain access to the hospital for emergency care, EMTALA would mandate that the hospital (as a whole) would provide for screening and stabilizing the individual. For example, upon presentation of an individual requesting emergency care, if the department to which the individual presents cannot readily provide screening and, if needed, stabilization services, the department may arrange for appropriate staff to provide these services. Care required to be provided under EMTALA should be provided in the most appropriate setting, as determined by the hospital.

Example 2: An individual bleeding profusely from a severe scalp laceration enters a hospital through the main entry for hospital visitors, and says to one of the receptionists: ''I need help.'' The receptionist sees that the individual's head is bleeding and, noting his request, arranges to have the individual taken to the dedicated emergency department. Minutes later, the staff from the emergency department arrive and transport the individual to the hospital's emergency department to complete the screening and to give any necessary stabilizing treatment.

Application: The individual presented at an on-campus area of the hospital other than the dedicated emergency department (in this case, the main entry for hospital visitors), with his head bleeding profusely, asking for help. The receptionist, a prudent layperson observing the individual, believed that the individual was seeking emergency examination or treatment, thereby triggering an EMTALA obligation on the part of the hospital. (We note that EMTALA would have been triggered even if no verbal request had been made, since the individual's appearance indicated the clear possibility of an emergency medical condition.) Since the main entry for hospital visitors did not have emergency examination or treatment capabilities, the receptionist appropriately called the hospital's emergency department to summon emergency department staff to provide emergency care for that individual. Once the emergency department staff arrived and transported the individual to the hospital's emergency department, and provided him with the emergency care needed and stabilized the individual, the hospital had satisfied its EMTALA obligation to that individual.

Again, we solicit comments from hospitals and physicians that give examples of ways in which hospitals presently react to situations such as for the example noted above.

Most individuals who come to hospitals as outpatients come for many nonemergency purposes; under most circumstances, EMTALA would not apply. We are proposing that EMTALA would not apply to such an individual who then experiences what may be an emergency medical condition if the individual is an outpatient (as that term is defined at 42 CFR § 410.2) who has come to the hospital outpatient department for the purpose of keeping a previously scheduled appointment. We would consider such an individual to be an outpatient if he or she has begun an encounter (as that term is defined at § 410.2) with a health professional at the outpatient department. Because such individuals are patients of the hospital already, that is, they have a previously established relationship with the hospital, and have come to the hospital for previously scheduled medical appointments, we believe it is inappropriate that they be considered to have ''come to the hospital'' for purposes of EMTALA. However, we note that such an outpatient under this proposal who experiences what may be an emergency medical condition after the start of an encounter with a health professional would have all protections afforded to patients of a hospital under the Medicare hospital conditions of participation (as discussed in section V.J.13. of this proposed rule). Hospitals that fail to provide treatment to these patients could face termination of their Medicare provider agreements for a violation of the conditions of participation. In addition, as patients of a health care provider, these individuals are accorded protections under State statutes or common law as well as under general rules of ethics governing the medical professions.

Example 3: A patient who had been discharged from inpatient status following knee replacement surgery comes to the hospital outpatient department for a physical therapy session which had been scheduled 2 weeks earlier. While undergoing therapy, the patient complains of chest pains and lightheadedness. Acting under protocols established by the hospital, staff of the outpatient department contact the hospital's dedicated emergency department, which dispatches appropriate personnel to the department. The patient is taken to the hospital's dedicated emergency department for examination. Upon arrival in the dedicated emergency department, she is given a medical screening examination, which reveals that she has an emergency medical condition related to coronary artery disease. She is stabilized in the dedicated emergency department and is released to the care of her daughter.

Application: In this case, the individual is an outpatient. While she is in a physical therapy session in an outpatient department of the hospital, she experiences what may be an emergency medical condition—chest pains and lightheadedness. This outpatient is under the care of the hospital; she is in a previously scheduled physical therapy appointment and clearly has a previously established relationship with the hospital. In addition, the encounter with hospital staff has begun since her condition arose while she was undergoing therapy. Therefore, although the individual may be experiencing what may be an emergency medical condition, the hospital is not obligated under EMTALA. However, the hospital appropriately provided treatment for this patient, as required under the Medicare conditions of participation (specifically, 42 CFR § 482.55, which requires the hospital to fulfill its condition of participation responsibility for emergency care by contacting the hospital's dedicated emergency department and providing care to the individual through staff of that department). We solicit comments from hospitals and physicians as to what current practices are when an outpatient with a previously scheduled appointment experiences an emergency medical condition.

We are proposing to retitle the definition of ''property'' at § 489.24(b) to ''hospital property'' and relocate it as a

separate definition. In addition, we are proposing to clarify which areas and facilities are not considered hospital property.

9. Scope of EMTALA Applicability to Hospital Inpatients

While most issues regarding EMTALA arise in connection with ambulatory patients, questions have occasionally been raised about whether EMTALA applies to inpatients. In late 1998, the United States Supreme Court considered a case (*Roberts* v. *Galen of Virginia*) that involved, in part, the question of whether EMTALA applies to inpatients in a hospital. In the context of that case, the United States Solicitor General advised the Supreme Court that the Department of Health and Human Services (DHHS) would develop a regulation clarifying its position on that issue. After reviewing the issue in the light of the EMTALA statute, we are proposing that EMTALA would apply to inpatients only under limited circumstances, as described in the following paragraphs.

As noted earlier, once a hospital has incurred an EMTALA obligation with respect to an individual, that obligation continues while the individual remains at the hospital, so that any transfer to another medical facility or discharge of the individual must be in compliance with the rules restricting transfer until the individual is stabilized under existing § 489.24(d). In many cases, medical judgment will dictate that a patient be admitted to the hospital for further treatment on an inpatient basis because the patient's emergency medical condition has not yet been stabilized.

In these cases, the hospital continues to be obligated under section 1867, irrespective of the inpatient admission. Admitting an individual whose emergency medical condition has not been stabilized does not relieve the hospital of further responsibility to the individual under this section. An individual's emergency medical condition will be considered to have been stabilized only when the criteria in § 489.24(b) are met; that is, the individual's condition must be such that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during a transfer of the individual from the facility or, if the patient is a pregnant woman who is having contractions, that the woman has delivered the child and the placenta.

Consistent with the above policy, we emphasize that an admission to inpatient status cannot be used to evade EMTALA responsibilities. Indeed, permitting inpatient admission to end EMTALA obligations would provide an obvious means of circumventing these requirements that would seemingly contradict the point of the statute to protect emergency patient health and safety. This point should be particularly evident in the case of a woman in labor, a central focus of the statute. Such women are frequently admitted, and the statute clearly contemplated protecting them until completion of the delivery (that is, stabilization). In addition, if an inpatient who had been admitted from the dedicated emergency department with an unstabilized emergency medical condition was never stabilized as an inpatient and is transferred, we would still apply EMTALA in reviewing the transfer. In this context, stability for transfer reflects a complex medical judgment that can be made only based on review of all relevant information in each particular case, including all conditions that could cause the patient to be medically unstable. A patient who goes in and out of apparent stability with sufficient rapidity or frequency would not be considered ''stabilized'' within the meaning of § 489.24; transient stability of such a patient does not relieve the hospital of its EMTALA obligation. Such a patient would continue to be covered by EMTALA until the patient's overall medical stability with respect to all conditions is achieved.

Except for the limited circumstances described above, we are proposing to clarify that EMTALA does not apply to hospital inpatients. We believe EMTALA does not apply to hospital inpatients because we interpret section 1867 of the Act by reading the statutory language as a whole, with the requirements of paragraphs (b), ''Necessary Stabilizing Treatment for Emergency Medical Conditions and Labor,'' and (c), ''Restricting Transfer Until Individual is Stabilized,'' applying only to those individuals who satisfy the threshold requirement of coming to the hospital and requesting emergency care (as interpreted in this proposed regulation). This interpretation is based upon the statutory language and the legislative history. First, the Congress defined ''emergency medical condition'' at section 1867(e)(1) of the Act by referring solely to ''acute symptoms,'' which are self-identified, and did not mention other potentially relevant indications, in particular, signs or objective data. ''Signs'' are observable findings that are identified or confirmed by a clinician based on examination and use of objective data (for example, physiologic measurements, x-ray results). When a patient's condition deteriorates in the inpatient setting, awareness of a situation potentially requiring emergency care is based on any symptoms, signs, and objective data, reflecting a situation that is not captured by the targeted definition at section 1867(e)(1) of the Act. If the Congress had intended EMTALA to apply to transfers at any time during an inpatient stay, it would not have used a definition of emergency medical condition that focuses exclusively on symptoms and that uniquely defines the individual's status at the time of his or her initial presentation to the hospital, not his or her status as an inpatient. Furthermore, the definition of ''appropriate transfer'' in paragraph (c)(2) of section 1867 of the Act includes a variety of terms (observation, signs, symptoms, preliminary diagnosis) associated with patient information that is gathered at the initial stage of clinical intervention, when the course of treatment is just beginning. Thus, it would appear to be clear that the authors of this legislation understood the precise meanings of these clinical terms and utilized them accordingly. Further indication that Congress intended this result is the language in section 1867(b)(1)(A) of the Act (stabilization), which requires that the hospital provide ''for such further medical examination'' as necessary to stabilize. Congress' use of the word ''further'' acknowledges that there was some initial treatment that occurred in the emergency department.

In addition, the legislative history of EMTALA is replete with references to the problem of individuals denied emergency medical care at hospital emergency rooms, whereas there is no explicit reference to similar problems faced by hospital inpatients. (*See,* for example, 131 Cong. Rec. 28.587 and 28.588 (1985)). When the Congress considered the need for EMTALA legislation, it noted that Medicare-participating hospitals were bound to meet hospital conditions of participation, but that no specific requirements then existed for appropriate treatment of emergency patients. (*See* H.R. Rept. No. 241 (I)(1985), reprinted in 1986 U.S.C.C.A.N. 579, 605.) Arguably, the Congress also considered other protections available to hospital inpatients (for example, private causes of action).

This interpretation that EMTALA was not intended to apply to transfers at any time during an inpatient's stay is further supported by the language of the appropriate transfer provisions of section 1867(c) of the Act. While that paragraph does refer to individuals at a

''hospital,'' rather than individuals at an ''emergency department,'' the same paragraph also makes reference to actions to be taken by ''a physician * * * physically present in the emergency department.'' This explicit mention of a hospital emergency department, even in a paragraph that generally cites an individual at a ''hospital,'' supports the view that EMTALA was not intended to apply to admitted inpatients who may become unstable subsequent to admission, but only to patients who initially come to the hospital's emergency department with an emergency medical condition, and only until the condition has been stabilized. Finally, we note that once a hospital admits an individual as a patient, that hospital has a variety of other legal, licensing, and professional obligations with respect to the continued proper care and treatment of such patients.

a. Admitted Emergency Patients. A related issue concerns whether a hospital may satisfy its EMTALA obligations to an admitted emergency inpatient only by effectuating an actual stable discharge or appropriate transfer. We are proposing to clarify that even when an admitted emergency patient is not actually transferred, a determination may be made as to whether or not the patient has been stabilized such that he or she could be transferred at a certain point without likely material deterioration of the patient's condition, as defined in section 1867(e)(3)(B) of the Act. Under our proposed policy, if the admitted emergency patient could have been transferred as ''stable'' under the statute and the period of stability is documented by relevant clinical data in the patient's medical record, the hospital has satisfied its EMTALA obligation by meeting the statutory requirement of providing stabilizing treatment to the point of stability for transfer, and the hospital's obligation under EMTALA ends, even though the patient may remain in inpatient status at the hospital. If, after stabilization, the individual who was admitted as an inpatient again has an apparent decline of his or her medical condition, either as a result of the injury or illness that created the emergency for which he or she initially came to the dedicated emergency department or as a result of another injury or illness, the hospital must comply with the conditions of participation under 42 CFR Part 482, but has no further responsibility under EMTALA with respect to the individual.

We also note that, just because a hospital may stabilize a patient for purposes of ending its EMTALA obligation to that patient, this does not relieve the hospital of any further health and safety obligations as to that patient under the Medicare program. While they remain patients in that hospital, these patients are still protected by a number of Medicare health and safety standards (conditions of participation), as explained further below. In addition, as explained above, nothing under EMTALA in any way changes a hospital's other legal, licensing, and professional obligations with respect to the continued proper care and treatment of its patients.

Example 4: A patient comes to Hospital C's emergency department and requests treatment for an emergency medical condition. The patient knows he has severe heart disease and his chest pains have become more frequent. The patient receives an appropriate medical screening examination and is found to have an emergency medical condition, as indicated by a pain pattern and EKG abnormalities consistent with unstable angina. Stabilizing treatment in the emergency department on an outpatient basis, consisting of oxygen, nitrates and heparin, is initiated.

After several hours of outpatient care, the emergency physician determines that the patient is still not stable for purposes of discharge to his home. The emergency physician concludes that the patient can be treated most effectively by being admitted to Hospital C where he is currently being treated as an outpatient. The patient is admitted as an inpatient for further treatment. The attending physician knows that patients with indications for coronary angioplasty are usually transferred to Hospital D in another city because Hospital D has specialized capabilities that are unavailable at admitting Hospital C. A trip to Hospital D typically requires 2 hours travel by ground ambulance. The physician determines that the patient is stable for purposes of this type of transfer; that is, such a transfer is not likely to result in a material deterioration of the patient's condition, and documents relevant clinical data in the patient's medical record. Even though patients with this degree of coronary arterial disease and acute infarction risk are usually transferred, the patient opposes transfer and wants to remain in the local community. In accordance with the wishes of the patient and his family, the attending physician agrees to treat the patient in Hospital C while informing the patient of the risks involved.

Application: In this situation, the admitted patient is not stable for purposes of discharge to his home but the attending physician determined that the patient is stable for the type of transfer usually undertaken by Hospital C for patients with unstable angina considered for angioplasty. This stabilization, which is documented by relevant clinical data in the patient's medical record, ends Hospital C's EMTALA obligation to the patient, and that obligation would not be reinstated by any subsequent deterioration in the patient's condition.

We are proposing to redesignate paragraph (c) of § 489.24 as paragraph (d), and include these stabilization requirements under a new proposed § 489.2(d)(2). (Proposed redesignated paragraph (d) would be revised further as explained in section V.K.9.b. of this preamble.)

b. Admitted Elective (Nonemergency) Patients. Most hospital admissions do not consist of emergency cases. In most cases, a patient who comes to the hospital and requests admission does so to obtain elective (nonemergency) diagnosis or treatment for a medical condition. Questions have arisen, however, as to whether a hospital would be bound under EMTALA in the situation in which an admitted nonemergency inpatient experiences a deterioration of his or her medical condition.

Under our interpretation of section 1867 of the Act as described above, we believe EMTALA was intended to provide protection to patients coming to a hospital to seek care for an emergency condition. Therefore, we believe that the EMTALA requirements do not extend to admitted nonemergency inpatients. These patients are protected by a number of the Medicare hospital conditions of participation, as explained further under section V.K.13. of this preamble. These patients are further protected by a hospital's other legal, licensing, and professional obligations with respect to the continued proper care and treatment of its patients.

We are proposing to also include these requirements under the proposed redesignated § 489.24(d)(2).

10. Applicability of EMTALA to Provider-Based Entities

On April 7, 2000, we published a final rule specifying the criteria that must be met for a determination regarding provider-based status (65 FR 18504). The regulations in that the April 2000 final rule were subsequently revised to incorporate changes mandated by section 404 of Public Law 106–554 (66 FR 59856, November 30, 2001). However, those revisions did not substantively affect hospitals' obligations with respect to off-campus departments.

a. Applicability of EMTALA to Off-Campus Hospital Departments. In the April 7, 2000 final rule (65 FR 18504), we also clarified the applicability of EMTALA to hospital departments not located on the main provider campus. At that time, we revised § 489.24 to include a new paragraph (i) to specify the antidumping obligations of hospitals

with respect to individuals who come to off-campus hospital departments for the examination or treatment of a potential emergency medical condition. As explained in the preamble to the April 7, 2000 final rule, we made this change because we believed it was consistent with the intent of section 1867 of the Act to protect individuals who present on hospital property (including off-campus hospital property) for emergency medical treatment. Since publication of the April 7, 2000 final rule, it has become clear that many hospitals and physicians continue to have significant concerns with our policy on the applicability of EMTALA to these off-campus locations. After further consideration, we are proposing to clarify the scope of EMTALA's applicability in this scenario to those off-campus departments that are treated by Medicare under § 413.65(b) to be departments of the hospital, and that are equipped and staffed areas that are used a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical conditions. That is, we are proposing to narrow the applicability of EMTALA to only those off-campus departments that are ''dedicated emergency departments'' as defined in proposed revised § 489.24(b).

This proposed definition would include such departments whether or not the words ''emergency room'' or ''emergency department'' were used by the hospital to identify the departments. The definition would also be interpreted to encompass those off-campus hospital departments that would be perceived by a prudent layperson as appropriate places to go for emergency care. Therefore, we are proposing to revise the definition of ''Hospital with an emergency department'' at § 489.24(b) to account for these off-campus dedicated emergency departments and to also amend the definition of ''Comes to the emergency department'' at § 489.24(b) to include this same language. We believe this proposed change would enhance the quality of emergency care by facilitating the prompt delivery of emergency care in those cases, thus permitting individuals to be referred to nearby facilities with the capacity to offer appropriate emergency care.

In general, we expect that off-campus departments that meet the proposed definitions stated above would in practice be functioning as ''off-campus emergency departments.'' Therefore, we believe it is reasonable to expect the hospital to assume, with respect to these off-campus departments, all EMTALA obligations that the hospital must assume with respect to the main hospital campus emergency department. For instance, the screening and stabilization or transfer requirements described in section V.K.1. of this preamble (''Background'') would extend to the off-campus emergency departments, as well as to any such departments on the main hospital campus.

In conjunction with this proposed change in the extent of EMTALA applicability with respect to off-campus facilities, we are also proposing to delete all of existing § 489.24(i), which, as noted above, was established in the April 7, 2000 final rule. We are proposing to delete this paragraph in its entirety because its primary purpose is to describe a hospital's EMTALA obligations with respect to patients presenting to off-campus departments that do not routinely provide emergency care. Under the proposals outlined above, however, a hospital would have no EMTALA obligation with respect to individuals presenting to such departments. Therefore, it would no longer be necessary to impose the requirements in existing § 489.24(i). Even though off-campus provider-based departments that do not routinely offer services for emergency medical conditions would not be subject to EMTALA, some individuals may occasionally come to them to seek emergency care. Under such circumstances, we believe it would be appropriate for the department to call an emergency medical service (EMS) if it is incapable of treating the patient, and to furnish whatever assistance it can to the individual while awaiting the arrival of EMS personnel. Consistent with the hospital's obligation to the community and similar to our requirements under § 482.12(f)(2) that apply to hospitals that do not provide emergency services, we would expect the hospital to have appropriate protocols in place for dealing with individuals who come to off-campus nonemergency facilities to seek emergency care. To clarify a hospital's responsibility in this regard, we are proposing to revise § 482.12(f) by adding a new paragraph (3) to state that if emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff of the hospital has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate. (We note that, in a separate document (62 FR 66758, December 16, 1997), we proposed to relocate the existing § 482.12(f) requirement to a new section of Part 482. Any change to the existing § 482.12(f) that is adopted as a result of the proposal described above will be taken into account in finalizing the December 19, 1997 proposal.) However, the hospital would not incur an EMTALA obligation with respect to the individual.

In summary, we are proposing in existing § 489.24(b) to revise the definitions of ''comes to the emergency department'' and ''hospital with an emergency department'', and to include these off-campus departments in our new definition of ''dedicated emergency department.'' We welcome comments on whether this new term is needed or if the term ''emergency department'' could be defined more broadly to encompass other departments that provide urgent or emergent care services. We are proposing to delete all of existing § 489.24(i) and to make conforming revisions to § 413.65(g)(1).

b. On-Campus Provider-Based Applicability. At existing § 413.65(g)(1), we state, in part, that if any individual comes to any hospital-based entity (including an RHC) located on the main hospital campus, and a request is made on the individual's behalf for examination or treatment of a medical condition, the entity must comply with the antidumping rules at § 489.24. Since provider-based entities, as defined in § 413.65(b), are not under the certification and provider number of the main provider hospital, this language, read literally, would appear to impose EMTALA obligations on providers other than hospitals, a result that would not be consistent with section 1867, which restricts EMTALA applicability to hospitals. To avoid confusion on this point and to prevent any inadvertent extension of EMTALA requirements outside the hospital setting, we are proposing to clarify that EMTALA applies in this scenario to only those *departments* on the hospital's main campus that are provider-based; EMTALA would not apply to provider-based *entities* (such as RHCs) that are on the hospital campus.

In addition, we are proposing in § 489.24(b) to revise the definition of ''Comes to the emergency department'' to include an individual who presents on hospital property, in which ''hospital property'' is in part defined as ''the entire main hospital campus as defined at § 413.65(b) of this chapter, including the parking lot, sidewalk, and driveway, but excluding other areas or structures that may be located within 250 yards of the hospital's main building but are not part of the hospital, such as physician offices, RHCs, SNFs, or other entities

that participate separately in Medicare, or restaurants, shops, or other nonmedical facilities.'' We are specifically seeking comments on this proposed revised definition. Generally, this proposed language would clarify that EMTALA does not apply to provider-based entities, whether or not they are located on a hospital campus. This language is also consistent with our policy as stated in questions and answers published on the CMS website: *www.cms.gov* (CMS EMTALA guidance, 7/20/01, Q/A # 1) that clarifies that EMTALA does not apply to other areas or structures located on the hospital campus that are not part of the hospital, such as fast food restaurants or independent medical practices.

If this proposed change limiting EMTALA applicability to only those on-campus departments of the hospital becomes finalized, we believe that if an individual comes to an on-campus provider-based entity or other area or structure on the campus not applicable under the new policy and presents for emergency care, it would be appropriate for the entity to call the emergency medical service if it is incapable of treating the patient, and to render whatever assistance it can to the individual while awaiting the arrival of emergency medical service personnel. However, the hospital on whose campus the entity is located would not incur an EMTALA obligation with respect to the individual.

We welcome comments from providers and other interested parties on the proper or best way to organize hospital resources to react to situations on campus where an individual patient or prospective patient requires immediate medical attention.

We are proposing in § 489.24(b) to revise the definition of ''Comes to emergency department'' (specifically, under proposed new paragraph (1)) and make conforming changes at § 413.65(g)(1).

11. EMTALA and On-Call Requirements

We have frequently received inquiries concerning the applicability of EMTALA for physicians on call. We believe there are a number of misconceptions in the provider industry concerning the extent to which EMTALA requires physicians to provide on-call coverage. Therefore, we are including a section in this preamble that clarifies what kinds of obligations physicians have to provide on-call coverage under EMTALA.

Section 1866(a)(1)(I)(iii) of the Act states, as a requirement for participation in the Medicare program, that hospitals must keep a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition. If a physician on the list is called by a hospital to provide emergency screening or treatment and either fails or refuses to appear within a reasonable period of time, the hospital and that physician may be in violation of EMTALA as provided for under section 1867(d)(1)(C) of the Act.

The CMS State Operations Manual (SOM) further clarifies a hospital's responsibility for the on-call physician. The SOM (Appendix V, page V–15, Tag A404) states:

- Each hospital has the discretion to maintain the on-call list in a manner to best meet the needs of its patients.
- Physicians, including specialists and subspecialists (for example, neurologists), are not required to be on call at all times. The hospital must have policies and procedures to be followed when a particular specialty is not available or the on-call physician cannot respond because of situations beyond his or her control.

Thus, hospitals are required to maintain a list of physicians on call at any one time and physicians or hospitals, or both, may be responsible under the EMTALA statute to provide emergency care if a physician who is on the on-call list fails to or refuses to appear within a reasonable period of time. However, Medicare does not set requirements on how frequently a hospital's staff of on-call physicians are expected to be available to provide on-call coverage. We are aware that practice demands in treating other patients, conferences, vacations, days off, and other similar factors must be considered in determining the availability of staff. We also are aware that some hospitals, particularly those in rural areas, have stated that they incur relatively high costs of compensating physician groups for providing on-call coverage to their emergency departments, and that doing so can strain their already limited financial resources. CMS allows hospitals flexibility to comply with EMTALA obligations by maintaining a level of on-call coverage that is within their capability.

We understand that some hospitals exempt senior medical staff physicians from being on call. This exemption is typically written into the hospital's medical staff bylaws or the hospital's rules and regulations, and recognizes a physician's active years of service (20 or more years) or age (that is, 60 years of age or older), or a combination of both. We wish to clarify that providing such exemptions to members of hospitals' medical staff does not necessarily violate EMTALA. On the contrary, we believe that the hospital is responsible for maintaining an on-call list in a manner that best meets the needs of its patients as long as the exemption does not affect patient care adversely. Thus, CMS allows hospitals flexibility in the utilization of their emergency personnel.

We also note that there is no predetermined ''ratio'' that CMS uses to identify how many days that a hospital must provide medical staff on-call coverage based on the number of physicians on staff for that particular specialty. In particular, CMS has no rule stating that whenever there are at least three physicians in a specialty, the hospital must provide 24 hour/7 day coverage. Generally, in determining EMTALA compliance, CMS will consider all relevant factors, including the number of physicians on staff, other demands on these physicians, the frequency with which the hospital's patients typically require services of on-call physicians, and the provisions the hospital has made for situations in which a physician in the specialty is not available or the on-call physician is unable to respond.

Example 5: Hospital D has 75 beds and is located in a rural area. The hospital provides on-call coverage of orthopedic services on all weekdays and the first 3 weekends of each month. On the fourth weekend of one month, an individual presents at Hospital D's dedicated emergency department and requests examination for a medical condition. The emergency physician on duty screens the individual and finds that she has an orthopedic emergency medical condition requiring the services of an orthopedist. Hospital D does not have on-call orthopedic physician coverage on this date and, therefore, transfers the individual to an urban hospital 20 miles away for necessary treatment. The transfer is arranged in accordance with procedures that Hospital D has for meeting patient needs when a particular specialty is not available or the physician cannot respond for reasons beyond his or her control.

Analysis: Hospital D incurred an EMTALA obligation when the individual presented at Hospital D's dedicated emergency department and requested examination for a medical condition. At that time, Hospital D did not have on-call coverage to provide necessary stabilizing treatment for what was an orthopedic emergency medical condition, even though an orthopedic physician was on-call at other times. The emergency physician at Hospital D weighed the risks involved to transfer the individual to an urban hospital with capabilities to treat the individual and found that it would be more beneficial to the individual to transfer him or her

to the urban hospital 20 miles away, than to provide screening and stabilizing treatment within Hospital D's capabilities (which, at that time, did not include orthopedic services). Hospital D has satisfied its EMTALA obligation by providing screening services within its capability, followed by an appropriate transfer, under procedures developed in advance. To clarify our policies on EMTALA requirements regarding the availability of on-call physicians, we are proposing to add to § 489.24 a new paragraph (j) to specify that each hospital has the discretion to maintain the on-call list in a manner to best meet the needs of its patients. This paragraph would further specify that physicians, including specialists and subspecialists (for example, neurologists), are not required to be on call at all times, and that the hospital must have policies and procedures to be followed when a particular specialty is not available or the on-call physician cannot respond because of situations beyond his or her control.

12. EMTALA Applicability to Hospital-Owned Ambulances

We stated in the June 22, 1994 final rule (59 FR 32098) that if an individual is in an ambulance owned and operated by a hospital, the individual is considered to have come to the hospital's emergency department, even if the ambulance is not on hospital property. This policy, currently set forth at § 489.24(b), was necessary because we were concerned that some hospitals that owned and operated ambulances at that time were transporting individuals who had called for an ambulance to other hospitals, thereby evading their EMTALA responsibilities to the individuals.

Concerns have since been raised by the provider industry about applications of this policy to ambulances that are owned by hospitals but are operating under communitywide EMS protocols that may require the hospital-owned and other ambulances to transport individuals to locations other than the hospitals that own the ambulances. For instance, we understand that some community protocols require ambulances to transport individuals to the nearest hospital to the patient geographically, whether or not that hospital owns the ambulance.

To avoid imposing requirements that are inconsistent with local EMS requirements, we are proposing to clarify, at proposed revised § 489.24(b) in the definition of ''Comes to the emergency department'', an exception to our existing rule requiring EMTALA applicability to hospitals that own and operate ambulances. Our proposal would account for hospital-owned ambulances operating under communitywide EMS protocols. Under our proposal, the rule on hospital-owned ambulances and EMTALA does not apply if the ambulance is operating under a communitywide EMS protocol that requires it to transport the individual to a hospital other than the hospital that owns the ambulance. In this case, the individual is considered to have come to the emergency department of the hospital to which the individual is transported, at the time the individual is brought onto hospital property.

13. Conditions of Participation for Hospitals

We are reminding hospitals and others that while this proposed regulation would make it clear that stabilizing an emergency inpatient relieves the hospital of its EMTALA obligations, it does not relieve the hospital of all further responsibility for the patient who is admitted or indicate that the hospital is thus free to improperly discharge or transfer him or her to another facility. Inpatients who experience acute medical conditions receive protections under the hospital conditions of participation, which are found at 42 CFR part 482. In addition, as noted earlier in this preamble, we believe that outpatients who experience what may be an emergency medical condition after the start of an encounter with a health professional would have all protections afforded to patients of a hospital under the Medicare conditions of participation. There are six conditions of participation that provide these protections: emergency services, governing body, discharge planning, quality assurance, medical staff, and outpatient services. We are not proposing in this proposed rule to make changes to any of the conditions of participation.

If a hospital inpatient develops an acute medical condition and the hospital is one that provides emergency services, the hospital is required to ensure that it meets the emergency needs of the patient in accordance with accepted standards of practice. Similarly, regardless of whether the hospital provides emergency services, if an inpatient develops an acute medical condition, the governing body condition of participation (§ 482.12(f)(2), which applies to all Medicare-participating hospitals) would apply. This condition of participation requires that the hospital governing body must ensure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

The discharge planning condition of participation (§ 482.43, which applies to all Medicare-participating hospitals) requires hospitals to have a discharge planning process that applies to all patients. This condition of participation ensures that patient needs are identified and that transfers and referrals reflecting adequate discharge planning are made by the hospital. If an inpatient develops an acute medical condition and the hospital either does not offer emergency services or does not have the capability to provide necessary treatment, a transfer to another hospital with the capabilities to treat the emergency medical condition could be warranted. Hospitals are required to meet the discharge planning condition of participation in carrying out such a transfer.

The hospital condition of participation governing medical staff (§ 482.22) requires that the hospital have an organized medical staff that operates under bylaws approved by the governing body and is responsible to the governing body for the quality of medical care provided to patients by the hospital. Should the medical staff not be held accountable to the governing body for problems regarding a lack of provision of care to an inpatient who develops an emergency medical condition, this lack of accountability may be reviewed under the medical staff condition of participation, as well, and may result in a citation of noncompliance at the medical staff condition level for the hospital.

Finally, the quality assurance condition of participation (§ 482.21, which applies to all Medicare-participating hospitals) requires the governing body to ensure that there is an effective, hospital-wide quality assurance program to evaluate the provision of patient care. In order to comply with this condition of participation, the hospital must evaluate the care it provides hospital-wide. Complaints regarding a lack of provision of care to an inpatient who develops an emergency medical condition must be addressed under the hospital's quality assurance program and may be reviewed under the quality assurance condition of participation.

A hospital's failure to meet the conditions of participation requirements cited above may result in a finding of noncompliance at the condition level for the hospital and lead to termination of the hospital's Medicare provider agreement.

K. Provider-Based Entities

1. Background

a. The April 7, 2000 Final Rule

Since the beginning of the Medicare program, some providers, which we refer to as ''main providers,'' have functioned as a single entity while owning and operating multiple provider-based departments, locations, and facilities that were treated as part of the main provider for Medicare purposes. Having clear criteria for provider-based status is important because this designation can result in additional Medicare payments for services furnished at the provider-based facility, and may also increase the coinsurance liability of Medicare beneficiaries for those services.

In the April 7, 2000 **Federal Register** (65 FR 18504), we published a final rule specifying the criteria that must be met for a determination regarding provider-based status. The regulations at § 413.65(a)(2) define provider-based status as ''the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section.'' The regulations at existing § 413.65(b)(2) state that before a main provider may bill for services of a facility as if the facility is provider-based, or before it includes costs of those services on its cost report, the facility must meet the criteria listed in the regulations at § 413.65(d). Among these criteria are the requirements that the main provider and the facility must have common licensure (when appropriate), the facility must operate under the ownership and control of the main provider, and the facility must be located in the immediate vicinity of the main provider.

The effective date of these regulations was originally October 10, 2000, but was subsequently delayed and is now in effect for new facilities or organizations for cost reporting periods beginning on or after January 10, 2001, as explained further below. Program instructions on provider-based status issued before that date, found in Section 2446 of the Provider Reimbursement Manual, Part 1 (PRM–1), Section 2004 of the Medicare State Operations Manual (SOM), and CMS Program Memorandum (PM) A–99–24, will apply to any facility for periods before the new regulations become applicable to it. (Some of these instructions will not be applied because they have been superseded by specific legislation on provider-based status, as described in section V.K.3. of this preamble).

b. Frequently Asked Questions Regarding Provider-Based Issues

Following publication of the April 7, 2000 final rule, we received many requests for clarification of policies on specific issues related to provider-based status. In response, we published a list of ''Frequently Asked Questions'' and the answers to them on the CMS website at *www.hcfa.gov/medlearn/provqa.htm.* (This document can also be obtained by contacting any of the CMS (formerly, HCFA) Regional Offices.) These questions and answers did not revise the regulatory criteria, but do provide subregulatory guidance for their implementation.

c. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106–554)

On December 21, 2000, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 (Public Law 106–554) was enacted. Section 404 of BIPA contains provisions that significantly affect the provider-based regulations at § 413.65. Section 404 includes a grandfathering provision for facilities treated as provider-based on October 1, 2000; alternative criteria for meeting the geographic location requirement; and criteria for temporary treatment as provider-based.

(1) Two-Year ''Grandfathering''

Under section 404(a) of BIPA, any facilities or organizations that were ''treated'' as provider-based in relation to any hospital or CAH on October 1, 2000, will continue to be treated as such until October 1, 2002. For the purpose of this provision, we interpret ''treated as provider-based'' to include those facilities with formal CMS determinations, as well as those facilities without formal CMS determinations that were being paid as provider-based as of October 1, 2000. As a result, existing provider-based facilities and organizations may retain that status without meeting the criteria in the existing regulations under §§ 413.65(d), (e), (f), and (h) until October 1, 2002. These provisions concern provider-based status requirements, joint ventures, management contracts, and services under arrangement. Thus, the provider-based facilities and organizations affected under section 404(a) of BIPA are not required to submit an application for or obtain a provider-based status determination in order to continue receiving reimbursement as provider-based during this period.

These provider-based facilities and organizations are not exempt from the EMTALA responsibilities of provider-based facilities and organizations set forth at § 489.24, which we are proposing to revise as discussed above, or from the other obligations of hospital outpatient departments and hospital-based entities in existing § 413.65(g), such as the responsibility of off-campus facilities to provide written notices to Medicare beneficiaries of coinsurance liability. These rules are not preempted by the grandfathering provisions of section 404 of BIPA because they do not set forth criteria that must be met for provider-based status as a department of a hospital, but instead identify responsibilities that flow from that status. These responsibilities become effective for hospitals on the first day of the hospital's cost reporting period beginning on or after January 10, 2001.

(2) Geographic Location Criteria

Section 404(b) of BIPA provides that those facilities or organizations that are not included in the grandfathering provision at section 404(a) are deemed to comply with the ''immediate vicinity'' requirements of the existing regulations under § 413.65(d)(7) if they are located not more than 35 miles from the main campus of the hospital or CAH. Therefore, those facilities located within 35 miles of the main provider satisfy the immediate vicinity requirement as an alternative to meeting the ''75/75 test'' under existing § 413.65(d)(7).

In addition, BIPA provides that certain facilities or organizations are deemed to comply with the requirements for geographic proximity (either the ''75/75 test'' or the ''35-mile test'') if they are owned and operated by a main provider that is a hospital with a disproportionate share adjustment percentage greater than 11.75 percent and is (1) owned or operated by a unit of State or local government, (2) a public or private nonprofit corporation that is formally granted governmental powers by a unit of State or local government, or (3) a private hospital that has a contract with a State or local government that includes the operation of clinics of the hospital to ensure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare or Medicaid.

These geographic location criteria will continue indefinitely. While those facilities or organizations treated as provider-based on October 1, 2000 are covered by the 2-year grandfathering

provision noted above, the geographic location criteria at section 404(b) of BIPA and the existing regulations at § 413.65(d)(7) will apply to facilities or organizations not treated as provider-based as of that date, effective with the hospital's cost reporting period beginning on or after January 10, 2001. On October 1, 2002, the statutory moratorium on application of these criteria to the grandfathered facilities will expire. In this proposed rule, we are proposing a further delay, as discussed below.

(3) Criteria for Temporary Treatment as Provider-Based

Section 404(c) of BIPA also provides that a facility or organization that seeks a determination of provider-based status on or after October 1, 2000, and before October 1, 2002, shall be treated as having provider-based status for any period before a determination is made. Thus, recovery for overpayments will not be made retroactively once a request for a determination during that time period has been made. For hospitals that do not qualify for grandfathering under section 404(a) of BIPA, a request for provider-based status should be submitted to the appropriate CMS Regional Office. Until a uniform application is available, at a minimum, the request should include the identity of the main provider and the facility or organization for which provider-based status is being sought and supporting documentation for purposes of applying the provider-based status criteria in effect at the time the application is submitted. Once such a request has been submitted on or after October 1, 2000, and before October 1, 2002, CMS will treat the facility or organization as being provider-based from the date it began operating as provider-based until the effective date of a CMS determination that the facility or organization is not provider-based.

Facilities requesting a provider-based status determination on or after October 1, 2002, will not be covered by the provision concerning temporary treatment as provider-based in section 404(c) of BIPA. Thus, as stated in § 413.65(n), the CMS Regional Offices will make provider-based status effective as of the earliest date on which a request for determination has been made and all requirements for provider-based status in effect as of the date of the request are shown to have been met, not on the date of the formal CMS determination. Under existing regulations at § 413.65(j), if a facility or organization does not qualify for provider-based status and CMS learns that the provider has treated the facility or organization as provider-based without having obtained a provider-based determination under applicable regulations, CMS will review all payments and may seek recovery for overpayments, including overpayments made for the period of time between submission of the request or application for provider-based status and the issuance of a formal CMS determination. (As explained in the previous paragraph, such retroactive recovery of payments would not be made for any period to the extent it is prohibited by section 404(c) of BIPA.)

d. The August 24, 2001 and November 30, 2001 Published Regulations

In August 24, 2001 **Federal Register** (66 FR 44672), we proposed to revise the provider-based regulations to reflect the changes mandated by section 404 of BIPA and to make other technical and clarifying changes in those regulations. In the November 30, 2001 **Federal Register** (66 FR 59856), following consideration of public comments received on the August 24, 2001 proposal, we published a final rule that revised the provider-based regulations. However, the only substantive changes in the provider-based regulations were those required by the BIPA legislation.

2. Proposed Changes

In the preamble to the proposed rule published on August 24, 2001 (66 FR 44709), we stated our intent to reexamine the EMTALA regulations and, in particular, to reconsider the appropriateness of applying EMTALA to off-campus locations. We announced that we planned to review these regulations with a view toward ensuring that these locations are treated in ways that are appropriate to the responsibility for EMTALA compliance of the hospital as a whole. We also pointed out that, at the same time, we want to ensure that those departments that Medicare pays as hospital-based departments are appropriately integrated with the hospital as a whole.

In addition, since the statutory grandfathering provision in the BIPA legislation remains in effect only until October 1, 2002, many hospital representatives have contacted CMS to request more guidance because they are concerned that their facilities are not in compliance with existing regulations and would not be able to continue billing as provider-based once the grandfathering provision expires. These hospital representatives are also concerned that the organizational and contractual changes needed to meet current provider-based requirements could take several months to complete. Moreover, resolution of some of the issues surrounding the provider-based regulations is needed in order to allow development of a uniform application form to enable the CMS Regional Offices to efficiently process the multitudes of requests for provider-based determinations that we expected as the grandfathering period expires.

To address the provider-based issues raised by the hospital industry and to allow for an orderly and uniform implementation strategy once grandfathering ends, we are proposing the following regulatory changes:

a. Scope of Provider-Based Requirements (§ 413.65(a))

Since publication of the April 2000 final rule, we have received many questions about which specific facilities or organizations are subject to the provider-based requirements. In the ''Frequently Asked Questions'' posted on the CMS website, we identified a number of facility types for which provider-based determinations would not be made, since such determinations would not affect either Medicare payment or Medicare beneficiary liability or scope of benefits. The regulations at § 413.65(a) were further revised to incorporate the exclusion of these facility types from review under the provider-based criteria. We now are proposing to further revise § 413.65(a)(1)(ii) to state that provider-based determinations will not be made with respect to independent diagnostic testing facilities that furnish only services paid under a fee schedule, such as facilities that furnish only screening mammography services, as defined in section 1861(jj) of the Act, facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services. A provider-based determination would not be appropriate for a facility that furnishes only screening mammography because of a change made by section 104 of BIPA. That legislation, which amended section 1848(j)(3) of the Act, mandates that all payment for screening mammography services furnished on or after January 1, 2000, be made under the Medicare Physician Fee Schedule (MPFS). Under the MPFS methodology, Medicare payment for the service, regardless of the setting in which it is furnished, is set at the lesser of the fee schedule amount or the actual charge; and no Part B deductible applies. Regardless of the setting, Part B coinsurance is assessed at 20 percent of the lesser of the fee schedule amount or the actual charge. Because the status of a facility as provider-based or freestanding would

not affect the amount of Medicare or Medicaid payment, the beneficiary's scope of benefits, or the beneficiary's liability for coinsurance or deductible amounts, it is not necessary to make a provider-based determination regarding facilities that furnish only screening mammography. We are also proposing to revise § 413.65(a)(1)(ii) by adding a new paragraph (J) to state that we will not make provider-based determinations with respect to departments of providers (for example, laundry or medical records departments) that do not furnish types of health care services for which separate payment could be claimed under Medicare or Medicaid. (Such services frequently are referred to as ''billable'' services.) As explained more fully below, we would not make determinations with respect to these departments because their status (that is, whether they are provider-based or not) would have no impact on Medicare or Medicaid payment or on the scope of benefits or beneficiary liability under either program.

Despite the previous clarifications described above, providers, associations, and their representatives have continued to state that they are confused as to which facilities or organizations will be the subject of provider-based determinations.

In this document, we are proposing to further clarify the types of facilities that are subject to the provider-based rules, by making several changes to the definitions of key terms in § 413.65(a)(2). First, we are proposing to revise the definition of ''department of a provider'' to remove the reference to a physician office as being a department of a provider. While a hospital outpatient department, in fact, may furnish services that are clinically indistinguishable from those of physician offices, physician offices and provider departments are paid through separate methods under Medicare and beneficiaries may be liable for different coinsurance amounts. Thus, it is essential to distinguish between these facility types, and we believe avoiding confusion on this issue requires us to remove the reference to a hospital department as a physician office.

We also are proposing to revise § 413.65(a)(2) to state that a ''department of a provider'', ''provider-based entity'', or ''remote location of a hospital'' comprises both the specific physical facility that serves as the site of services of a type for which separate payment could be claimed under the Medicare or Medicaid programs, and the personnel and equipment needed to deliver the services at that facility. We believe this change would help to clarify that we would make determinations with respect to entities considered in their role as sources of health care services and not simply as physical locations. We also wish to clarify that we do not intend to make provider-based determinations with respect to various organizational components or units of providers that may be designated as ''departments'' or ''organizations'' but do not themselves furnish types of services for which separate payment could be claimed under Medicare or Medicaid. Examples of components for which we would not make provider-based determinations include the medical records, housekeeping, and security departments of a hospital. Such departments do perform functions that are essential to the provision of inpatient and outpatient hospital services, but the departments do not provide health care services for which Medicare or Medicaid benefits are provided under title XVIII or title XIX of the Act, and for which separate payment therefore could be claimed, assuming certification and other applicable requirements were met, to one or both programs. Therefore, neither Medicare or Medicaid program liability nor beneficiary liability or scope of benefits would be affected by the ability or inability of these departments to qualify as ''provider-based.'' (We also would not make a provider-based determination with respect to any facility or organization that furnishes only types of health care services for which separate payment could be claimed under either Medicare or Medicaid, even if the facility or organization met all requirements for provider-based status. For example, if a hospital that is not eligible for DSH payments under Medicare or Medicaid or for IME payments under Medicare were to establish a dedicated facility providing only types of cosmetic surgery or experimental therapies that could not be covered under either Medicare or Medicaid, no determination would be made with respect to that facility.)

By contrast, Medicare or Medicaid payment (or both) to hospital departments that provide diagnostic or therapeutic radiology services to outpatients, or primary care, ophthalmology, or other specialty services to outpatients are affected by provider-based status, as would beneficiary liability for Medicare coinsurance amounts. Therefore, we would make provider-based determinations for these departments.

Similarly, if two acute care hospitals that have approved graduate medical education (GME) programs were to merge to form a single, multicampus hospital consisting of the main hospital campus and a remote location, it would be appropriate to make a determination as to whether the remote location is provider-based with respect to the main hospital campus. Such a determination would be needed because each hospital with an approved residency training program has its own hospital-specific cap on the number of residents (or FTE cap), its own PRA, and its own Medicare utilization used for purposes of receiving Medicare GME payments. A merger of the two hospitals would aggregate the two hospitals' individual FTE caps into a merged FTE cap under the main hospital's provider number, and would require recalculation of the hospital's PRA and a merging of these entities' respective Medicare utilization, resulting in a level of Medicare GME payment to the merged hospital that exceeds the sum of the payments that would be made to each hospital as separate entities. Thus, a provider-based determination would be appropriate and necessary in such a case, even though payment for services by both facilities would be made under the Medicare acute care hospital inpatient prospective payment system.

In deciding whether to make a provider-based determination with respect to a particular facility, it would not be significant that the facility might have a low rate of Medicare utilization, might be utilized by only Medicare or only Medicaid patients, or might not have admitted any Medicare or Medicaid patients in a particular period. The fact that the facility furnishes types of services that are billable under Medicare or Medicaid, or both, would be sufficient to make a determination appropriate.

We are proposing to retain the rules that a department of a provider or a remote location of a hospital (such as, for example, one campus of a multicampus hospital) may not by itself be qualified to participate in Medicare as a provider under the regulations on provider agreements in § 489.2, and the Medicare conditions of participation do not apply to a department as an independent entity. However, we are proposing to delete the requirement at § 413.65(a)(2) that such a department may not be licensed to provide services in its own right. Some States require separate licensing of facilities that Medicare would treat as a department of a hospital or other provider. In these States, we would not require a common license. We would retain the provision that, for purposes of Part 413, the term ''department of a provider'' does not

include an RHC or, except as specified in § 413.65(m), an FQHC.

Questions have arisen regarding whether the provider-based criteria in § 413.65 are applicable in determining payment for ambulance services. Medicare is converting payment for ambulance services to a fee schedule, as described in a final rule published on February 27, 2002 (67 FR 9100). The ambulance fee schedule is effective April 1, 2001, and involves a transition period. During this transition period, the status of an ambulance supplier as provider-based could influence the amount of Medicare payment. However, the specific provider-based criteria in § 413.65 were not developed for ambulance suppliers, and we believe that many of these criteria could not reasonably be applied to them. Therefore, we are not proposing to apply the criteria at § 413.65 to ambulance services.

b. Further Delay in Effective Date of Provider-Based Rules

As noted earlier, § 413.65(b) was recently revised to reflect the ''grandfathering'' provision in section 404(a)(1) of BIPA. Under that provision, if a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until October 1, 2002.

It now appears likely that any new provider-based rules that may be adopted as the result of this rulemaking effort will not be published in final before mid-summer of 2002. To allow hospitals and other facilities the time they need to make contractual and organizational changes to comply with the new rules, and to ensure that CMS Regional Offices and contractors are able to provide for an orderly transition to the new provider-based rules, we believe an additional delay in the effective date of the provider-based criteria is needed. Therefore, we are proposing to revise § 413.65(b)(2) to state that if a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. We are proposing to further provide that the requirements, limitations, and exclusions specified in § 413.65(d) through (j) (as proposed to be redesignated) will not apply to that hospital or CAH for that facility until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. For purposes of paragraph (b)(2), a facility would be considered as having been provider-based on October 1, 2000, if on that date it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital. We are proposing to make the new requirements effective on October 1, 2002, with respect to provider-based status for facilities not qualifying for the grandfathering provision.

c. Revision of Application Requirement

Existing regulations at § 413.65(b)(2) establish an explicit application requirement for all facilities seeking provider-based status, except for grandfathered facilities and those treated as provider-based pending a determination on an application filed on or after October 1, 2000, and before October 1, 2002. Under existing § 413.65(b)(3), a main provider or a facility must contact CMS, and the facility must be determined by CMS to be provider-based, before the main provider bills for services of the facility as if the facility were provider-based, or before it includes costs of those services on its cost report. Many providers and provider representatives have expressed concern that the requirement to file an application will increase paperwork burden for hospitals unnecessarily. In response to these concerns, we are proposing to revise the application requirements as follows:

First, we would delete the existing application requirement under § 413.65(b)(3). We are proposing to revise this section to state that except where payment is required to be made under BIPA, as specified in proposed revised § 413.65(b)(2) and (b)(5), if a potential main provider seeks an advance determination of provider-based status for a facility that is located on the main campus of the potential main provider, the provider would be required to submit an attestation stating that its facility meets the criteria in § 413.65(d) and, if it is a hospital, also attest that its facility will fulfill the obligations of hospital outpatient departments and hospital-based entities, as described in proposed § 413.65(g). The provider also would be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS upon request. We note that, under our proposal, there would no longer be an explicit requirement that a provider-based approval be obtained before a facility is treated as provider-based for billing or cost reporting purposes. However, under the proposed revisions to existing § 413.65(k) (Correction of errors) as described below, CMS would provide a delay in the effective date for any facility that is found not to meet the provider-based criteria following a previous advance determination, if the reason the provider-based criteria are not met is a material change in the provider-facility relationship that was properly reported to CMS. The removal of provider-based status would be effective as of the first cost reporting period following notification of the redetermination, but not less than 6 months after the date of notification.

We are further proposing that if the facility is not located on the main campus of the potential main provider, the provider that wishes to obtain an advance determination of provider-based status would be required to submit an attestation stating that its facility meets the criteria in proposed revised §§ 413.65(d) and (e) and, if the facility is operated as a joint venture or under a management contract, the requirements in proposed §§ 413.65(f) and (h), as applicable. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in proposed revised § 413.65(g). The provider seeking such an advance determination would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations. We believe the use of a self-attestation process would strike an appropriate balance between the legitimate interests of hospitals in reducing paperwork and reporting, and the equally legitimate need of CMS to ensure proper accountability for compliance with the qualification requirements for a status that typically leads to a higher level of Medicare or Medicaid payment.

We note that, under these proposed revisions to the application procedures at § 413.65(b), a hospital would not be explicitly required to submit an application and receive a provider-based determination for a facility before the time at which the hospital may bill for services at that facility as provider-based. However, we are considering, alternatively, retaining the existing regulations at § 413.65(b)(2) which state that, except where payment is required to be made under BIPA as specified in proposed revised §§ 413.65(b)(2) and (b)(5), hospitals are explicitly required to submit provider-based applications, and to withhold billing as provider-based until CMS determines that a facility meets the provider-based rules. We are soliciting comments on the

appropriateness of this or other alternative application procedures.

d. Requirements Applicable to All Facilities or Organizations

Under existing § 413.65, all facilities seeking provider-based status with respect to a hospital or other main provider must meet a common set of requirements. These include requirements relating to common licensure (paragraph (d)(1)), operation under the ownership and control of the main provider (paragraph (d)(2)), administration and supervision (paragraph (d)(3)), integration of clinical services (d)(4)), financial integration (paragraph (d)(5)), public awareness (paragraph (d)(6)), and location in the immediate vicinity of the main provider (paragraph (d)(7)). (In addition, as described more fully below, specific rules applicable to all facilities rule out provider-based status for facilities operated as joint ventures by two or more providers (paragraph (e)) and limit the types of management contracts that facilities seeking provider-based status may operate under (paragraph (f)).)

Since publication in final of the existing provider-based rules in April 2000, hospitals and other providers have expressed concern that the requirements outlined above are overly restrictive and do not allow them enough flexibility to enter into appropriate business arrangements with other facilities. We understand these concerns, and agree that Medicare rules should not restrict legitimate business arrangements that do not lead to abusive practices or disadvantage Medicare beneficiaries. At the same time, we believe our existing rules provide a high level of assurance that a facility complying with them is, in fact, an integral and subordinate part of the facility with which it is based, and do not accord provider-based status to facilities that are not integral and subordinate to a main provider, but in fact have only a nominal relationship with that provider.

After considering all comments received on these issues, we believe that further changes in the provider-based rules would be appropriate. In particular, we agree with those who argue that a facility's or organization's location relative to the main campus of the provider is relevant to the integration that is likely to exist between the facility or organization and the main provider. For example, if a facility or organization is located on the main campus of a provider, is operated under the main provider's State license, is medically and financially integrated with that provider, and is held out to the public and other payers as a part of that provider, we believe the necessary degree of integration of the facility or organization into the main provider can be assumed to exist. We also are concerned that further prescribing the types of management contracts or other business arrangements that may exist between the main provider and the facility or organization would unnecessarily restrict its flexibility to establish cost-effective agreements without significantly enhancing the integration of the facility or organization into the main provider. Therefore, we are proposing to simplify the requirements applicable to facilities or organizations located on the campus of the main provider (as campus is defined in existing regulations at § 413.65(a)(2)). Under our proposal, all facilities seeking provider-based status, including both on-campus and off-campus facilities, would be required to comply with the existing requirements regarding licensure, clinical services integration, financial integration, and public awareness. (These requirements are currently codified at §§ 413.65(d)(1), (d)(4), (d)(5), and (d)(6) and, under this proposed rule, would be redesignated as paragraphs (d)(1) through (d)(4), respectively, of § 413.65.)

With respect to financial integration, existing regulations at § 413.65(d)(5) require that the financial operations of the facility or organization be fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The regulations also require that costs of a provider-based facility or organization be reported in a cost center of the provider, and that the financial status of any provider-based facility or organization be incorporated and readily identified in the main provider's trial balance.

Some hospital representatives have questioned the appropriateness of requiring that the costs of a remote location of a hospital be reported in a single cost center, noting that such costs ordinarily would appear in multiple cost centers of the main provider, with (for example) employee health and welfare costs of the remote location being included in the corresponding cost center of the main provider. In recognition of this concern, we are proposing to revise the requirement to state that the costs of a facility or organization that is a hospital department must be reported in a cost center of the provider, and that costs of a provider-based facility or organization other than a hospital department must be reported in the appropriate cost center or cost centers of the main provider.

Paragraph (d) of § 413.65 would be retitled ''Requirements applicable to all facilities or organizations'' and, as indicated by its revised title, would set forth those core requirements that any facility or organization would have to meet to qualify for provider-based status.

We are proposing to delete from this paragraph (d) the requirements in existing paragraphs (d)(2) and (d)(3) relating to operation under the ownership and control of the main provider and administration and supervision because we are proposing to no longer apply these requirements to on-campus facilities or organizations. These requirements would be moved to paragraph (e) as described below to reflect the proposed limitation of their applicability to off-campus departments. The core requirements for all facilities or organizations, including facilities located on the main campus, also would not include the requirement regarding location in the immediate vicinity of the main provider (existing § 413.65(d)(7)). Because any facilities or organizations located on the campus of the main provider automatically meet the requirement regarding location in the immediate vicinity (existing § 413.65(d)(7)), the requirement is only of relevance to off-campus facilities or organizations. For clarity, we are proposing to relocate the requirement to paragraph (e) as described below.

We also are proposing to require, in paragraph (d)(5) of § 413.65, all hospital outpatient departments and hospital-based entities, including those located on campus and those located off the campus of the main provider hospital, to fulfill the obligations currently codified and proposed to be retained at § 413.65(g) in order to qualify for provider-based status. (Fulfillment of these obligations is currently required under § 413.65(g).) As explained further below, we also are proposing other changes to paragraph (g).

e. Additional Requirements Applicable to Off-Campus Facilities or Organizations

We recognize that facilities or organizations located off the main provider campus may also be sufficiently integrated with the main provider to justify provider-based designation. However, the off-campus location of the facilities or organizations may make such integration harder to achieve, and such integration should not simply be presumed to exist. Therefore, to ensure that off-campus facilities or organizations seeking

provider-based status are appropriately integrated, we are proposing to retain for these facilities or organizations certain requirements that we are proposing to remove for on-campus facilities or organizations. These requirements are set forth in proposed new § 413.65(e). The requirements set forth in proposed paragraphs (e)(1), (e)(2), and (e)(3) include the requirements on operation under the ownership and control of the main provider (existing § 413.65(d)(2)), administration and supervision (existing § 413.65(d)(3)), and location (existing § 413.65(d)(7)). We also are proposing to include language in proposed new § 413.65(e) to state more clearly that a facility or organization seeking provider-based status must be located in the same State or, when consistent with the laws of both States, in adjacent States.

f. Joint Ventures

Consistent with our views as expressed earlier in this preamble regarding the assumption that a higher degree of integration can be presumed for on-campus facilities or organizations and in recognition of the need to promote reasonable cooperation among providers and avoid costly duplication of specialty services, we are proposing to revise the regulations on joint ventures (currently set forth under § 413.65(e)) to limit their scope to facilities or organizations not located on the campus of any potential main provider. Specifically, we would redesignate § 413.65(e) as § 413.65(f) and revise it to state that a facility or organization that is not located on the campus of the potential main provider cannot be considered provider-based if the facility or organization is owned by two or more providers engaged in a joint venture. We also are proposing to make minor changes to the second sentence of the redesignated paragraph (f) to clarify its meaning.

g. Clarification of Obligations of Hospital Outpatient Departments and Hospital-Based Entities

Existing regulations impose specific obligations for hospital outpatient departments and hospital-based entities, but do not specify the sanction that applies if the facility or organization does not fulfill its obligations. To clarify policy on this issue and emphasize the importance of compliance with the requirements in this area, we are proposing to revise existing § 413.65(g) to state that to qualify for provider-based status in relation to a hospital, a facility or organization must comply with these requirements. In regard to these obligations, we are proposing to make three changes in existing 413.65(g). First, for reasons explained in section V.J. of this preamble, we are proposing to revise paragraph (g)(1) by deleting the second sentence of that paragraph. In paragraph (g)(2), we are proposing to delete the reference to site-of-service reductions and instead refer to more accurately determined physician payment amounts, in order to more accurately describe how payment under the physician fee schedule is determined. In addition, we are proposing to revise the first sentence of paragraph (g)(7) to clarify that the notice requirements in it do not apply where a beneficiary is examined or treated for a medical condition in compliance with the antidumping rules in § 489.24. This clarification is needed because we believe it would be a violation of the antidumping requirements if examination or treatment required under § 489.24 was delayed in order to permit notification of the beneficiary or the beneficiary's authorized representative. We would further revise § 413.65(g)(7) to state that notice is required once the beneficiary has been appropriately screened and the existence of an emergency has been ruled out or the emergency condition has been stabilized.

h. Management Contracts

Under existing regulations, facilities or organizations operated under management contracts may be considered provider-based only if they meet specific requirements in § 413.65(f) (proposed to be redesignated as § 413.65(h)). In particular, staff of the facility or organization, other than management staff, may not be employed by the management company but must be employed either by the provider or by another organization, other than the main provider, which also employs the staff of the main provider. Under existing regulations, these requirements apply equally to on-campus and off-campus facilities or organizations.

Consistent with our intent to simplify provider-based requirements for on-campus facilities or organizations, we are proposing to restrict the applicability of proposed redesignated paragraph (h) to off-campus facilities or organizations. In addition, we are proposing two additional changes that we believe are needed to respond to questions that are raised frequently about the regulation. First, we would specify that a facility or organization operated under a management contract may be considered provider-based only if the main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations at 42 CFR Part 414. We would not specify who may employ other support staff, such as maintenance or security personnel, and who are not directly involved in providing patient care, nor would we require licensed professional caregivers such as physicians, physician assistants, or certified registered nurse anesthetists to become provider employees. We also are proposing to revise the regulations to clarify at § 413.65(h)(2) that so-called ''leased'' employees (that is personnel who are actually employed by the management company but provide services for the provider under a staff leasing arrangement) are not considered to be employees of the provider for purposes of this provision.

i. Inappropriate Treatment of a Facility or Organization as Provider-Based

Below we describe the steps that we would take if we discover that a facility is billing as provider-based without having requested a determination, or if the facility received a provider-based determination but the main provider did not inform CMS of a subsequent material change that affected the provider-based status of its facility.

(1) Inappropriate Billing

The existing regulations at § 413.65(i) state that if we discover that a provider is billing inappropriately, we will recover the difference between the amount of payments that actually were made and the amount of payments that CMS estimates should have been made in the absence of a determination of provider-based status. Existing § 413.65(j)(2) states that we would adjust future payments to approximate as closely as possible the amounts that would be paid, in the absence of a provider-based determination, if all other requirements for billing are met. In addition, existing § 413.65(j)(5) describes a procedure under which CMS would continue payments to a provider for services of a facility or organization that had been found not to be provider-based, at an adjusted rate calculated as described in existing paragraph (j)(2), for up to 6 months in order to permit the facility or organization adequate time to meet applicable enrollment and other billing requirements. While CMS is not legally obligated to continue payments in this matter, we believe it would be

appropriate to do so, on a time-limited basis, to allow for an orderly transition to either provider-based or freestanding status for the facility and to avoid disruption in the delivery of services to patients, particularly Medicare patients, who may be relying on the facility for their medical care.

We are proposing to adopt a policy concerning recoupment and continuation of payment that closely parallels the policy stated in existing regulations at § 413.65(j). Under proposed § 413.65(j)(1), if CMS learns that a provider has treated a facility or organization as provider-based and the provider did not request an advance determination of provider-based status from CMS under proposed § 413.65(b)(3), and CMS determines that the facility or organization did not meet the requirements for provider-based status under proposed § 413.65(d) through (i), as applicable (or, in any period before the effective date of these regulations, the provider-based requirements in effect under Medicare program regulations or instructions), CMS would take several actions. First, we are proposing to issue notice to the provider, in accordance with proposed paragraph (j)(3), that payments for past cost reporting periods may be reviewed and recovered as described in proposed paragraph (j)(2)(ii), that future payments for services in or at the facility or organization will be adjusted as described in proposed paragraph (j)(4), and that continued payments to the provider for services of the facility or organization will be made only in accordance with proposed paragraph (j)(5). In addition, as detailed in proposed § 413.65(j)(1)(ii), CMS would, except for providers protected under section 404(a) or (c) of BIPA (implemented at § 413.65(b)(2) and (b)(5)) or the exception for good faith effort at existing § 413.65(i)(2) and (i)(3)), recover the difference between the amount of payments that actually was made to that provider for services at the facility or organization and an estimate of the payments that CMS would have made to that provider for services at the facility or organization in the absence of compliance with the requirements for provider-based status. We are proposing to make recovery for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889. Also, we are proposing to adjust future payments to approximate the amounts that would be paid for the same services furnished by a freestanding facility.

Recovery of past payments would be limited in certain circumstances. If a provider did not request a provider-based determination for a facility by October 1, 2002, but is included in the grandfathering period under § 413.65(b)(2), we are proposing to recoup all payments subject to the reopening rules at §§ 405.1885 and 405.1889, but not for any period before the provider's cost reporting period beginning on or after July 1, 2003.

(2) Good Faith Effort

We are proposing to retain the existing exception for good faith effort (proposed redesignated § 413.65(j)(2)). Under this exception, we would not recover any payments for any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001 (the effective date of the existing provider-based regulations for providers not grandfathered under § 413.65(b)(2)) if during all of that period—

- The requirements regarding licensure and public awareness at § 413.65(d)(1) and proposed redesignated (d)(4) were met;
- All facility services were billed as if they had been furnished by a department of a provider, a remote location of a hospital, a satellite facility, or a provider-based entity of the main provider; and
- All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described at proposed redesignated and revised § 413.65(h)(2).

Under proposed § 413.65(j)(5), CMS would continue payment to a provider for services of a facility or organization for a limited period of time, in order to allow the facility or organization or its practitioners to meet necessary enrollment and other requirements for billing on a freestanding basis. Specifically, the notice of denial of provider-based status sent to the provider would ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, as to whether the provider intends to seek an advance determination of provider-based status for the facility or organization, or whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services as a freestanding facility. If the provider indicates that it will not be seeking an advance determination or that the facility or organization or its practitioners will not be seeking to enroll, or if CMS does not receive a response within 30 days of the date the notice was issued, all payments under proposed paragraph (j)(5) would end as of the 30th day after the date of notice. If the provider indicates that it will be seeking an advance determination, or that the facility or organization or its practitioners will be seeking to meet enrollment and other requirements for billing for services in a freestanding facility, payment for services of the facility or organization would continue, at the adjusted amount described in proposed paragraph (j)(4) for as long as is required for all billing requirements to be met (but not longer than 6 months). Continued payment would be allowed only if the provider or the facility or organization or its practitioners submits, as applicable, a complete request for an advance provider-based determination or a complete enrollment application and provide all other required information within 90 days after the date of notice; and the facility or organization or its practitioners furnishes all other information needed by CMS to process the request for provider-based status or, as applicable, the enrollment application and verify that other billing requirements are met. If the necessary applications or information are not provided, CMS would terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted.

j. Temporary Treatment as Provider-Based and Correction of Errors

Under proposed revised § 413.65(k), we would specify the procedures for payment for the period between the time a request is submitted until a provider-based determination is made, and the steps we would take if we discover that a facility for which a provider previously received a provider-based determination no longer meets the requirements for provider-based status.

First, we are proposing that, if a provider submits a complete request for a provider-based determination for a facility that has not previously been found by CMS to have been inappropriately treated as provider-based under proposed revised § 413.65(j), the provider may bill and be paid for services at the facility as provider-based from the date of the application until the date that we determine that the facility or organization does not meet the provider-based rules under § 413.65. If CMS determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the complete request for a provider-based determination was submitted and the amount of payments that CMS estimates

should have been made in the absence of compliance with the provider-based requirements. We would consider a request ''complete'' only if it included all information we need to make an advance determination of provider-based status under § 413.65(b)(3).

Second, similar to what we specify in existing § 413.65(k), if we determine that a facility or organization that previously received a provider-based determination no longer qualifies for provider-based status, and the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider reported to CMS as is required under § 413.65(c), treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.

Third, if we determine that a facility or organization that had previously received a provider-based determination no longer qualifies for provider-based status, and if the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did not report to CMS, as required under § 413.65(c), we are proposing to take the actions with respect to notice to the provider, adjustment of payments, and continuation of payment described in proposed paragraphs (j)(3), (j)(4), and (j)(5). In short, we would treat such cases in the same way as if the provider had never obtained an advance determination. However, with respect to recovery of past payments for providers included in the grandfathering provision at proposed revised § 413.65(b)(2), we would not recover payments for any period before the provider's first cost reporting period beginning on or after July 1, 2003.

Also, we are proposing that the exception for good faith effort concerning recovery of overpayments under proposed revised §§ 413.65(j)(2) described above would apply to any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001.

k. Technical Amendments

We are proposing to correct a typographical error in the heading of paragraph (m) of § 413.65 so that it reads ''FQHCs and 'look alikes' ''.

In paragraph (n) of § 413.65, we are proposing to add a cross-reference to the requirements for provider-based status described in paragraph (b), for purposes of specifying the effective date of provider-based status.

L. CMS Authority Over Reopening of Intermediary Determinations and Intermediary Hearing Decisions on Provider Reimbursement

Our existing regulations provide various means for the reopening and revision of an intermediary determination or an intermediary hearing decision on provider reimbursement by the fiscal intermediary or the intermediary hearing officer(s) responsible for the determination or the hearing decision, respectively. (In this discussion, we will use the term ''intermediary'' to refer to, as applicable, the intermediary responsible for an intermediary determination (see §§ 405.1801(a) and 405.1803) or the intermediary hearing officer or panel of intermediary hearing officers responsible for an intermediary hearing decision (see §§ 405.1817 and 405.1831.)) Section 405.1885(a) provides that an intermediary ''may'' reopen an intermediary determination or an intermediary hearing decision, on its own initiative or at the request of a provider, within 3 years of the date of the notice of the intermediary determination or intermediary hearing decision. However, while § 405.1885(a) provides the intermediary with some discretion about whether to reopen an intermediary determination or an intermediary hearing decision, we have always considered the intermediary's discretion to be limited by any directives that may be issued by CMS. Thus, although § 405.1885(a) provides that the intermediary ''may'' reopen, that provision neither states nor implies that the Secretary lacks authority to direct the intermediary to reopen or not reopen a specific matter. Furthermore, CMS has prescribed, in Medicare Provider Reimbursement Manual, Part I (''PRM''), section 2931.2, criteria that guide the intermediary's reopening actions under ''405.1885(a) in the absence of a particular directive from CMS. Also, given that the intermediaries are CMS' contractors, we have always believed that, under basic principles of agency law, we have inherent authority to direct the actions of our own agents with respect to reopening matters under ''405.1885(a), just as for any other aspect of program administration. *See also* 42 U.S.C. 1395h and 1395kk(a); and 42 CFR 421.1(c), 421.5(b), 421.100(f), 421.124(a), and 421.126(b).

Under § 405.1885(b), an intermediary determination or an intermediary hearing decision ''shall be reopened and revised by the intermediary if, within the aforementioned 3-year period, the Centers for Medicare & Medicaid Services notifies the intermediary that such determination or decision is inconsistent with the applicable law, regulations, or general instructions issued by the Centers for Medicare & Medicaid Services.'' We have always considered the CMS notice, which is a precondition of mandatory intermediary reopening under § 405.1885(b), to be one in which we explicitly direct the intermediary to reopen. We have never considered a notice or other document from CMS that only states or implies that an intermediary determination or an intermediary hearing decision is inconsistent with law, regulations, CMS ruling, or CMS general instructions, sufficient to require intermediary reopening under § 405.1885(b). Moreover, our understanding has always been that the phrase ''law, regulations, or general instructions'' in § 405.1885(b) refers to the legal provisions in effect, as we understand such legal provisions, at the time the intermediary rendered the determination or hearing decision. Conversely, we have never considered changes in, or judicial explications of, ''law, regulations, or general instructions,'' that occur after the intermediary rendered the determination or hearing decision, sufficient to require intermediary reopening under § 405.1885(b). Also, § 405.1885(b) refers to the Secretary's agreement with an intermediary; we believe such agreement requires the intermediary to apply the law, regulations, CMS rulings, and CMS general instructions in effect, as we understand such legal provisions, when the intermediary determination or hearing decision was rendered. Accordingly, we have not instructed intermediaries to reopen and recover reimbursement, or to reopen and award additional reimbursement, due to a subsequent change in law or policy, whether the subsequent change is made in response to judicial precedent or otherwise.

Section 405.1885(c) provides: ''Jurisdiction for reopening a determination or decision rests exclusively with that administrative body that rendered the last determination or decision.'' We have always interpreted § 405.1885(c) to provide that authority to reopen an intermediary determination or an intermediary hearing decision is vested exclusively with the responsible intermediary, as distinct from the Provider Reimbursement Review Board (PRRB) and the Administrator of CMS (in the context of reviewing PRRB

decisions (see § 405.1875)) which may not reopen an intermediary determination or hearing decision and may not review an intermediary's denial of reopening. However, we have never considered the intermediary's authority to reopen an intermediary determination or hearing decision, which is exclusive under § 405.1885(c) only as to the PRRB and the Administrator of CMS (in the context of reviewing PRRB decisions), to limit CMS' authority to direct the actions of its own agents with respect to reopening matters. *See Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. 449, 452–53 (1999). (Section 405.1885(c) divests the PRRB of ''appellate jurisdiction to review the intermediary's refusal'' to reopen, but does not limit the Secretary's authority to direct an intermediary's ''original jurisdiction'' in the reopening area). As discussed previously, the regulations do not constrain CMS' authority to direct the intermediary to reopen or not reopen a specific matter; instead, CMS has placed generally applicable limits on the intermediary's discretion through the reopening criteria prescribed in section 2931.2 of the PRM. In addition, we have always believed that, under basic principles of agency law, the intermediary's discretion over a particular reopening matter is no less circumscribed by any directives that may be issued by CMS than would be the case for any other aspect of program administration.

Two recent court decisions conflict with our longstanding interpretation of the forgoing provisions of the reopening regulations. In *Monmouth Medical Center* v. *Thompson*, 257 F.3d 807 (D.C. Cir. 2001), the court found that a statement in a CMS ruling, changing CMS' interpretation of the statute in response to circuit court precedent, constituted a directive to the intermediary under § 405.1885(b) to reopen, notwithstanding an explicit directive in the CMS ruling that the change in interpretation was to be applied only prospectively. The court ordered the intermediary to reopen over the Secretary's objection. We disagree with the court's decision, which we believe does not comport with our settled interpretation (discussed above) of § 405.1885(b). Therefore, we are proposing to revise § 405.1885(b) to make clear that, in order to trigger the intermediary's obligation to reopen, the notice from CMS to the intermediary must explicitly direct the intermediary to reopen based on a finding that an intermediary determination or an intermediary hearing decision is inconsistent with the law, regulations, CMS ruling, or CMS general instructions in effect, and as we understood those legal provisions, at the time the determination or decision was rendered. We are also proposing to clarify § 405.1885 to reflect our longstanding interpretation (discussed above) that a change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening an intermediary determination or an intermediary hearing decision under this section.

The *Monmouth Medical Center* decision was followed in *Bartlett Memorial Medical Center* v. *Thompson*, 171 F. Supp. 2d 1215 (W.D. Okla. 2001). In a subsequent order in the *Bartlett Memorial Medical Center* case, the court concluded that a CMS ruling, which prohibited intermediary reopening on a particular reimbursement issue, improperly interfered with the intermediary's discretion under § 405.1885(c) over provider requests for reopening under § 405.1885(a). Accordingly, the court ordered the intermediary to act on the provider reopening requests without regard to the CMS ruling or any other involvement of the Secretary. We disagree with the court's decision, which we believe is contrary to our settled interpretation (discussed above) of § 405.1885(a) and (c). We believe the court's decision is also inconsistent with CMS' inherent authority to direct the activities of its own contractor-agents, the fiscal intermediaries, with respect to particular reopening matters, just as with any other aspect of program administration. Therefore, we are proposing, in a new paragraph (e) of § 405.1885 (the existing paragraph is proposed to be redesignated as paragraph (f)), to clarify that, notwithstanding an intermediary's discretion to reopen or not reopen under paragraphs (a) and (c) of § 405.1885, CMS may direct an intermediary to reopen, or not to reopen, an intermediary determination or an intermediary hearing decision in accordance with paragraphs (a) and (c) of this section. To illustrate our proposal, revised § 405.1885(e) would clarify that CMS has full authority to direct an intermediary to reopen, or not to reopen, an intermediary determination or an intermediary hearing decision under § 405.1885(a) and (c) based on the reopening criteria of ''new and material evidence'' or ''clear and obvious error.'' *See* PRM § 2931.2.

VI. Proposed Changes to the Prospective Payment System for Capital-Related Costs

A. Background

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services ''in accordance with a prospective payment system established by the Secretary.'' Under the statute, the Secretary has broad authority in establishing and implementing the capital prospective payment system. We initially implemented the capital prospective payment system in the August 30, 1991 final rule (56 FR 43358), in which we established a 10-year transition period to change the payment methodology for Medicare inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

Federal fiscal year (FY) 2001 was the last year of the 10-year transition period established to phase in the prospective payment system for hospital capital-related costs. Beginning in FY 2001, capital prospective payment system payments were based solely on the Federal rate for the vast majority of hospitals. The basic methodology for determining capital prospective payments based on the Federal rate is set forth in § 412.312. For the purpose of calculating payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor(GAF)) × (Large Urban Add-on, if applicable) × (COLA Adjustment for Hospitals Located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor)

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year that are specified in § 412.312(c) of existing regulations. (Refer to the August 1, 2001 final rule (66 FR 39910) for a summary of the statutory basis for the system, the development and evolution of the system, the methodology used to determine capital-related payments to hospitals both during and after the transition period, and the policy for providing special exceptions.)

B. New Hospitals

Under the prospective payment system for capital-related costs, at § 412.300(b), a new hospital is defined as a hospital that is newly participating in the Medicare program (under current or previous ownership) for less than 2 years (see 56 FR 43418, August 30,

1991). During the 10-year transition period, under § 412.324(b), a new hospital was exempt from capital prospective payment system for its first 2 years of operation and was paid 85 percent of its reasonable costs during that period. Effective with its third cost reporting period, a new hospital was paid under the appropriate transition methodology (either hold-harmless or fully prospective) for the remainder of the transition period. (If the hold-harmless methodology was applicable, hold-harmless payments would be made for 8 years, even if they extend beyond the 10-year transition period, which ended beginning with cost reporting periods beginning during FY 2002.)

This payment provision was implemented to provide special protection to new hospitals during the transition period in response to concerns that prospective payments under a DRG system may not be adequate initially to cover the capital costs of newly built hospitals. These hospitals may not have sufficient occupancy in those initial 2 years and may have incurred significant capital startup costs, so that capital prospective payment system payments may not be sufficient. For instance, hospitals newly participating in the Medicare program may not initially have adequate Medicare utilization. Because capital prospective payment system payments are made on a per discharge basis, a hospital only receives payments for its capital-related costs upon discharge of its Medicare patients. In addition, these hospitals did not have an opportunity to reserve previous years' capital prospective payment system payments to finance capital projects.

While the regulations provided for payments based on a percentage of costs for new hospitals for the first 2 years during the 10-year transition period, no provision was made for new hospitals once the 10-year transition was completed. However, we believe that the rationale for the policy applies equally to new hospitals even after the completion of the 10-year transition period. Accordingly, we are proposing, under § 412.304(c)(2), to provide special payment to new hospitals for cost reporting periods beginning on or after October 1, 2002. That is, we would pay new hospitals, as defined under § 412.300(b), 85 percent of their reasonable costs for their first 2 years of operation. Effective with their third year of operation, a new hospital would be paid based on the Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital prospective payment system). We believe this proposal would provide for more appropriate payments to new hospitals for their capital-related costs since initial capital expenditures may reasonably exceed the capital prospective payment system per discharge payment based on the Federal rate. The capital prospective payment Federal rate is based on industry-wide average capital costs rather than the experience of a new hospital. We believe this proposed policy would allow new hospitals to provide efficiency in the delivery of services and still make reasonable payments for their capital expenditures.

As was the case during the 10-year transition period, this proposed new hospital exemption would only be available to those hospitals that have not received reasonable cost-based payments under the Medicare program in the past, and would need special protection during their initial period of operation. This proposed exemption from the capital prospective payment system for the first 2 years of operation would not apply to a hospital that is ''new'' as an acute care hospital but that has operated in the past (under current or previous ownership) and has an historical Medicare asset base. Furthermore, a hospital that replaces its entire facility (regardless of a change of ownership) would not qualify for the new hospital exemption even though it may experience a significant change in its asset base. Thus, in accordance with § 412.300(b), a new hospital exemption would not apply in the following situations:

- A hospital that builds new or replacement facilities at the same or a new location, even if a change of ownership or a new leasing arrangement is involved;
- A hospital that closes and then reopens under the same or different ownership;
- A hospital that has been in operation for more than 2 years but has been participating in the Medicare program for less than 2 years; or
- A hospital that changes status from a prospective payment system-excluded hospital (paid under the TEFRA methodology) or another hospital prospective payment system (such as the inpatient rehabilitation facility prospective payment system) to a hospital that is subject to the capital prospective payment system for acute care hospitals.

C. Extraordinary Circumstances

When we implemented the capital prospective payment system in FY 1992, a number of commenters requested that we provide for a separate exceptions payment to account for extraordinary circumstances beyond a hospital's control that would require the hospital to make unanticipated major capital expenditures (56 FR 43411, August 30, 1991). In response to the commenters' request, we provided in the regulations at § 412.348(f) that a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Extraordinary circumstances include, but are not limited to, a flood, a fire, or an earthquake. For more detailed information regarding this policy, refer to the August 30, 1991 **Federal Register** (56 FR 43411).

To clarify that this policy regarding additional payments for extraordinary circumstances also applies to periods beginning on or after October 1, 2001, we are proposing to revise § 412.312 by adding a new paragraph (e) to specify that payment is made for extraordinary circumstances as provided for in § 412.348(f) for cost reporting periods after the transition period, that is, on or after October 1, 2001.

D. Restoration of the 2.1 Percent Reduction to the Standard Federal Capital Prospective Payment System Payment Rate

Section 1886(g)(1)(A) of the Act, as amended by section 4402 of Public Law 105–33, requires the Secretary to reduce the unadjusted standard Federal capital prospective payment system payment rate (and the unadjusted hospital-specific rate) by 2.1 percent for discharges on or after October 1, 1997, and through September 30, 2002, in addition to applying the budget neutrality factor used to determine the Federal capital prospective payment system payment rate in effect on September 30, 1995. The budget neutrality factor effective for September 30, 1995, was 0.8432 (59 FR 45416). Therefore, application of the budget neutrality factor (as specified under section 1886(g)(1)(A) of the Act) was equivalent to a 15.68 percent reduction to the unadjusted standard Federal capital prospective payment system payment rate and the unadjusted hospital-specific rate in effect on September 30, 1997. The additional 2.1 reduction to the rates in effect on September 30, 1997 resulted in a total reduction of 17.78 percent. Accordingly, under the statute, the additional 2.1 percent reduction no longer applies to discharges occurring after September 30, 2002 (§ 412.308(b)(5)). Therefore, we are proposing to revise § 412.308(b) to add a new paragraph (b)(6) to restore the 2.1 percent reduction to the unadjusted

standard Federal capital prospective payment system payment rate (as provided under § 412.308(c)) for discharges occurring on or after October 1, 2002, to the level that it would have been without the reduction. (Since FY 2001 was the final year of the 10-year transition period, we no longer update the hospital-specific rate and, therefore, we also no longer restore the 2.1 percent reduction to that rate as provided under § 412.328(e)(1).)

As described in the August 29, 1997 final rule (62 FR 46012), we determined the reduction factor for FY 1998 by deducting both the FY 1995 budget neutrality factor (0.1568) and the 2.1 percent reduction (0.021) from 1 (1 − 0.1568 − 0.021 = 0.8222). We then applied the 0.8222 to the unadjusted standard Federal rate. Therefore, to determine the adjustment factor needed to restore the 2.1 percent reduction, we would divide the amount of the adjustment without the 2.1 percent reduction (1 − 0.1568 = 0.8432) by the amount of the adjustment with the 2.1 percent reduction (0.8222). Accordingly, we are proposing to restore the 2.1 percent reduction for discharges occurring on or after October 1, 2002, under proposed § 413.308(b)(6), by applying a factor of 1.02554 (0.8432/0.8222) to the unadjusted standard Federal capital prospective payment system payment rate under § 412.308(c), that was in effect on September 30, 2002.

E. Clarification of Special Exceptions Policy

Under the special exceptions provisions at § 412.348(g), an additional payment may be made through the 10th year beyond the end of the capital prospective payment system transition period for eligible hospitals that meet (1) a project need requirement as described at § 412.348(g)(2), which, in the case of certain urban hospitals, includes an excess capacity test described at § 412.348(g)(4); and (2) a project size requirement as described at § 412.348(g)(5). In accordance with § 412.348(g)(7), hospitals are eligible to receive special exceptions payments for the 10 years after the cost reporting year in which they complete their project, which can be no later than the hospital's cost reporting period beginning before October 1, 2001.

During the 10-year capital prospective payment system transition period, regular exceptions under §§ 412.348(b) through (e) paid the same as or more (between 70 percent and 90 percent of costs, depending on the type of hospital) than the special exceptions provision under § 412.348(g) (70 percent for all eligible hospitals). Therefore, it was not until cost reporting periods beginning on or after October 1, 2001 (the end of the transition period) that eligible hospitals could actually begin receiving additional payments under the special exceptions provision. As we stated in the July 30, 1999 final rule (64 FR 41528), we believe that, since any substantive changes to this policy could have a significant impact, the appropriate forum for addressing the special exceptions policy is through the legislative process in Congress rather than the regulations process. Since hospitals are beginning to receive additional payments under this provision, we have received several questions regarding current policy at § 412.348(g). Therefore, while we are not proposing any changes to the special exceptions policy, we are providing the following clarifications to the existing regulations.

Under § 412.348(g)(1), to be eligible for special exception payments, a hospital must be either a sole community hospital (SCH), an urban hospital with at least 100 beds that has a disproportionate share (DSH) percentage of at least 20.2 percent or qualify for DSH payments under § 412.106(c)(2), or a hospital with a combined Medicare and Medicaid inpatient utilization of at least 70 percent. Because a hospital's SCH status, DSH patient percentage, and combined utilization may fluctuate from one cost reporting year to the next, the special exceptions eligibility criteria are applied for each cost reporting period throughout the 10-year special exceptions period. A hospital receives special exceptions payments only for those years in the 10-year period in which it meets the eligibility requirements in § 412.348(g)(1). Therefore, a hospital might be eligible for a special exception payment in one year, not be eligible the next year, and then subsequently qualify during the 10-year special exceptions period.

The project need criteria in § 412.348(g)(2) also state that a hospital must obtain any required approval from a State or local planning authority. However, in States where a certificate of need or approval is not required by the State or local planning authority, the hospital must provide the fiscal intermediary with appropriate documentation (such as project plans from the hospital's board of directors) that demonstrates that the requirements of § 412.348(g)(3) concerning the age of assets test and § 412.348(g)(4) concerning the excess capacity test for urban hospitals are met. We understand that a State planning authority and a hospital may define a project differently. Accordingly, we would allow the hospital to use either the definition provided by the project within the certificate of need (in States where a certificate of need is required), or other appropriate documentation provided from the hospital's project plans (such as project plans as specified in the minutes of the meetings of the hospital's board of directors).

In determining a hospital's special exceptions payment amount, as described in § 412.348(g)(8), for each cost reporting period, the cumulative payments made to the hospital under the capital prospective payment system are compared to the cumulative minimum payment levels applicable to the hospital for each cost reporting period subject to the capital prospective payment system. This comparison is offset by any amount by which the hospital's current year Medicare inpatient operating and capital prospective payment system payments (excluding 75 percent of its operating DSH payments) exceed its Medicare inpatient operating and capital costs (or its Medicare inpatient margin). The minimum payment level is 70 percent for all hospitals, regardless of class, as set forth in § 412.348(g)(6), for the duration of the special exceptions provision.

In order to assist our fiscal intermediaries in determining the end of the 10-year period in which an eligible hospital will no longer be entitled to receive special exception payments, § 412.348(g)(9) requires that hospitals eligible for special exception payments submit documentation to the intermediary indicating the completion date of their project (the date the project was put in use for patient care) that meets the project need and project size requirements outlined in §§ 412.348(g)(2) through (g)(5). In order for an eligible hospital to receive special exception payments, this documentation had to be submitted in writing to the intermediary by the later of October 1, 2001, or within 3 months of the end of the hospital's last cost reporting period beginning before October 1, 2001, during which a qualifying project was completed.

VII. Proposed Changes for Hospitals and Hospital Units Excluded From the Acute Care Hospital Inpatient Prospective Payment System

A. Payments to Excluded Hospitals and Hospital Units (§§ 413.40(c), (d), and (f))

1. Payments to Existing Excluded Hospitals and Hospital Units

Section 1886(b)(3)(H) of the Act (as amended by section 4414 of Public Law 105–33) established caps on the target amounts for certain existing hospitals and hospital units excluded from the acute care hospital inpatient prospective payment system for cost reporting periods beginning on or after October 1, 1997 through September 30, 2002. For this period, the caps on the target amounts apply to the following three classes of excluded hospitals or units: psychiatric hospitals and units, rehabilitation hospitals and units, and long-term care hospitals.

In accordance with section 1886(b)(3)(H)(i) of the Act and effective for cost reporting periods beginning on or after October 1, 2002, payments to these classes of existing excluded hospitals or hospital units are no longer subject to caps on the target amounts. In accordance with existing §§ 413.40(c)(4)(ii) and (d)(1)(i) and (ii), these excluded hospitals and hospital units continue to be paid on a reasonable cost basis, and payments are based on their Medicare inpatient operating costs, not to exceed the ceiling. The ceiling would be computed using the hospital's or unit's target amount from the previous cost reporting period updated by the rate-of-increase specified in § 413.40(c)(3)(viii) of the regulations.

2. Updated Caps for New Excluded Hospitals and Units

Section 1886(b)(7) of the Act establishes a payment methodology for new psychiatric hospitals and units, new rehabilitation hospitals and units, and new long-term care hospitals. A discussion of how the payment limitation was calculated can be found in the August 29, 1997 final rule with comment period (62 FR 46019); the May 12, 1998 final rule (63 FR 26344); the July 31, 1998 final rule (63 FR 41000); and the July 30, 1999 final rule (64 FR 41529). Under the statutory methodology, a ''new'' hospital or unit is a hospital or unit that falls within one of the three classes of hospitals or units (psychiatric, rehabilitation or long-term care) that first receives payment as a hospital or unit excluded from the acute care hospital inpatient prospective payment system on or after October 1, 1997. The amount of payment for a ''new'' hospital or unit would be determined as follows:

- Under existing § 413.40(f)(2)(ii), for the first two 12-month cost reporting periods, the amount of payment is the lesser of: (1) the operating costs per case; or (2) 110 percent of the national median (as estimated by the Secretary) of the target amounts for the same class of hospital or unit for cost reporting periods ending during FY 1996, updated by the hospital market basket increase percentage to the fiscal year in which the hospital or unit first receives payments under section 1886 of the Act, as adjusted for differences in area wage levels.
- Under existing § 413.40(c)(4)(v), for cost reporting periods following the hospital's or unit's first two 12-month cost reporting periods, the target amount is equal to the amount determined under section 1886(b)(7)(A)(i) of the Act for the third period, updated by the applicable hospital market basket increase percentage.

The proposed amounts included in the following table reflect the updated 110 percent of the national median target amounts proposed for each class of new excluded hospitals and hospital units for cost reporting periods beginning during FY 2003. These figures are updated to reflect the proposed projected market basket increase percentage of 3.4 percent. This projected percentage change in the market basket reflects the average change in the price of goods and services purchased by hospitals to furnish inpatient hospital services (as projected by the CMS Office of the Actuary based on its historical experience with the hospital inpatient prospective payment system). For a new provider, the labor-related share of the target amount is multiplied by the appropriate geographic area wage index, without regard to prospective payment system reclassifications, and added to the nonlabor-related share in order to determine the per case limit on payment under the statutory payment methodology for new providers.

Class of excluded hospital or unit	FY 2003 proposed labor-related share	FY 2003 proposed nonlabor-related share
Psychiatric	$7,047	$2,801
Long-Term Care	17,269	6,866

Effective for cost reporting periods beginning on or after October 1, 2002, this payment limitation is no longer applicable to new rehabilitation hospitals and units since they will be paid under the inpatient rehabilitation facility prospective payment system.

3. Establishment of a Prospective Payment System for Inpatient Rehabilitation Hospitals and Units

Section 1886(j) of the Act, as added by section 4421(a) of Public Law 105–33, provided the phase-in of a case-mix adjusted prospective payment system for inpatient hospital services furnished by a rehabilitation hospital or a rehabilitation hospital unit (referred to in the statute as rehabilitation facilities) for cost reporting periods beginning on or after October 1, 2000 and before October 1, 2002, with a fully implemented prospective payment system for cost reporting periods beginning on or after October 1, 2002. Section 1886(j) of the Act was amended by section 125 of Public Law 106–113 to require the Secretary to use a discharge as the payment unit under the prospective payment system for inpatient hospital services furnished by rehabilitation facilities and to establish classes of patient discharges by functional-related groups. Section 305 of Public Law 106–554 further amended section 1886(j) of the Act to allow rehabilitation facilities to elect to be paid the full Federal prospective payment rather than the transitional period payments specified in the Act.

On August 7, 2001, we issued a final rule in the **Federal Register** (66 FR 41316) establishing the prospective payment system for inpatient rehabilitation facilities, effective for cost reporting periods beginning on or after January 1, 2002. Under the inpatient rehabilitation prospective payment system, for cost reporting periods beginning on or after January 1, 2002, and before October 1, 2002, payment will consist of 33⅓ percent of the facility-specific payment amount (based on the reasonable cost-based reimbursement methodology) and 66⅔ percent of the adjusted Federal prospective payment. For cost reporting periods beginning on or after October 1, 2002, payment will be based entirely on the Federal prospective payment rate determined under the inpatient rehabilitation facility prospective payment system.

4. Implementation of a Prospective Payment System for Long-Term Care Hospitals

In accordance with the requirements of section 123 of Public Law 106–113, as modified by section 307(b) of Public Law 106–554, we are proposing (as published in the March 22, 2002 proposed rule (67 FR 13415)) the establishment of a per discharge, DRG-based prospective payment system for long-term care hospitals as described in

section 1886(d)(1)(B)(iv) of the Act for cost reporting periods beginning on or after October 1, 2002. As part of the implementation process, we are proposing a 5-year transition period from reasonable cost-based reimbursement to the long-term care hospital prospective payment system Federal rate. We are also proposing that a long-term care hospital may elect to be paid based on 100 percent of the Federal prospective rate. Under the March 22, 2002 proposed rule, a blend of the reasonable cost-based reimbursement percentage and the prospective payment Federal rate percentage would be used to determine a long-term care hospital's total payment under the prospective payment system during the transition period. We would expect long-term care hospitals to be paid under the full Federal prospective rate for cost reporting periods beginning on or after October 1, 2006.

B. Criteria for Exclusion of Satellite Facilities from the Hospital Inpatient Prospective Payment System

Existing regulations at 42 CFR 412.22(e) define a hospital-within-a-hospital as a hospital that occupies space in the same building as another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. Section 412.22(h), relating to satellites of hospitals excluded from the acute care hospital inpatient prospective payment system, defines a satellite facility as a part of a hospital that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. Section 412.25(e), relating to satellites of excluded hospital units, defines a satellite facility as a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. Because of the similarities between the definitions of the two types of satellite facilities and the definition of a hospital-within-a-hospital, questions have been raised as to whether satellite facilities must meet the ''hospital-within-a-hospital'' criteria in § 412.22(e) regarding having a governing body, chief medical officer, medical staff, and chief executive officer that are separate from those of the hospital with which space is shared.

Although the separateness of satellite facilities of excluded hospitals and satellite facilities of excluded units of hospitals is not explicitly required under existing regulations, we believe these two types of satellite facilities are similar enough to hospitals-within-hospitals to warrant application of more closely related criteria to all of them. Specifically, satellite facilities are like hospitals-within-hospitals in that the satellites are physically located in acute care hospitals that are paid for their inpatient services under the acute care hospital inpatient prospective payment system. Moreover, both satellite facilities and hospitals-within-hospitals provide inpatient hospital care that is paid for at higher rates than would apply if the facility were treated by Medicare as a part of the acute care hospital.

In view of these facts, it is important that we establish clear criteria for ensuring that these facilities are not merely units of the hospitals in which they are located, but are, in fact, organizationally and functionally separate from those hospitals. Therefore, we are proposing to revise § 412.22(h)(2) to specify that, effective for cost reporting periods beginning on or after October 1, 2002, a hospital having a satellite facility would qualify for exclusion from the acute care hospital inpatient prospective payment system only if that satellite facility is not under the authority or control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the authority or control of the medical staff or chief medical officer of the hospital in which it is located. We also are proposing to revise § 412.25(e)(2)(iii) to state that, effective for cost reporting periods beginning on or after October 1, 2002, a hospital unit having a satellite facility would qualify for exclusion from the acute care hospital inpatient prospective payment system only if it is not under the authority or control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the authority or control of the medical staff or chief medical officer of the hospital in which it is located.

C. Critical Access Hospitals (CAHs)

1. Background

Section 1820 provides for a nationwide Medicare Rural Hospital Flexibility Program (MRHF). (MRHF replaced the 7-State Essential Access Community Hospital/Rural Primary Care Hospital (EACH/RPCH) program.) Under section 1820 of the Act, as amended, certain rural providers may be designated as critical access hospitals (CAHs) under the MRHF program if they meet qualifying criteria and the conditions for designation specified in the statute. Implementing regulations for section 1820 of the Act are located at 42 CFR Part 485, Subpart F.

2. Election of Optional Payment Method

Under existing regulations at 42 CFR 413.70(b), CAHs may elect to be paid for services to their outpatients under an optional method. Facilities making this election are paid an amount for each outpatient visit that is the sum of the reasonable costs of facility services, as determined under applicable regulations, and, for professional services otherwise payable to the physician or other practitioner, 115 percent of the amounts that otherwise would be paid for the services if the CAH had not elected payment under the optional method. To enable intermediaries to make these payments accurately and to avoid possible delays in or duplications of payment, we specify in § 413.70(b)(3) that each CAH electing payment under the optional method must inform the intermediary in writing of that election annually, at least 60 days before the start of the affected cost reporting period (65 FR 47100, August 1, 2000, and 66 FR 31272, June 13, 2001).

Since the publication of this regulation, some CAHs have expressed concern that requiring a 60-day advance notice of the election of the optional payment method limits their flexibility, and have suggested that a shorter advance notice period would be appropriate. We have contacted our fiscal intermediaries to obtain feedback on the feasibility of changing the period of advance notification, since the fiscal intermediaries would need to make appropriate bill processing changes to allow any shorter time for notification of election of the optional method. Some fiscal intermediaries stated that requiring less than 60 days' advance notice is impractical, while others believed that needed changes could be made with as little as 2 weeks' advance notice. Given the diversity of feedback on this issue and our desire to allow CAHs as much flexibility as possible, we are proposing to revise § 412.30(b)(3) to allow the required advance notice period to be determined by each individual fiscal intermediary for the CAHs it services, as long as the required advance notice is not less than 14 days or more than 60 days before the start of each affected cost reporting period.

3. Use of the Resident Assessment Instrument (RAI) by CAHs

Among the existing regulations implementing section 1820 of the Act are specific conditions that a hospital must meet to be designated as a CAH. To help protect the health and safety of Medicare patients who are being furnished post-hospital skilled nursing facility (SNF) level of care in a CAH, our regulations require CAHs to comply with some, but not all, of the Medicare SNF conditions of participation at 42 CFR part 483, subpart B. Specifically, the regulations at § 485.645(d) provide that in order for a CAH to use its beds to provide post-hospital SNF care, the CAH must be in substantial compliance with nine of the SNF requirements contained in part 483, subpart B. Included among the nine requirements are requirements for comprehensive assessments, comprehensive care plans, and discharge planning as specified in § 483.20(b), (k), and (l). (We note that the existing § 485.645(d)(6) incorrectly cites these regulation cross-references as ''§ 483.20(b), (d), and (e).'' When we revised § 483.20 on December 23, 1997 (63 FR 53307), we inadvertently did not make conforming cross-reference changes in § 485.645(d)(6). In this proposed rule, we are proposing to make these conforming cross-reference changes.) Section 483.20(b) provides that a facility must make a comprehensive assessment of a resident's needs using the resident assessment instrument (RAI), specified by the State, on all its swing-bed patients.

We have received inquiries regarding the need for CAHs to use the RAI for patient assessment and care planning. The inquirers consider the RAI a lengthy and burdensome instrument and pointed out that CMS currently does not require CAHs to report data from the RAI for quality or payment purposes.

We required former RPCHs to use the RAI for the assessment of swing-bed patients to avoid the possibility of negative outcomes that might extend the length of stays in these hospitals, which provided limited services. In addition, we believed that the use of the RAI would help to ensure that patient needs are met when patients are in the facility for an extended period of time. Swing-bed hospitals were not required to use any patient assessment instrument because we believed that the hospital conditions of participation included requirements that were appropriate safeguards to protect the health and safety of Medicare patients. Currently, the regulations at § 483.20(f) require all long-term care facilities to collect and submit assessment data from the RAI to the State for quality and payment purposes. There are no such collection and submission requirements for CAHs.

We have gathered information from the provider community, State surveyors, and staff involved in the development of quality indicators and prospective payment system rates for SNFs to determine the feasibility of continuing to require CAHs to comply with the requirement for use of the RAI for patient assessments. Based on the information received, we have determined that there are no specific patient benefits involved in requiring CAHs to use the RAI for patient assessment purposes.

In the interest of reducing burden, where possible, and based on our analysis of the current significance of the requirement for use of the RAI for patient assessments in CAHs, we believe it is appropriate to propose the elimination of the requirement for CAHs to complete an RAI without jeopardizing patient health and safety. A CAH would still be required to capture assessment data for its SNF patients but would have the flexibility to document the assessment data in the medical record in a manner appropriate for its facility. We believe there are sufficient safeguards in the CAH regulations to ensure the health and safety of each SNF patient in a CAH. The facility would still be required to develop a comprehensive care plan for each SNF patient that includes measurable objectives and a timetable to meet a patient's medical, nursing, and psychosocial needs that are identified in an assessment. Also, a post-discharge plan of care would address post-hospital care needs of the patient. All of this information (assessment, plan of care, and discharge plans) must be maintained in the patient's medical record.

We are proposing to revise § 485.645 to specify that CAHs are required to complete a comprehensive assessment, comprehensive care plan, and discharge planning in accordance with the requirements of § 483.20(b), (k), and (l), except that the CAH is not required to use the RAI specified by the State, and is not required to comply with the requirements for frequency, scope, and number of assessments prescribed in § 413.343(b).

VIII. MedPAC Recommendations

We have reviewed the March 1, 2002 report submitted by MedPAC to Congress and have given it careful consideration in conjunction with the proposals set forth in this document. MedPAC's recommendations for payments for Medicare inpatient hospital services in its March 2002 report focused mainly on accounting for changes in input prices for the hospital market basket (Recommendation 2A) and on increases in the base rate for inpatient hospital services by applying the annual update factors (Recommendations 2B–1 and 2B–2).

In Recommendation 2A, MedPAC recommended that the Secretary should use wage and benefit proxies that most closely match the training and skill requirements of health care occupations in all input price indexes used for updating payments. MedPAC further indicated that, in determining index weights, measures specific to the health sector and to occupation categories in which health care plays a major role should be emphasized. Our proposal to rebase and revise the hospital market basket, including cost category weights and price proxies, that is used in determining the update factors for payments for inpatient hospital services is presented in section IV. of this proposed rule.

Recommendations 2B–1 and 2B–2 concerning the update factor for inpatient hospital operating costs and for hospitals and hospital distinct-part units excluded from the acute care hospital inpatient prospective payment system are discussed in Appendix C to this proposed rule.

IX. Other Required Information

A. Requests for Data From the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are available in computer tape or cartridge format; however, some files are available on diskette as well as on the Internet at *http://www.hcfa.gov/stats/pufiles.htm.* Data files, and the cost for each, are listed below. Anyone wishing to purchase data tapes, cartridges, or diskettes should submit a written request along with a company check or money order (payable to CMS–PUF) to cover the cost to the following address: Centers for Medicare & Medicaid Services, Public Use Files, Accounting Division, P.O. Box 7520, Baltimore, Maryland 21207–0520, (410) 786–3691. Files on the Internet may be downloaded without charge.

1. Expanded Modified MedPAR-Hospital (National)

The Medicare Provider Analysis and Review (MedPAR) file contains records

for 100 percent of Medicare beneficiaries using hospital inpatient services in the United States. (The file is a Federal fiscal year file, that is, discharges occurring October 1 through September 30 of the requested year.) The records are stripped of most data elements that would permit identification of beneficiaries. The hospital is identified by the 6-position Medicare billing number. The file is available to persons qualifying under the terms of the Notice of Proposed New Routine Uses for an Existing System of Records published in the **Federal Register** on December 24, 1984 (49 FR 49941), and amended by the July 2, 1985 notice (50 FR 27361). The national file consists of approximately 11,420,000 records. Under the requirements of these notices, an agreement for use of CMS Beneficiary Encrypted Files must be signed by the purchaser before release of these data. For all files requiring a signed agreement, please write or call to obtain a blank agreement form before placing an order. Two versions of this file are created each year. They support the following:

- Notice of Proposed Rulemaking (NPRM) published in the **Federal Register**. This file, scheduled to be available by the end of April, is derived from the MedPAR file with a cutoff of 3 months after the end of the fiscal year (December file).
- Final Rule published in the **Federal Register**. The FY 2001 MedPAR file used for the FY 2003 final rule will be cut off 6 months after the end of the fiscal year (March file) and is scheduled to be available by the end of April.

Media: Tape/Cartridge.
File Cost: $3,655.00 per fiscal year.
Periods Available: FY 1988 through FY 2001.

2. Expanded Modified MedPAR-Hospital (State)

The State MedPAR file contains records for 100 percent of Medicare beneficiaries using hospital inpatient services in a particular State. The records are stripped of most data elements that will permit identification of beneficiaries. The hospital is identified by the 6-position Medicare billing number. The file is available to persons qualifying under the terms of the Notice of Proposed New Routine Uses for an Existing System of Records published in the December 24, 1984 **Federal Register** notice, and amended by the July 2, 1985 notice. This file is a subset of the Expanded Modified MedPAR-Hospital (National) as described above. Under the requirements of these notices, an agreement for use of CMS Beneficiary Encrypted Files must be signed by the purchaser before release of these data. Two versions of this file are created each year. They support the following:

- NPRM published in the **Federal Register**. This file, scheduled to be available by the end of April, is derived from the MedPAR file with a cutoff of 3 months after the end of the fiscal year (December file).
- Final Rule published in the **Federal Register**. The FY 2001 MedPAR file used for the FY 2003 final rule will be cut off 6 months after the end of the fiscal year (March file) and is scheduled to be available by the end of April.

Media: Tape/Cartridge.
File Cost: $1,130.00 per State per year.
Periods Available: FY 1988 through FY 2001.

3. CMS Wage Data

This file contains the hospital hours and salaries for FY 1999 used to create the proposed FY 2003 prospective payment system wage index. The file will be available by the beginning of January for the NPRM and the beginning of May for the final rule.

Processing year	Wage data year	PPS fiscal year
2002	1999	2003
2001	1998	2002
2000	1997	2001
1999	1996	2000
1998	1995	1999
1997	1994	1998
1996	1993	1997
1995	1992	1996
1994	1991	1995
1993	1990	1994
1992	1989	1993
1991	1988	1992

These files support the following:

- NPRM published in the **Federal Register**.
- Final Rule published in the **Federal Register**.

Media: Diskette/most recent year on the Internet.
File Cost: $165.00 per year.
Periods Available: FY 2003 PPS Update.

4. CMS Hospital Wages Indices (Formerly: Urban and Rural Wage Index Values Only)

This file contains a history of all wage indices since October 1, 1983.

Media: Diskette/most recent year on the Internet.
File Cost: $165.00 per year.
Periods Available: FY 2003 PPS Update.

5. PPS SSA/FIPS MSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Social Security Administration (SSA) and the Federal Information Processing Standards (FIPS), county name, and a historical list of Metropolitan Statistical Area (MSA).

Media: Diskette/Internet.
File Cost: $165.00 per year.
Periods Available: FY 2003 PPS Update.

6. Reclassified Hospitals New Wage Index (Formerly: Reclassified Hospitals by Provider Only)

This file contains a list of hospitals that were reclassified for the purpose of assigning a new wage index. Two versions of these files are created each year. They support the following:

- NPRM published in the **Federal Register**.
- Final Rule published in the **Federal Register**.

Media: Diskette/Internet.
File Cost: $165.00 per year.
Periods Available: FY 2003 PPS Update.

7. PPS–IV to PPS–XII Minimum Data Set

The Minimum Data Set contains cost, statistical, financial, and other information from Medicare hospital cost reports. The data set includes only the most current cost report (as submitted, final settled, or reopened) submitted for a Medicare participating hospital by the Medicare fiscal intermediary to CMS. This data set is updated at the end of each calendar quarter and is available on the last day of the following month.
Media: Tape/Cartridge.
File Cost: $770.00 per year.

	Periods beginning on or after	and before
PPS–IV	10/01/86	10/01/87
PPS–V	10/01/87	10/01/88
PPS–VI	10/01/88	10/01/89
PPS–VII	10/01/89	10/01/90
PPS–VIII	10/01/90	10/01/91
PPS–IX	10/01/91	10/01/92
PPS–X	10/01/92	10/01/93
PPS–XI	10/01/93	10/01/94
PPS–XII	10/01/94	10/01/95

(Note: The PPS–XIII, PPS–XIV, PPS–XV, PPS–XVI, and PPS–XVII Minimum Data Sets are part of the PPS–XIII, PPS–XIV, PPS–XV, PPS–XVI, and PPS–XVII Hospital Data Set Files (refer to item 9 below).)

8. PPS–IX to PPS–XII Capital Data Set

The Capital Data Set contains selected data for capital-related costs, interest expense and related information and complete balance sheet data from the Medicare hospital cost report. The data set includes only the most current cost report (as submitted, final settled or

reopened) submitted for a Medicare certified hospital by the Medicare fiscal intermediary to CMS. This data set is updated at the end of each calendar quarter and is available on the last day of the following month.

Media: Tape/Cartridge.
File Cost: $770.00 per year.

	Periods beginning on or after	and before
PPS–IX	10/01/91	10/01/92
PPS–X	10/01/92	10/01/93
PPS–XI	10/01/93	10/01/94
PPS–XII	10/01/94	10/01/95

(Note: The PPS–XIII, PPS–XIV, PPS–XV, PPS–XVI, and PPS–XVII Capital Data Sets are part of the PPS–XIII, PPS–XIV, PPS–XV, PPS–XVI, and PPS–XVII Hospital Data Set Files (refer to item 9 below).)

9. PPS–XIII to PPS–XVII Hospital Data Set

The file contains cost, statistical, financial, and other data from the Medicare Hospital Cost Report. The data set includes only the most current cost report (as submitted, final settled, or reopened) submitted for a Medicare-certified hospital by the Medicare fiscal intermediary to CMS. The data set are updated at the end of each calendar quarter and is available on the last day of the following month.

Media: Diskette/Internet.
File Cost: $2,500.00.

	Periods beginning on or after	and before
PPS–XIII	10/01/95	10/01/96
PPS–XIV	10/01/96	10/01/97
PPS–XV	10/01/97	10/01/98
PPS–XVI	10/01/98	10/01/99
PPS–XVII	10/01/99	10/01/00

10. Provider-Specific File

This file is a component of the PRICER program used in the fiscal intermediary's system to compute DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: Diskette/Internet.
File Cost: $265.00.
Periods Available: FY 2003 PPS Update.

11. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number as published in each year's update of the Medicare hospital inpatient prospective payment system. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year. They support the following:

- NPRM published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Diskette/most recent year on Internet.
Price: $165.00 per year/per file.
Periods Available: FY 1985 through FY 2001.

12. DRG Relative Weights (Formerly Table 5 DRG)

This file contains a listing of DRGs, DRG narrative description, relative weights, and geometric and arithmetic mean lengths of stay as published in the **Federal Register**. The hard copy image has been copied to diskette. There are two versions of this file as published in the **Federal Register:**

- NPRM.
- Final rule.

Media: Diskette/Internet.
File Cost: $165.00.
Periods Available: FY 2003 PPS Update.

13. PPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, Minimum Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. This file is available for release 1 month after the proposed and final rules are published in the **Federal Register**.

Media: Diskette/Internet.
File Cost: $165.00.
Periods Available: FY 2003 PPS Update.

14. AOR/BOR Tables

This file contains data used to develop the DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by DRG for length of stay and standardized charges. The BOR tables are ''Before Outliers Removed'' and the AOR is ''After Outliers Removed.'' (Outliers refers to statistical outliers, not payment outliers.) Two versions of this file are created each year. They support the following:

- NPRM published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Diskette/Internet.
File Cost: $165.00.
Periods Available: FY 2003 PPS Update.

15. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the prospective payment system. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, disproportionate share, and the Metropolitan Statistical Area (MSA). The file supports the following:

- NPRM published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet.
File cost: No charge.
Periods Available: FY 2003 PPS Update.

For further information concerning these data tapes, contact the CMS Public Use Files Hotline at (410) 786–3691.

Commenters interested in obtaining or discussing any other data used in constructing this rule should contact Stephen Phillips at (410) 786–4548.

B. Information Collection Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

However, the majority of the collection requirements contained in this proposed rule are currently approved.

Section IX.B.1. below lists the OMB approval numbers and the current

expiration dates for the collection requirements, referenced by 42 CFR Part, in this proposed rule that are currently approved. In addition, as summarized below, section IX.B.2. of this proposed rule outlines the proposed collection requirements referenced in this proposed rule for which we are seeking public comment, as required under the PRA of 1995.

1. Currently Approved Requirements

Regulation references in 42 CFR	OMB approval No.	Current expiration date
Part 412	0938–0691	September 30, 2002.
	0938–0050	May 31, 2004.
	0938–0573	September 30, 2002.
Part 413	0938–0050	May 31, 2004.
	0938–0667	October 31, 2002.
	0938–0477	June 30, 2002.
Part 489	0938–0667	October 31, 2002.

2. Proposed Requirements for Public Comment

Section 412.230 Criteria for an Individual Hospital Seeking Redesignation to Another Rural Area or an Urban Area.

Appropriate Wage Data

As specified in this section, a new hospital must accumulate and provide at least 1 year of wage data to CMS for the purposes of applying for reclassification. While this collection requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3).

Section 413.65 Requirements for a Determination That a Facility or an Organization Had Provider-Based Status

Responsibility for Obtaining Provider-Based Determinations

As summarized in this section, a potential main provider seeking an advance determination of provider-based status for a facility that is located on the main campus of the potential main provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and, if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. In addition, the provider seeking such an advance determination would be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS upon request.

We believe the burden associated with these requirements is estimated to average 1.5 hours per provider, for approximately 3,000 providers per year, for an annual burden of 4,500 annual burden hours. This estimate is based on fact the providers currently maintain the necessary data and that minimal effort would be required to locate and review the appropriate data.

Clinical Services

The clinical services of the facility or organization seeking provider-based status and the main provider would be required to maintain an unified retrieval system (or cross reference) of the main provider for all patient medical records for those patients treated in the facility or organization.

While this collection requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b) (2) and (b)(3).

Section 482.12 Conditions of Participation: Governing Body

Standard: Emergency Services

If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital would be required to assure that the medical staff have written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

While this collection requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3).

Section 489.24 Special Responsibilities of Medicare Hospitals in Emergency Cases

Application to Inpatients—Admitted Emergency Patients

If a hospital admits an individual with an unstable emergency medical condition for stabilizing treatment, as an inpatient, and stabilizes that individual's emergency medical condition, the period of stability would be required to be documented by relevant clinical data in the individual's medical record, before the hospital has satisfied its special responsibilities under this section with respect to that individual.

While this collection requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3).

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Information Technology Investment Management Group, Attn.: John Burke, Attn: CMS–1203–P, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Eydt, CMS Desk Officer Attn: CMS–1203–P.

C. Public Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments concerning the provisions of this proposed rule that we receive by the date and time specified in the ''DATES'' section of this preamble and respond to those comments in the preamble to that rule. We emphasize that section 1886(e)(5) of the Act requires the final rule for FY 2003 to be published by August 1, 2002, and we will consider only those comments that deal specifically with the matters discussed in this proposed rule.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant program-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this proposed rule, 42 CFR chapter IV is proposed to be amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Part 405 is amended as follows:

1. The authority citation for Part 405, Subpart R continues to read as follows:

Authority: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

2. Section 405.1885 is amended by revising paragraph (b), redesignating paragraph (e) as paragraph (f), and adding a new paragraph (e), to read as follows:

§ 405.1885 Reopening a determination or decision.

* * * * *

(b)(1) An intermediary determination or an intermediary hearing decision shall be reopened and revised by the intermediary if, within the aforementioned 3-year period, CMS—

(i) Provides notice to the intermediary that the intermediary determination or the intermediary hearing decision is inconsistent with the applicable law, regulations, CMS ruling, or CMS general instructions in effect, and as CMS understood those legal provisions, at the time the determination or decision was rendered by the intermediary; and

(ii) Explicitly directs the intermediary to reopen and revise the intermediary determination or the intermediary hearing decision.

(2) A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening an intermediary determination or an intermediary hearing decision under this section.

* * * * *

(e) Nothwithstanding an intermediary's discretion to reopen or not reopen an intermediary determination or an intermediary hearing decision under paragraphs (a) and (c) of this section, CMS may direct an intermediary to reopen, or not to reopen, an intermediary determination or an intermediary hearing decision in accordance with paragraphs (a) and (c) of this section.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

B. Part 412 is amended as follows:

1. The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 412.4 [Amended]

2. In § 412.4 (f)(1), the reference ''paragraph (b) or (c)'' is removed and ''paragraph (b)(1) or (c)'' is added in its place.

3. Section 412.22 is amended by—

a. Revising the introductory text of paragraph (h)(2).

b. Republishing the introductory text of paragraph (h)(2)(iii).

c. Redesignating paragraphs (h)(2)(iii)(A) through (F) as paragraphs (h)(2)(iii)(B) through (G), respectively. d. Adding new paragraph (h)(2)(iii)(A).

§ 412.22 Excluded hospitals and hospital units: General rules.

* * * * *

(h) *Satellite facilities.* * * *

(2) Except as provided in paragraph (h)(3) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

* * * * *

(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the authority or control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the authority or control of the medical staff or chief medical officer of the hospital in which it is located.

* * * * *

4. Section 412.25 is amended by—

a. Revising the introductory text of paragraph (e)(2).

b. Republishing the introductory text of paragraph (e)(2)(iii).

c. Redesignating paragraphs (e)(2)(iii)(A) through (F) as paragraphs (e)(2)(iii)(B) through (G), respectively.

d. Adding new paragraph (e)(2)(iii)(A).

§ 412.25 Excluded hospitals units: Common requirements.

* * * * *

(e) *Satellite facilities.* * * *

(2) Except as provided in paragraph (e)(3) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

* * * * *

(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the authority or control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the authority or control of the medical staff or chief medical officer of the hospital in which it is located.

* * * * *

§ 412.63 [Amended]

5. Section 412.63 is amended by—

a. In paragraph (x)(2)(i)(A), removing the phrase ''tabulating the hospital's data'' and adding in its place ''tabulating its data''.

b. Removing paragraphs (x)(3) and (x)(4).

c. Redesignating paragraph (x)(5) as paragraph (x)(3).

6. Section 412.80 is amended by revising paragraph (a)(2) to read as follows:

§ 412.80 Outlier cases: General provisions.

(a) *Basic rule.* * * *

(2) *Discharges occurring on or after October 1, 1997 and before October 1, 2001.* For discharges occurring on or after October 1, 1997 and before October 1, 2001, except as provided in paragraph (b) of this section concerning transfers, CMS provides for additional payment, beyond standard DRG payments, to a

hospital for covered inpatient hospital services furnished to a Medicare beneficiary if the hospital's charges for covered services, adjusted to operating costs and capital costs by applying cost-to-charge ratios, as described in § 412.84(h), exceed the DRG payment for the case, payments for indirect costs of graduate medical education (§ 412.105), and payments for serving disproportionate share of low-income patients (§ 412.106), plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

* * * * *

7. Section 412.92 is amended by revising paragraph (c)(2), to read as follows:

§ 412.92 Special treatment: Sole community hospitals.

* * * * *

(c) *Terminology.* * * *

(2) The term *like hospital* means a hospital furnishing short-term, acute care. Effective with cost reporting periods beginning on or after October 1, 2002, if a hospital seeking sole community hospital designation can demonstrate that no more than 3 percent of the services it provides overlap with the services provided by a nearby hospital that would otherwise be considered a like hospital under this definition, CMS will not consider the nearby hospital to be a like hospital.

* * * * *

8. Section 412.105 is amended by—

A. Republishing the introductory text of paragraph (a).

B. Revising paragraph (a)(1).

C. Revising paragraph (b).

D. Revising paragraph (f)(1)(vi).

E. Making the following cross-reference changes in paragraph (f)(1):

i. In paragraph (f)(1)(vii), the reference ''§ 413.86(g)(12)'' is removed and ''§ 413.86(g)(13)'' is added in its place.

ii. In paragraph (f)(1)(viii), the reference ''§ 413.86(g)(7)'' is removed and ''§ 413.86(g)(8)'' is added in its place.

iii. In paragraph (f)(1)(ix), the reference ''§§ 413.86(g)(8)(i) and (g)(8)(ii) of this subchapter'' is removed and ''§ 413.86(g)(9)(i) and (g)(9)(ii) of this subchapter'' is added in its place; the reference ''§§ 413.86(g)(8)(i) and (g)(8)(iii)(B) of this subchapter'' is removed and ''§ 413.86(g)(9)(i) and (g)(9)(iii)(B) of this subchapter'' is added in its place; and the reference ''§§ 413.86(g)(8)(i) and (g)(8)(iii)(A) of this subchapter'' is removed and ''§ 413.86(g)(9)(i) and (g)(9)(iii)(A) of this subchapter'' is added it its place.

iv. In paragraph (f)(1)(x), the reference ''§ 413.86(g)(12)'' is removed and ''§ 413.86(g)(13)'' is added in its place; and the reference ''§ 413.86(g)(11)'' is removed and ''§ 413.86(g)(12)'' is added in its place.

v. In paragraph (f)(1)(xi), the reference ''§ 413.86(g)(9)'' is removed and ''§ 413.86(g)(10)'' is added in its place.

vi. In paragraph (f)(1)(xii), the reference ''§ 413.86(g)(10)'' is removed and ''§ 413.86(g)(11)'' is added in its place.

The revisions read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(a) *Basic data.* CMS determines the following for each hospital:

(1) The hospital's ratio of full-time equivalent residents (except as limited under paragraph (f) of this section) to the number of beds (as determined under paragraph (b) of this section).

(i) Except for the special circumstances for affiliated groups and new programs described in paragraphs (f)(1)(vi) and (f)(1)(vii) of this section for cost reporting periods beginning on or after October 1, 1997, and for the special circumstances for closed hospitals or closed programs described in paragraph (f)(1)(ix) of this section for cost reporting periods beginning on or after October 1, 2002, this ratio may not exceed the ratio for the hospital's most recent prior cost reporting period after accounting for the cap on the number of allopathic and osteopathic full-time equivalent residents as described in paragraph (f)(1)(iv) of this section, and adding to the capped numerator any dental and podiatric full-time equivalent residents.

(ii) The exception for new programs described in paragraph (f)(1)(vii) of this section applies to each new program individually for which the full-time equivalent cap may be adjusted based on the period of years equal to the minimum accredited length of each new program.

(iii) The exception for closed hospitals and closed programs described in paragraph (f)(1)(ix) of this section applies only in the first cost reporting period in which the receiving hospital trains the displaced full-time equivalent residents.

(iv) In the cost reporting period following the last year the receiving hospital's full-time equivalent cap is adjusted for the displaced resident(s), the resident-to-bed ratio cap in paragraph (a)(1) of this section is calculated as if the displaced full-time equivalent residents had not trained at the receiving hospital in the prior year.

* * * * *

(b) *Determination of number of beds.* (1) For purposes of this section, subject to the provisions of paragraph (b)(2) of this section, the number of beds in a hospital is determined by counting the number of available bed days during the cost reporting period, not including beds or bassinets in the healthy newborn nursery, custodial care beds, or beds in excluded distinct part hospital units, and dividing that number by the number of days in the cost reporting period.

(2) Effective for discharges occurring on or after October 1, 2002, a hospital's number of beds is equal to the lower of the number of beds as determined under paragraph (b)(1) of this section, or the average daily census (as determined in accordance with § 412.322(a)(2) of this chapter) divided by 35 percent.

* * * * *

(f) *Determining the total number of full-time equivalent residents for cost reporting periods beginning on or after July 1, 1991.*

(1) * * *

(vi) Hospitals that are part of the same affiliated group (as defined in § 413.86(b) of this subchapter) may elect to apply the limit at paragraph (f)(1)(iv) of this section on an aggregate basis, as specified in § 413.86(g)(7) of this chapter.

* * * * *

9. Section 412.108 is amended by revising paragraph (b) to read as follows:

§ 412.108 Special treatment: Medicare-dependent, small rural hospitals.

* * * * *

(b) *Classification procedures.* (1) The fiscal intermediary determines whether a hospital meets the criteria specified in paragraph (a) of this section.

(2) A hospital must submit a written request along with qualifying documentation to its fiscal intermediary to be considered for MDH status based on the criterion under paragraph (a)(1)(iii)(C) of this section.

(3) The fiscal intermediary will make its determination and notify the hospital within 90 days from the date that it receives the hospital's request and all of the required documentation.

(4) A determination of MDH status made by the fiscal intermediary is effective 30 days after the date the fiscal intermediary provides written notification to the hospital. An approved MDH status determination remains in effect unless there is a change in the circumstances under which the status was approved.

(5) The fiscal intermediary will evaluate on an ongoing basis, whether or not a hospital continues to qualify for MDH status. This evaluation includes an ongoing review to ensure that the hospital continues to meet all of the

criteria specified in paragraph (a) of this section.

(6) If the fiscal intermediary determines that a hospital no longer qualifies for MDH status, the change in status will become effective 30 days after the date the fiscal intermediary provides written notification to the hospital.

(7) A hospital may reapply for MDH status following its disqualification only after it has completed another cost reporting period that has been audited and settled. The hospital must reapply for MDH status in writing to its fiscal intermediary and submit the required documentation.

(8) If a hospital disagrees with an intermediary's determination regarding the hospital's initial or ongoing MDH status, the hospital may notify its fiscal intermediary and submit other documentable evidence to support its claim that it meets the MDH qualifying criteria.

(9) The fiscal intermediary's initial and ongoing determination is subject to review under subpart R of Part 405 of this chapter. The time required by the fiscal intermediary to review the request is considered good cause for granting an extension of the time limit for the hospital to apply for that review.

* * * * *

10. Section 412.113 is amended by revising paragraphs (c)(2)(ii) and (c)(2)(iii) to read as follows:

§ 412.113 Other payments.

* * * * *

(c) *Anesthesia services furnished by hospital employed nonphysician anesthetists or obtained under arrangements.* * * *

(2) * * *

(ii) To maintain its eligibility for reasonable cost payment under paragraph (c)(2)(i) of this section in calendar years after 1989, a qualified hospital or CAH must demonstrate prior to January 1 of each respective year that for the prior year its volume of surgical procedures requiring anesthesia service did not exceed 500 procedures; or, effective October 1, 2002, did not exceed 800 procedures.

(iii) A hospital or CAH that did not qualify for reasonable cost payment for nonphysician anesthetist services furnished in calendar year 1989 can qualify in subsequent years if it meets the criteria in paragraphs (c)(2)(i)(A), (B), and (D) of this section, and demonstrates to its intermediary prior to the start of the calendar year that it met these criteria. The hospital or CAH must provide data for its entire patient population to demonstrate that, during calendar year 1987 and the year immediately preceding its election of reasonable cost payment, its volume of surgical procedures (inpatient and outpatient) requiring anesthesia services did not exceed 500 procedures, or, effective October 1, 2002, did not exceed 800 procedures.

* * * * *

11. Section 412.230 is amended by adding a new paragraph (e)(2)(iii) to read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

* * * * *

(e) *Use of urban or other rural area's wage index.* * * *

(2) *Appropriate wage data.* * * *

(iii) For purposes of this paragraph (e)(2), if a new owner does not accept assignment of the existing hospital's provider agreement in accordance with § 489.18 of this chapter, the hospital will be treated as a new provider with a new provider number. In this case, the wage data associated with the previous owner of the hospital cannot be used in calculating the new hospital's 3-year average hourly wage. Once a new hospital has accumulated at least 1 year of wage data, it is eligible to apply for reclassification on the basis of those data.

* * * * *

12. Section 412.273 is amended by—

A. Revising the section heading.

B. Revising paragraph (b)(2).

C. Redesignating paragraph (d) as paragraph (e).

D. Add a new paragraph (d).

§ 412.273 Withdrawing an application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination.

* * * * *

(b) *Request for termination of approved 3-year wage index reclassifications.* * * *

(2) *Reapplication within the approved 3-year period.* (i) If a hospital elects to withdraw its wage index application after the MGCRB has issued its decision, it may cancel its withdrawal in a subsequent year and request the MGCRB to reinstate its wage index reclassification for the remaining fiscal year(s) of the 3-year period.

(ii) A hospital may apply for reclassification for purposes of the wage index to a different area (that is, an area different from the one to which it was originally reclassified for the 3-year period). If the application is approved, the reclassification will be effective for 3 years. Once a 3-year reclassification becomes effective, a hospital may no longer cancel a withdrawal or termination of another 3-year reclassification, regardless of whether the withdrawal or termination request is made within 3 years from the date of the withdrawal or termination.

(iii) In a case in which a hospital with an existing 3-year wage index reclassification applies to be reclassified to another area, its existing 3-year reclassification will be terminated when a second 3-year wage index reclassification goes into effect for payments for discharges on or after the following October 1.

* * * * *

(d) *Process for canceling a previous withdrawal or termination.* A hospital may cancel a previous withdrawal or termination by submitting written notice of its intent to the MGCRB no later than the deadline for submitting reclassification applications for the following fiscal year, as specified in § 412.256(a)(2).

* * * * *

13. Section 412.304 is amended by revising paragraph (c) to read as follows:

§ 412.304 Implementation of the capital prospective payment system.

* * * * *

(c) *Cost reporting periods beginning on or after October 1, 2001.*

(1) *General.* Except as provided in paragraph (c)(2) of this section, for cost reporting periods beginning on or after October 1, 2001, the capital payment amount is based solely on the Federal rate determined under § 412.308(a) and (b) and updated under § 412.308(c).

(2) *Payment to new hospitals.* For cost reporting periods beginning on or after October 1, 2002—

(i) A new hospital, as defined under § 412.300(b), is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its cost report ending at least 2 years after the hospital accepts its first patient.

(ii) For the third year and subsequent years, the hospital is paid based on the Federal rate as described under § 412.312.

* * * * *

14. Section 412.308 is amending by adding a new paragraph (b)(6) to read as follows:

§ 412.308 Determining and updating the Federal rate.

* * * * *

(b) *Standard Federal rate.* * * *

(6) For discharges occurring on or after October 1, 2002, the 2.1 percent reduction provided for under paragraph (b)(5) of this section is eliminated from the unadjusted standard Federal rate in effect on September 30, 2002, used to

determine the Federal rate each year under paragraph (c) of this section.

* * * * *

15. Section 412.312 is amended by adding a new paragraph (e) to read as follows:

§ 412.312 Payment based on the Federal rate.

* * * * *

(e) *Payment for extraordinary circumstances.* Payment for extraordinary circumstances is made as provided for in § 412.348(f) for cost reporting periods beginning on or after October 1, 2001.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

C. Part 413 is amended as follows:

1. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395hh, 1395rr, 1395tt, and 1395ww).

2. Section 413.65 is amended by—

A. Revising paragraph (a)(1)(ii)(G) and adding a new paragraph (a)(1)(ii)(J).

B. Revising the definition of ''Department of a provider'', ''Provider-based entity'', and ''Remote location of a hospital'' under paragraph (a)(2).

C. Revising paragraphs (b)(2), (b)(3), and (d).

D. Removing paragraph (j).

E. Redesignating paragraphs (h) and (i) as paragraphs (i) and (j), respectively.

F. Redesignating paragraph (f) as paragraph (h).

G. Redesignating paragraph (e) as paragraph (f).

H. Adding a new paragraph (e).

I. Revising redesignated paragraph (f).

J. Revising the introductory text of paragraph (g), and paragraphs (g)(1), (g)(2), and (g)(7).

K. Revising redesignated paragraphs (h), (i), and (j).

L. Revising paragraph (k).

M. Revising the heading of paragraph (m).

N. Revising paragraph (n).

§ 413.65 Requirements for a determination that a facility or an organization had provider-based status.

(a) *Scope and definitions.* (1) *Scope.*

* * *

(ii) This section does not apply to the following facilities:

* * * * *

(G) Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services (as defined in section 1861(jj) of the Act), facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services.

* * * * *

(J) Departments of providers that perform functions necessary for the successful operation of the providers but do not furnish services of a type for which separate payment could be claimed under Medicare or Medicaid (for example, laundry or medical records departments).

(2) *Definitions.* * * *

Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term ''department of a provider'' does not include an RHC or, except as specified in paragraph (m) of this section, an FQHC.

* * * * *

Provider-based entity means a provider of health care services, or an RHC as defined in § 405.2401(b) of this chapter, that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the name, ownership, and administrative and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-based entity may, by itself, be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.

* * * * *

Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term ''remote location of a hospital'' does not include a satellite facility as defined in § 412.22(h)(1) and § 412.25(e)(1) of this chapter.

(b) *Responsibility for obtaining provider-based determinations.* * * *

(2) If a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. The requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), (g), (h), and (i), of this section will not apply to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. For purposes of this paragraph (b)(2), a facility is considered as provider-based on October 1, 2000 if, on that date, it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital.

(3)(i) Except as specified in paragraphs (b)(2) and (b)(5) of this section, if a potential main provider seeks an advance determination of provider-based status for a facility that is located on the main campus of the potential main provider, the provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and

hospital-based entities described in paragraph (g) of this section. The provider seeking such an advance determination would also be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS upon request.

(ii) If the facility is not located on the main campus of the potential main provider, the provider seeking an advance determination would be required to submit an attestation stating that the facility meets the criteria in paragraphs (d) and (e) of this section, and if the facility is operated as a joint venture or under a management contract, the requirements of paragraph (f) or paragraph (h) of this section, as applicable. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations.

* * * * *

(d) *Requirements applicable to all facilities or organizations.* Any facility or organization for which provider-based status is sought, whether located on or off the campus of a potential main provider, must meet all of the following requirements to be determined by CMS to have provider-based status:

(1) *Licensure.* The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. If a State health facilities' cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a State finds that a particular facility or organization is not part of a provider, CMS will determine that the facility or organization does not have provider-based status.

(2) *Clinical services.* The clinical services of the facility or organization seeking provider-based status and the main provider are integrated as evidenced by the following:

(i) Professional staff of the facility or organization have clinical privileges at the main provider.

(ii) The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.

(iii) The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

(iv) Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.

(v) Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross reference) of the main provider.

(vi) Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

(3) *Financial integration.* The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.

(4) *Public awareness.* The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.

(5) *Obligations of hospital outpatient departments and hospital-based entities.* In the case of a hospital outpatient department or a hospital-based entity, the facility or organization must fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section.

(e) *Additional requirements applicable to off-campus facilities or organizations.* Except as described in paragraphs (b)(2) and (b)(5) of this section, any facility or organization for which provider-based status is sought that is not located on the campus of a potential main provider must meet both the requirements in paragraph (d) of this section and all of the following additional requirements, in order to be determined by CMS to have provider-based status.

(1) *Operation under the ownership and control of the main provider.* The facility or organization seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by the following:

(i) The business enterprise that constitutes the facility or organization is 100 percent owned by the provider.

(ii) The main provider and the facility or organization seeking status as a department of the provider, a remote location of a hospital, or a satellite facility have the same governing body.

(iii) The facility or organization is operated under the same organizational documents as the main provider. For example, the facility or organization seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the provider where it is based.

(iv) The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility or organization.

(2) *Administration and supervision.* The reporting relationship between the facility or organization seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its existing departments, as evidenced by

compliance with all of the following requirements:

(i) The facility or organization is under the direct supervision of the main provider.

(ii) The facility or organization is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility or organization director or individual responsible for daily operations at the entity—

(A) Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and

(B) Is accountable to the governing body of the main provider, in the same manner as any department head of the provider.

(iii) The following administrative functions of the facility or organization are integrated with those of the provider where the facility or organization is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are—

(A) Contracted out under the same contract agreement; or

(B) Handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.

(3) *Location.* The facility or organization is located within a 35-mile radius of the main campus of the hospital or CAH that is the potential main provider, except when the requirements in paragraph (e)(3)(i), (e)(3)(ii), or (e)(3)(iii) of this section are met:

(i) The facility or organization is owned and operated by a hospital or CAH that has a disproportionate share adjustment (as determined under § 412.106 of this chapter) greater than 11.75 percent or is described in § 412.106(c)(2) of this chapter implementing section 1886(e)(5)(F)(i)(II) of the Act and is—

(A) Owned or operated by a unit of State or local government;

(B) A public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or

(C) A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).

(ii) The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period—

(A) At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider;

(B) At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider); or

(C) If the facility or organization is unable to meet the criteria in paragraph (e)(3)(ii)(A) or paragraph (e)(3)(ii)(B) of this section because it was not in operation during all of the 12-month period described in paragraph (e)(3)(ii) of this section, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in paragraph (e)(3)(ii) of this section, accounted for at least 75 percent of the patients served by the main provider.

(iv) A facility or organization may qualify for provider-based status under this section only if the facility or organization and the main provider are located in the same State or, when consistent with the laws of both States, in adjacent States.

(v) An RHC that is otherwise qualified as a provider-based entity of a hospital that is located in a rural area, as defined in § 412.62(f)(1)(iii) of this chapter, and has fewer than 50 beds, as determined under § 412.105(b) of this chapter, is not subject to the criteria in paragraphs (e)(3)(i) through (e)(3)(iii) of this section.

(f) *Provider-based status for joint ventures.* A facility or organization that is not located on the campus of the potential main provider cannot be considered provider-based if the facility or organization is owned by two or more providers engaged in a joint venture. For example, where a hospital has jointly purchased or jointly created a facility under joint venture arrangements with one or more other providers, and the facility is not located on the campus of the hospital or the campus of any other provider engaged in the joint venture arrangement, no party to the joint venture arrangement can claim the facility as provider-based.

(g) *Obligations of hospital outpatient departments and hospital-based entities.* To qualify for provider-based status in relation to a hospital, a facility or organization must comply with the following requirements:

(1) The following departments must comply with the antidumping rules of § 489.20(l), (m), (q), and (r) and § 489.24 of this chapter:

(i) Any facility or organization that is located on the main hospital campus and is treated by Medicare under this section as a department of the hospital; and

(ii) Any facility or organization that is located off the main hospital campus that is treated by Medicare under this section as a department of the hospital and is a dedicated emergency department, as defined in § 489.24(b) of this chapter.

(2) Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) must be billed with the correct site-of-service so that appropriate physician and practitioner payment amounts can be determined under the rules of part 414 of this chapter.

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(7) When a Medicare beneficiary is treated in a hospital outpatient department of hospital-based entity (other than an RHC) that is not located on the main provider's campus, and the treatment is not required to be provided by the antidumping rules in § 489.24 of this chapter, the hospital must provide written notice to the beneficiary, before the delivery of services, of the amount of the beneficiary's potential financial liability (that is, that the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, and of the amount of that liability).

(i) The notice must be one that the beneficiary can read and understand.

(ii) If the exact type and extent of care needed is not known, the hospital may furnish a written notice to the patient that explains that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based.