DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, and 485

[CMS–1203–F]

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: Final rule.

SUMMARY: We are revising 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 final rule, we describe the changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes are applicable to discharges occurring on or after October 1, 2002. We also are setting forth rate-of-increase limits as well as policy changes for hospitals and hospital units excluded from the acute care hospital inpatient prospective payment systems.

In addition, we are setting forth 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); and requirements and responsibilities related to provider-based entities.

DATES: The provisions of this final rule are effective on October 1, 2002. This rule is a major rule as defined in 5 U.S.C. 804(2). Pursuant to 5 U.S.C. 801(a)(1)(A), we are submitting a report to Congress on this rule on August 1, 2002.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

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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 an average 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.

Additional payments may be made for cases that involve new technologies that have been approved for special add-on payments. To qualify, the technologies must be shown to be a substantial clinical improvement over technologies otherwise available and that they would be inadequately paid otherwise (absent the add-on payments) under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any outlier payment due is added to the DRG-adjusted base payment rate.

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 (Pub. L. 105–33), the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) provide for the implementation of 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, for cost reporting periods beginning in FY 2003, inpatient rehabilitation facilities that are subject to the blend methodology 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, during the transition, long-term care hospitals subject to the blend methodology would also be permitted to elect to be paid based on full Federal prospective rates. The final regulations governing payments under the long-term care hospital prospective payment system are under development and will 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. Summary of the Provisions of the May 9, 2002 Proposed Rule

On May 9, 2002, we published a proposed rule in the **Federal Register** (67 FR 31404) that set forth proposed changes to the Medicare hospital inpatient prospective payment systems for operating costs and for capital-related costs in FY 2003. We also set forth proposed changes relating to payments for GME costs; payments to excluded hospitals and units; policies implementing the Emergency Medical Treatment and Active Labor Act (EMTALA); clinical requirements for swing beds in CAHs; and other hospital payment policy changes. These 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 proposed and the issues we addressed in the May 9, 2002 proposed rule:

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

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

Among the proposed changes discussed were:

- 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 major diagnostic category (MDC) 24.
- Reconfiguration and retitling of existing 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 525 (Heart Assist System Implant) 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.
- Redesignation of a code for insertion of totally implantable vascular access device (VAD) as an operating room procedure.
- Changes in the DRG assignment for the bladder reconstruction procedure code.
- Changes in DRG and MDC assignments for numerous newborn and neonate diagnosis codes. (We note that, based on public comments received on the proposed rule, we are not making these changes in this final rule, as discussed in section II.B.6. of this preamble.)
- Changes in DRG assignment for cases of tracheostomy and continuous mechanical ventilation greater than 96 hours.
- We also discussed other DRG classification issues for which we did not propose changes. One of those was the new drug-eluting stent technology. We received many public comments suggesting higher payments would be needed in order to adequately compensate hospitals for the higher costs of this technology. Therefore, in this final rule, we are creating new DRG 525 (Percutaneous Cardiovascular Procedure with, Drug-Eluting Stent with AMI) and new DRG 527 (Percutaneous Cardioascular Procedure with Drug-Eluting Stent without AMI).

We also presented our analysis of applicants for add-on payments for high-cost new medical technologies. We have approved one new technology, the drug drotrecogin alfa (activated), trade name Xigris™, as a new technology eligible for add-on payments. Xigris™ is used to treat patients with severe sepsis.

2. Changes to the Hospital Wage Index

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

- The FY 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

We proposed rebasing and revising the hospital market basket to be used in developing the 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 revised market basket relative weights and choice of price proxies.

In the proposed rule, we also reestimated the labor-related share of the average standardized amount that is adjusted by the wage index. In response to public comments received recommending further evaluation of the methodology used to estimate the labor-related share, we are not proceeding with that reestimation in this final rule.

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

We discussed 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. Based on public comments received, we are not expanding the policy at this time.
- Clarification of the application of the statutory provisions on the calculation of hospital-specific rates for SCHs.
- Exclusion of certain limited-service specialty hospitals from the like hospital definition for purposes of granting SCH status. We proposed to set the threshold for determining a specialty hospital is not a like hospital at 3 percent service overlap between the SCH and the specialty hospital. In this final rule, in response to public comments, we are establishing that threshold at 8 percent.
- Technical change regarding additional payments for outlier cases.
- Proposed case-mix index values for FY 2003 for rural referral centers.
- Changes relating to the IME adjustment, including resident-to-bed ratio caps and counting beds. (We note that because of the need for a future comprehensive analysis on bed and patient day counting policies, and our limited timeframe for preparing the FY 2003 final rule for the acute care hospital inpatient prospective payment systems for publication by the statutory deadline of August 1, 2002, we have decided to postpone finalizing the proposed changes and will address the comments in a separate document.)
- 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 reclassification decisions made by the MGCRB.
- Changes relating to payment for the direct costs of GME.
- Changes relating to emergency medical conditions in hospital emergency departments under the EMTALA provisions. (We note that because of the number and nature of the public comments we received on these proposed changes and our limited timeframe for preparing the FY 2003 final rule for the acute care hospital inpatient prospective payment systems for publication by the statutory deadline of August 1, we have decided to postpone finalizing the proposed changes and will address the comments in a separate document.)
- Criteria for, and responsibilities related to, payments for provider-based entities.
- CMS-directed reopening of intermediary determinations and hearing decisions on provider reimbursements.

We proposed to revise our methodology used to determine the fixed-loss cost threshold for outlier cases based on a 3-year average of the rates of change in hospitals' costs. We received many public comments opposing this change. In this proposed rule, we are using a 2-year average of the rate of change in charges to establish the threshold.

5. Prospective Payment System for Capital-Related Costs

We proposed payment requirements for capital-related costs effective October 1, 2002, which included:

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

We discussed 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 the May 9, 2002 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 proposed threshold amounts for outlier cases. In addition, we proposed 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 of the proposed rule, we set forth an analysis of the impact that the proposed changes 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

In Appendix B of the proposed rule, as required by section 1886(e)(3) of the Act, we set forth our 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.

10. Recommendation of Update Factor for Hospital Inpatient Operating Costs

In Appendix C of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we included 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 the proposed rule, we discussed the MedPAC recommendations concerning hospital inpatient payment policies and presented our response to those recommendations. For further information relating specifically to the MedPAC March 1 report or to obtain a copy of the report, contact MedPAC at (202) 653–7220 or visit MedPAC's Web site at: *www.medpac.gov.*

C. Public Comments Received in Response to the May 9, 2002 Proposed Rule

We received approximately 1,196 timely items of correspondence containing multiple comments on the May 9, 2002 proposed rule. Summaries of the public comments and our responses to those comments are set forth below under the appropriate heading.

II. Changes to DRG Classifications and Relative Weights

A. Background

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. Changes to the DRG classification system and the 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 2003, cases are assigned to one of 510 DRGs in 25 major diagnostic categories (MDCs). Most MDCs are based on a particular organ system of the body. For example, MDC 6 is Diseases and Disorders of the Digestive System. 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 2003, 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.

We proposed numerous changes to the DRG classification system for FY 2003. The proposed changes, the public comments we received concerning them, and the final DRG changes and the methodology used to recalibrate the DRG weights are set forth below. Unless otherwise noted, the changes we are implementing will be effective in the revised GROUPER software (Version 20.0) to be implemented for discharges on or after October 1, 2002. Also, unless otherwise noted, we are relying on the DRG data analysis in the proposed rule for the changes discussed below.

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

a. Revisions of DRGs 1 and 2

Currently, adult craniotomy patients are assigned to either DRG 1 (Craniotomy Age >17 Except for Trauma) or DRG 2 (Craniotomy for Trauma Age >17). The trauma distinction recognizes that head trauma patients requiring a craniotomy often have multiple injuries affecting other body parts. However, we note that the structure of these DRGs predates the creation in FY 1991 of MDC 24 (Multiple Significant Trauma). The creation of MDC 24 resulted in head trauma patients with other significant injuries being assigned to MDC 24 and removed from DRG 2. In FY 1990, there was a 16-percent difference in the DRG weights for DRG 1 and DRG 2. In FY 1992, after the creation of MDC 24, the percentage difference in the DRG weights for DRG 1 and DRG 2 had declined to 1.2 percent. The FY 2002 payment weight for DRG 1 is 3.2713 and for DRG 2 is 3.3874, a 3.5 percent difference.

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

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

Thus, there is an 85.1 percent difference in average charges for the groups with and without CC for the combined DRGs 1 and 2. On this basis, we proposed 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).

Comment: Nine commenters addressed this proposal. Three of the commenters supported the proposal. One commenter was concerned about the significant redefinition of DRGs to the extent that longitudinal DRG data analysis would be seriously comprised. This commenter recommended that we consider creating new DRGs when significant changes to the structure of existing DRGs are necessary in order to preserve the core definition of the existing DRGs for data analysis purposes. The commenter believed that this proposed revision would significantly alter the definition of these DRGs.

Response: We appreciate the support of the commenters for our position on this issue. In response to the commenter's concern that this revision would significantly alter the definition of these DRGs, thus affecting longitudinal DRG data analysis, our practice in the past has been to alter current DRGs to account for better clinical coherence as well as similar patterns of resource intensity. For example, last year we removed defibrillator cases from DRGs 104 and 105 to make these DRGs and the new DRGs 514 and 515 that were created for defibrillators, more homogenous in terms of patient characteristics and resource consumption.

Currently, the DRGs are generally ordered by MDC, which gives the DRGs a logical structure. Adding new DRGs sequentially at the end of the existing DRGs disturbs that order. However, because there is not a perfect solution to this problem, we will take the commenter's concerns into consideration as we proceed with future DRG revisions.

Longitudinal data analysis can be performed by mapping prior year's data with the current Medicare GROUPER. A conversion table is available for this purpose through the National Center for Health Statistics' website: *http://www.cdc.gov/nchs/icd9.htm* or may be purchased from the American Hospital Association (1–800–261–6246).

Comment: A commenter from a manufacturer of an implantable intracranial neurostimulator device used in the treatment of Parkinson's disease and essential tremor recommended that we revise the proposed revisions to DRGs 1 and 2 so that all deep brain stimulation procedures, such as intracranial neurostimulators for Parkinson's disease, are paid under proposed DRG 1. The commenter stated that, based on its review of FY 2000 MedPAR data,

approximately 75 percent of these cases would be assigned to proposed DRG 2 (and subject to an approximate 40-percent payment reduction under the proposed rule).

Response: Our proposed modification was based on FY 2001 MedPAR data. DRGs 1 and 2 included many different procedures with a range of costs associated with these procedures. Our analysis indicated a substantial cost differential between patients with CCs and patients without CCs, and the current DRGs 1 and 2 do not reflect this difference. We believe that the revision we proposed will improve the payment accuracy for cases in these DRGs. The prospective payment system is an average-based payment methodology under which losses that may be incurred for specific procedures or classes of patients are offset by payment gains from other procedures or classes of patients.

In our analysis, we found 847 cases in which an implantation of intracranial neurostimulator procedures was reported. The majority of these cases were being assigned to DRG 2 with average standardized charges of approximately $37,546. These charges are higher than the overall average standardized charges for all cases within DRG 2. However, this group of cases represents a small subset of all of the cases that are assigned to DRG 2. As noted above, we believe our proposed changes represent an overall improvement in payment accuracy for the over 40,000 cases assigned to these two DRGs.

Comment: Three commenters expressed concern with the proposed restructuring of DRGs 1 and 2 as it pertains to the open or endovascular treatment of ruptured or nonruptured aneurysms and arteriovenous malformation.

One commenter submitted data showing the average charges for ruptured aneurysm cases at $34,794 (and in some cases, $52,568), which are more than the average charges for DRG 1, and lengths of stay that are significantly higher than those for the proposed DRG 1. Another commenter assumed that treatment for ruptured aneurysms will remain in the revised DRG 1, and stated that our proposal to reduce the cost variance of these DRGs is a good beginning. However, according to the commenter, this proposed change does not go far enough because it will continue to underpay these extremely resource intensive cases. The commenter recommended that these cases be assigned to a different DRG (DRG 484 (Craniotomy for Multiple Significant Trauma) was suggested) or that a new DRG be created for these cases.

With respect to the treatment of nonruptured aneurysms, the commenters noted that we did not specify whether these cases would be assigned to DRG 1 or 2 and urged that these cases be assigned to DRG 1. The commenter noted that nonruptured interventional aneurysm cases are complex, and patients spend an average of 4.2 days in intensive care.

Response: In these cases, the patients' principal diagnosis would probably be the aneurysm. It is the secondary diagnosis or secondary condition that may be classified as a CC. Under the proposed changes, cases would be assigned to DRG 1 on the basis of a complication that occurred during the hospital stay or a comorbidity that existed at the time of admission or developed during the course of hospitalization. We found in our analysis that the majority of ruptured aneurysm cases and over half of craniotomy procedures in nonruptured aneurysm cases were being assigned to DRG 1, where charges for these cases were similar to the average for all cases in this DRG. The remaining nonruptured aneurysm cases were assigned to DRG 2 ($33,144 compared to $52,254). Our analysis did show the average standardized charges for the ruptured aneurysm to be $109,698, which is higher than the overall average charges of all cases within DRG 1. However, we point out, as noted by the commenter, these cases actually do receive higher payments under the changes we proposed.

Currently, DRG 484 includes complex, multiple significant trauma cases; that is, patients with a principal diagnosis of trauma and at least two significant trauma diagnosis codes (either as principal or secondaries) from different body site categories. While the intensity of treatment for aneurysms and arteriovenous malformations is significant, we do not believe aneurysm and arteriovenous malformation cases are clinically similar to other cases currently assigned to DRG 484.

Comment: One commenter stated that procedures involving implantation of a chemotherapeutic agent into the brain will be underpaid, causing hospitals to further limit use of this technology. The commenter provided data based on 24 patients being treated with this procedure and concluded that the hospital claims data did not reflect the true hospital cost for this product. The commenter stated that the average cost for this procedure is approximately $26,113. The commenter believed that these cases would be assigned to DRG 2 with an estimated payment of approximately $13,225.

Response: Procedure code 00.10 (Implantation of a chemotherapeutic agent) will be effective October 1, 2002, that will enable specific identification of these procedures. At this point, there are limited data available to assess the payment implications of our proposed change on this procedure. As noted above, cases that remain in DRG 1 would receive higher payments as a result of this change. Further, we would expect hospitals to generally be able to offset payment losses associated with a procedure that is used only rarely with payment gains associated with the higher payments for higher volume cases in DRG 1. Also, a low markup associated with one device or procedure is often offset by relatively higher markups associated with another device or procedure, leading to higher relative weights, and thus higher payments, for the latter device or procedure.

We believe that our proposal is appropriate according to currently available data. Therefore, we are adopting as final our proposal 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. Revisions of DRGs 14 and 15

To assess the appropriate classification of patients with stroke symptoms, we evaluated the assignment of cases to DRG 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. We proposed 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 latter 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 a non-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 proposed to remove code 436 from DRG 14 and reassign it to DRG 15. We also proposed to create a third new DRG that would help further differentiate cases currently assigned to DRGs 14 and 15. The proposed revised and new DRG titles were as follows: DRG 14 (Intracranial Hemorrhage and Stroke with Infarction); DRG 15 (Nonspecific Cerebrovascular Accident and Precerebral Occlusion without Infarction) (a corrected title from the one in the proposed rule); and DRG 524 (Transient Ischemia).

The following table represents a reconfiguration of DRGs 14 and 15 and the creation of a new DRG 524 reflecting these three categorizations (based on more recent data than that used in the proposed rule):

DRG and Title	Number of cases	Average length of stay (days)	Average charge
Revised DRG 14 (Intracranial Hemorrhage and Stroke with Infarction)	236,067	6.1	$15,643
Revised DRG 15 (Nonspecific Cerebrovascular Accident and Precerebral Occlusion without Infarction)	101,726	4.9	11,595
New DRG 524 (Transient Ischemia)	136,857	3.4	8,633

The reconfiguration of DRGs 14 and 15 results in the following codes being designated as principal diagnosis codes in 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.

We proposed 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.

We proposed redefining DRG 15 so that it contains 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.

We proposed 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 proposed 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 represented a modification to improve clinical coherence and seems to be a logical change for the construction of the proposed new DRG 524.

Comment: Several commenters opposed the movement of code 436 from DRG 14 into DRG 15. One commenter stated that the change is not supported in either the ICD–9–CM coding manual or the *Coding Clinic* for ICD–9–CM. The commenter noted that an inclusion note under code 436 identified this code as a diagnosis code for a stroke patient with cerebral infarctions. In addition, the commenter cited the *Coding Clinic,* Fourth Quarter, 1993 (pages 38 and 39), as including the term ''cerebral infarction'' following the term ''stroke'', which indicated to the commenter that these terms are synonymous. The commenter recommended that, prior to making any changes, CMS work with the ICD–9–CM Coordination and Maintenance Committee to revise the ICD–9–CM tabular section to correct this inconsistency.

Response: We agree with the commenter that the ICD–9–CM code 436 does, in fact, describe a stroke. However, the code is nonspecific as to the nature of a stroke. In addition, data on cases containing code 436 that were reported in our MedPAR file indicated that these types of cases have a shorter length of stay and lower hospital charges associated with them. Our revised title of DRG 15 reflects our recognition of code 436 as describing a stroke; that is, we are changing the title of DRG 15 to ''Nonspecific Cerebrovascular Accident and Precerebral Occlusion without Infarction.'' With regard to the revision

of the ICD–9–CM diagnosis tabular section describing code 436, we understand that the National Center for Health Statistics (NCHS) plans to address this issue at the December 4th and 5th, 2003 meeting of the ICD–9–CM Coordination and Maintenance Committee. While we agree with NCHS' plan to examine this issue, we are not delaying these DRG changes while waiting for modifications to this section of the coding manual.

Comment: Two commenters opposed any changes in DRGs 14 and 15 until better data become available. One of these commenters noted that moving approximately 80,000 cases from a higher paying DRG to a lower paying DRG will significantly impact many hospital's financial status.

Both commenters opposed moving code 436 from DRG 14 into DRG 15, noting that code 436 is a common code for stroke or cerebrovascular accident when the physician does not specify whether the stroke is an intracranial hemorrhage or cerebral infarction. The commenters noted that performance of diagnostic imaging may add specificity to determine which artery was involved, thus allowing more specific coding to occur. However, it may not change the course of treatment for the stroke. In addition, the commenters stated that, in some cases, it is ill-advised to subject the patient to further testing to make this determination. Further, in some cases, the tests may be inconclusive but in most cases the course of treatment would not be changed.

One commenter indicated that there is probably inconsistency among coders in the use of the more specific 5-digit codes for ''with cerebral infarction'' for categories 433 (Occlusion and stenosis of precerebral arteries) and 434 (Occlusion of cerebral arteries) due to variable interpretations of coding instructions. The commenter noted that there are currently efforts to provide clarification regarding the proper use of these 5-digit codes.

Response: We recognize that some of the diagnostic codes in section 430 through 437 of ICD–9–CM may be more specific than the diagnostic documentation in the medical record, which may make it difficult to precisely code cerebrovascular disease. We also recognize that code 436 may be a catchall code when more specific information on the patient's condition is not available in the record. Further, it is possible that other less severe cases are being labeled ''stroke,'' absent more thorough testing or workup. However, our proposed changes to DRGs 14 and 15 were based on actual MedPAR data from FY 2001. As demonstrated above, there is a clear demarcation between average charges and lengths of stay across the two revised DRGs and one new DRG. Further, payment for many cases is higher after these changes than it was previously. For FY 2003, the DRG relative weights for DRGs 14 and 15 were 1.1655 and 0.7349, respectively. The proposed FY 2003 relative weights for DRGs 14, 15 and 524 were 1.2742, 0.9844, and 0.7236. Therefore, cases remaining in DRG 14 would receive higher payments as a result of moving less expensive cases into DRG 15 or 524. Similarly, cases remaining in DRG 15 would receive much higher payments than they had previously.

We believe these changes improve the clinical and resource cohesiveness of the DRGs for these cases. We acknowledge the concerns expressed by the commenters that code 436 may frequently be used in lieu of more specific codes that require further tests even though the cases are as severely ill as those with more specific diagnosis indicated on the bill. However, this is not borne out by the data.

To the prospect of more available data in the future, we note that changes to codes in the related section of the ICD–9–CM coding book have been in place since 1993. We believe that 9 years is sufficient time to clarify the coding issues and to adequately train both the coding and medical staffs regarding documentation of cerebrovascular disease.

Comment: One commenter opposed the movement of code 437.1 to new DRG 524, noting that conditions classified to this code are generally chronic or long term in nature, not transient.

Response: The titles of DRGs are not intended to uniquely identify each case within the DRG, but to logically group cases that globally have similar characteristics in terms of clinical requirements and resources utilized. We proposed the movement of code 437.1 from DRGs 16 and 17 in order to improve the clinical coherence of DRGs 16 and 17, and the new DRG 524; we believe this change accomplishes that. Therefore, we are adopting the proposed change as final.

Comment: One commenter supported the movement of codes 437.3 and 784.3 from DRG 14 to DRGs 34 and 35.

Response: We appreciate the commenter's support. Accordingly, we are adopting the proposed change to move codes 437.3 and 784.3 to DRGs 34 and 35, as final.

We are adopting as final the proposed changes to DRGs 14 and 15 and the creation of new DRG 524 without modifications. We will continue to monitor these DRGs for shifts in resource consumption and validity of DRG assignment and will specifically monitor code 436 for appropriate placement in DRG 15. We support the concept of clarification of the coding guidelines in this section of ICD–9–CM and will also monitor these DRGs when the guidelines are updated.

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 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 DRG average charges to any great degree.

Therefore, we proposed to create a new DRG 525 (Heart Assist System Implant), which would contain these cases. The FY 2003 relative weight for the new DRG 525 is 11.6479.

As discussed below, the comments we received supported this change. Therefore, we are creating new DRG 525, which consists 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 will 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.*

Comment: Several commenters supported the proposed creation of a new DRG 525 for patients receiving implanted heart assist systems. One commenter stated that the creation of a new DRG 525 would be more sensitive to the patient population, more accurate in statistical analysis and data reports, and more responsive to changes in LVAD charges and utilization patterns.

Other commenters suggested that the payment amount still understates the reasonable cost of LVAD implantation. One commenter provided analysis that purported to show that the net payment effect of this change is insignificant due to the increase in the outlier threshold as discussed in the proposed rule (and in the Addendum to this final rule). Another commenter stated that this new DRG results in payment that does not even compensate for the costs to the hospital of the device itself. The commenter noted that current payment levels for LVADs do not take into account the equipment required for discharge, that is, both disposable and durable medical equipment.

Some of the commenters recommended that we consider allowing LVADs to qualify for a new technology add-on payment in addition to establishing a new DRG specific to this technology.

Response: Regarding the commenter's analysis of the net payment effect of the proposed new DRG 525, the increase in the outlier threshold is not related to the creation of the new DRG 525. As discussed in detail in the Addendum, the FY 2002 outlier threshold was set at a point that resulted in excessive outlier payments. The commenter's analysis compared payments if these cases remained in DRGs 104 and 105 and received outlier payments in accordance with the lower FY 2002 outlier threshold to payments under the new DRG 525 using the proposed outlier threshold. Therefore, the commenter's analysis does not accurately represent payments under the DRGs. The correct analysis is to compare payments under DRGs 104 and 105 with payments under the new DRG 525, absent outlier payments, which results in an increase in payments of over 40 percent per case. Since cases qualify for outlier payments on the basis of a constant fixed-dollar loss threshold and receive payments equal to 80 percent of costs above the threshold, the 40-percent differential in payments is not affected by outlier payments.

With regard to the commenters' indication that the payment under the new DRG 525 is insufficient, we note that the DRG relative weights are based on charge data for actual LVAD cases in the Medicare discharge database, using the most recent information available (the FY 2001 MedPAR file). (Section II.C. of this final rule contains a complete discussion of this methodology.)

With regard to the commenter's suggestion that LVADs be eligible for add-on payments for new technology, we point out that our criteria require that the mean charges of the cases involving a new technology exceed a threshold of one standard deviation beyond the mean charge for all cases in the DRG. Since DRG 525 is specific to heart assist systems, the mean charge of the cases involving the new technology is the same as the mean charge for all cases in the DRG. Also, this technology does not meet our criteria to be considered new (see discussion at section II.D. below).

Finally, with regard to the concept that the DRG payment for LVAD should take into account disposable and

durable medical equipment after discharge, we point out that the Medicare Part A inpatient hospital payment is distinct from the Medicare Part B outpatient payments.

Comment: One commenter stated if LVAD implantation is approved for patients who are not heart transplant patients, the payment is likely to still be too low, as it is anticipated that these patients comprise a generally sicker population. The commenter suggested that we direct hospitals to bill uniformly for LVAD devices via the designated ICD–9–CM procedure codes that will classify into DRG 525.

Response: As we noted in the proposed rule, we understand that studies are currently underway to evaluate LVADs as permanent support for end-stage heart failure patients. However, at this time, these applications are only on a trial basis. Further, in the absence of specific data demonstrating additional costs associated with expanded uses of LVADs beyond bridge-to-transplant patients, we do not take anticipated higher costs into account in the DRG relative weight calculation. However, we will continue to monitor new DRG 525 as new developments occur in the approved uses of LVAD technology to ensure appropriate classification and payment of these cases.

With respect to the comment that we should provide further guidance on the correct ICD–9–CM coding procedures for LVADs, as explained above and in the proposed rule, cases with any principal diagnosis in MDC 5 reporting code 37.62, 37.63, 37.65, or 37.66 will be assigned to DRG 525 (in the absence of a transplant). Further information regarding the use of these codes may be obtained by referring to a relevant article from the *Coding Clinic,* Fourth Quarter, 1995 (pages 68 and 69).

Comment: One commenter, while approving the movement of codes 37.63, 37.65, and 37.66 to DRG 525, did not believe that cases with code 37.62 belong in this DRG. The commenter stated that code 37.62 includes centrifugal pumps, heart assist systems that are not specified as pulsatile, and the insertion of not otherwise specified heart assist systems, and urged CMS to reconsider inclusion of this code in the new DRG. The commenter stated that centrifugal pumps are more similar to cardiac bypass procedures than to ventricular assist systems, and inclusion of this code would likely reduce the relative weight of DRG 525 due to the lower cost of this type of technology. The commenter recommended that code 37.62 remain in DRG 104 and 105. The commenter was also concerned that the change would create a potential incentive for these technologies to be used for purposes not yet approved by the FDA.

Response: Our analysis indicates that these four codes represent the most expensive cases in MDC 5, aside from heart transplantation in DRG 103, which is the reason we moved them out of DRGs 104 and 105. However, we will continue to evaluate the appropriate assignment of cases into this new DRG, particularly if new uses for heart assist systems are approved by the FDA, and will take the commenter's recommendation into account when we conduct our annual MedPAR review next year.

Comment: One commenter suggested that we develop a new heart transplant DRG entitled ''Heart Transplant with LVAD,'' because the costs of the LVADs have not been incorporated into the heart transplant DRG. The commenter stated that, since a great number of LVAD cases remain inpatients until heart transplant occurs, there is a disparity in costs between heart transplant patients who receive LVADs during the stay, and those who do not remain inpatients.

Response: As we pointed out above, cases in which a subsequent heart transplant occurs during the hospitalization episodes are currently assigned to DRG 103 (Heart Transplant) because cases involving procedure codes 33.6 (Combined heart/lung transplant) and 37.5 (Heart transplant) are assigned to DRG 103, regardless of other codes included on the bill. We believe these cases are appropriately compensated in these DRGs, but we will continue to monitor this issue in the future.

Comment: One commenter requested that we review our data to determine if there is an incorrect mix of devices being included in the calculation of the DRG weight. The commenter suggested that perhaps that there is some inappropriate mixing of data, and that there are temporary assist devices used in the intensive care unit (ICU) that are quite distinct from those used for longer term bridge-to-transplant. This commenter noted that these ICU devices are much less expensive.

Response: As noted in the proposed rule, average length of stay and charge data were calculated for all cases including codes 37.62, 37.63, 37.65, and 37.66. These codes describe the implantation of heart assist systems, which is the construct of the new DRG 525. Therefore, we believe we have appropriately accounted for these cases in our analysis.

Comment: One commenter expressed concern that we did not separate payment for LVADs used in the acute care setting from LVADs used as chronic care devices, and pointed out that the short-term indication uses only a fraction of the resources required for a chronic or long-term LVAD. The commenter asked us to consider two DRGs, one for acute care devices and one for long-term care devices, that better reflect the resource consumption of each indication.

Response: The LVAD is currently being studied as a device that would support end-stage heart failure patients in the absence of a heart transplant. This use is not out of the clinical trial phase and, more importantly, has not been recognized as a Medicare covered service. It would be premature to establish a DRG based on the possibility that the LVAD may some day be approved for this indication is premature.

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 has 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 that 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 proposed 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.

Several commenters representing hospitals and medical coders supported our proposal to classify code 398.91 as a complex diagnosis within DRG 124, which moves these cases from DRG 125. Accordingly, we are adopting as final the proposed change.

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 an MDC principal diagnosis and code 92.27 do not meet the criteria for assignment to DRG 517 because there is no indication of a percutaneous cardiovascular procedure, they are currently assigned to DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis). Because DRG 468 is reserved for cases in which the O.R. procedure is unrelated to the principal diagnosis, we proposed to assign cases with code 92.27 that do not meet the criteria for assignment to DRG 517, but that would otherwise be assigned to MDC 5, to DRG 120 (Other Circulatory System O.R. Procedures).

Comment: One commenter supported the proposal. Another commenter was unclear why code 92.27 is designated as an operating room procedure and would be assigned to DRG 120 (Other Circulatory System O.R. Procedures) if reported as a stand-alone procedure. This commenter stated that it is not aware of instances when it is appropriate to report this code without a concomitant cardiovascular procedure, and believed that another procedure, such as angioplasty, is needed in order to insert the radioactive implants. The commenter believed that cases in which code 92.27 was reported by itself for treatment of a cardiovascular disorder may represent incorrect coding.

Response: We proposed this modification to MDC 5 (Diseases and Disorders of the Circulatory System), concerning the assignment of code 92.27 (when reported as the only procedure) to DRG 120 in part, as a result of a telephone call from a member of the general public. The inquirer questioned the assignment of code 92.27 without angioplasty and with a principal diagnosis in MDC 5 to DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis). When we created DRG 517 in the FY 2002 final rule, we also did not consider that a radioactive implant would be inserted without angioplasty as a delivery technique. We were advised by our medical advisors that it could occur, but it was unlikely. Code 92.27 has not yet been reported in our MedPAR data in MDC 5 as a stand-alone procedure. However, to address the possibility that it might be reported alone, we are taking this opportunity to assign code 92.27 to DRG 120 in MDC 5, consistent with the principal diagnosis, instead of a (higher-weighted) DRG in which the principal diagnosis and the procedure do not match (DRG 468).

With regard to the commenter's question about the designation of code 92.27 as an operating room procedure, we note that code 92.27 has always been considered by the Medicare GROUPER to be a procedure code affecting DRG assignment. It can be found in 12 MDCs and 20 DRGs in GROUPER version 19.0.

Comment: One commenter commended us for responding to its previously submitted comments concerning inadequate DRG payment for GP IIb–IIIa platelet inhibitors, but noted that its request from last year was not mentioned in our proposed rule in our review of several cardiovascular DRGs for both interventional and medical cases that receive GP IIb–IIIa inhibitors. The commenter stated that without a review of the presence of code 99.20 (Injection or infusion of platelet inhibitor) in DRGs 124 (Circulatory Disorders Except AMI, with Cardiac Catheterization and Complex Diagnosis) and 140 (Angina Pectoris), CMS cannot be certain that a significant number of cases are not significantly underpaid.

Response: We regret this omission in the proposed rule. We did, in fact review both DRGs 124 and 140 for the presence of code 99.20. In DRG 124, there were a total of 95,452 cases without code 99.20. These cases had an average length of stay of 4.4 days and average charges of $17,594. There were 1,120 cases in DRG 124 with code 99.20.

These cases had an average length of stay of 3.5 days, and average charges of $17,256. In DRG 140, there were a total of 45,886 cases without code 99.20, with an average length of stay of 2.5 days and average charges of $6,204. There were 126 cases in DRG 140 with code 99.20, with an average length of stay of 2.3 days, and average charges of $8,675.

The data do not demonstrate a level of disparity in days and charges that would warrant an adjustment to these DRGs based on the presence of code 99.20. Therefore, we are not making any changes concerning the status of code 99.20 in these DRGs for FY 2003.

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 cases involving code 277.00 as a principal diagnosis in DRGs 296, 297, and 298. Our analysis of the average charges for these cases indicates that resource utilization for these cases is quite different from resource utilization for other cases in these 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 without CC)	133	21,998
DRG 298 (Nutritional & Metabolic Disease Age 0–17)	0	

ALL CASES IN DRG 296, 297, 298

DRG 298 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 proposed 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 proposed to use the following three new principal diagnosis codes to further inform DRG assignment of these patients:

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

We proposed 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 the new code 277.02 would identify those patients with cystic fibrosis who have pulmonary manifestations, we proposed to assign cases in which this is the principal diagnosis 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 proposed that the 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 the new code 277.09 could involve a number of manifestations (excluding pulmonary and gastrointestinal), we proposed to assign this 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	MDC assignment	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
New 277.02 (Cystic fibrosis with pulmonary manifestations)	4	79, 80, 81
New 277.03 (Cystic fibrosis with gastrointestinal manifestations)	6	188, 189, 190
New 277.09 (Cystic fibrosis with other manifestations)	10	296, 297, 298

Several commenters representing hospitals, medical coders, and specialty groups supported the proposed DRG assignments relating to cystic fibrosis discussed above. Therefore, we are adopting the proposed DRG assignments as final, effective for discharges occurring on or after October 1, 2002.

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. In other words, the Medicare GROUPER software program does not recognize code 86.07 as a procedure code when reported with any principal diagnosis in this MDC. 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 venous (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 often involved complications, leading to higher average charges and longer lengths of stay for those cases. Therefore, we indicated that we would not assign 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 divided based on the presence or absence 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 proposed to designate code 86.07 as an O.R. procedure under MDC 11.

Specifically, code 86.07 will 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

We received two comments in support of this proposal. Therefore, we are adopting as final the proposed redesignation of code 87.06 as an O.R. procedure under MDC 11 and its assignment to DRG 315 when combined with the principal diagnosis codes from DRG 316 listed above.

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 proposed to classify code 57.87 as a major bladder procedure and to assign it to DRGs 303, 304, and 305.

We received several comments from associations representing hospitals and medical coders in support of the proposed reclassification of bladder reconstruction surgery from a minor bladder to a major bladder procedure. Accordingly, we are adopting as final the proposed reclassification, effective for discharges occurring on or after October 1, 2002.

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.

Because of our limited data and experience with newborn cases under Medicare, we contacted the National Association of Children's Hospitals and Related Institutions (NACHRI), 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 the May 9, 2002 proposed rule, we proposed to make extensive changes to multiple DRG categories in MDC 15. A complete description of these proposed changes appears in the May 9, 2002 **Federal Register** at 67 FR 31412 through 31414. In summary, the proposed changes involved removing a number of congenital anomalies from MDC 15 and assigning them to other MDCs. NACHRI advised us that these congenital anomalies would be better classified in the MDC for the body system affected. We also proposed revising DRG 386 (Extreme Immaturity or Respiratory Distress Syndrome, Neonate), to refine the assignment of newborn cases diagnosed with extreme immaturity. We proposed major revisions for DRG 387 (Prematurity With Major Problems) to redefine the codes for prematurity and the codes that define a ''major problem''. We proposed modifications of DRG 388 (Prematurity Without Problems), which involved changes in the classification of prematurity for newborns. We proposed revising the definition of a ''major problem'' for DRG 389 (Full Term Neonate With Major Problem) as well. By changing the definition of ''major problem'' in the other DRGs, our proposal would have increased the number of cases being assigned to DRG 390. Finally, we proposed to expand the number of minor problem newborn diagnoses included in DRG 391 (Normal Newborn). All of these extensive changes would have greatly shifted the DRG assignments for newborns, involving hundreds of ICD–9–CM codes.

Comment: One commenter, a national hospital association, opposed at this time the reassignment of a large number of diagnosis codes from the ''major problems'' list in DRGs 387 and 389 to DRG 391. The commenter agreed that refinements to MDC 15 would be beneficial to allow more accurate grouping of neonatal admissions but recommended that, prior to making extensive changes, CMS work with NACHRI, the commenter, and other interested parties to develop a separate DRG that would group neonates with minor problems that are not otherwise recognized currently or under the proposed changes.

Other commenters, representing hospitals, medical groups, and medical coders, offered a similar comment. One commenter stated that since NACHRI represents specialty hospitals, NACHRI's data may not fully represent the entire newborn population. Other commenters recommended that the proposed revisions to DRGs 387 through 391 not be implemented until input is obtained from representatives of general community hospitals that treat newborns. The commenters stated that newborn DRG data from general community hospitals may vary significantly from NACHRI's data and should be taken into consideration prior to implementing the proposed revisions to DRGs 387 through 391.

One commenter also stated that, while it supported the proposed removal of the listed codes for congenital anomalies, periventricular leukomalacia, and nonspecific abnormal findings on chromosomal analysis from MDC 15, the commenter was confused as to the rationale for the proposed DRG assignments for the codes for congenital anomalies. (We proposed that code 759.4, Conjoined twins, be classified to DRGs 188, 189, and 190.) In addition, several commenters stated that these DRGs are for digestive system diagnoses and conjoined twins may or may not have medical conditions involving the digestive system. The commenters stated that the rationale for the selection of these DRGs was not described in the proposed rule.

One commenter stated that additional study of newborn DRG classifications was needed. This commenter recommended that when cardiac surgery procedures are performed on neonates born in the hospital, the case be assigned to the applicable cardiac surgery DRG instead of one of the neonatal DRGs. The commenter pointed out that when a baby is born in a hospital and surgery is performed on a congenital heart condition during the same stay, the newborn is assigned to DRG 389 where the relative weight is approximately one-half the weight of the applicable cardiac surgery DRG. When the newborn is delivered at another facility and then transferred for surgery, the newborn is assigned to the appropriate cardiac surgery DRG. The commenter recommended that this issue be considered when MDC 15 is revised.

Response: The commenters raised a number of important issues. We solicited the assistance of NACHRI to develop refinements to MDC 15 because, while MDC 15 is part of the Medicare DRG system, the types of patients in classified to DRGs in MDC 15 are not a significant part of the Medicare program. It was our goal to develop refinements that could be useful for non-Medicare purposes. Given the extensive nature of the proposed revisions, we concur that additional study is necessary. Therefore, we are not implementing as final any of the proposed revisions to MDC 15. We are maintaining the existing structure of DRGs 385 through 390 within MDC 15 (Version 19.0) for FY 2003. Nonetheless we believe that changes in this area may be worthwhile, and we would be interested in considering a set of appropriate changes that might be broadly acceptable to the affected community. If we receive such suggested changes by December 1, 2002, we would consider it as part of our annual review and updates to the DRG system for FY 2004. Any proposals could be included in the notice of proposed rulemaking for FY 2004, which is scheduled to be published in early Spring 2003. In the meantime, as stated earlier, we are not making any of the proposed changes to MDC 15 for FY 2003.

Comment: One commenter supported the creation of the new ICD–9–CM codes that differentiate between extreme immaturity or gestational age, or both.

Response: As explained in the proposed rule, we are adding the new ICD–9–CM codes for newborns that were approved in 2002 for use by acute care hospitals in FY 2003. These codes are listed in Table 6A of this final rule. The codes are assigned to the existing DRGs as indicated in Table 6A under the column ''DRG'' (codes 747.83 through 779.89). Tables 6A through 6F in this final rule also reflect the assignment of these new codes.

Comment: One commenter pointed out several typographical errors and omissions in the proposed changes for MDC 15 in the proposed rule.

Response: The commenter is correct that there were typographical errors in the proposed rule. However, since we are not finalizing the proposed changes, we are not addressing the errors specifically in this final rule. We will provide clarifications of these errors to those interested parties who participating in future efforts to refine MDC 15.

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 that 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.

We received several comments in support of this change. Accordingly, in this final rule we are adding code V10.53 to the list of secondary diagnosis in DRG 465, effective for discharges occurring on or after October 1, 2002.

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 proposed 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 continuous mechanical ventilation for 96 consecutive hours or more 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 proposed 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) would be assigned to DRG 483. We would continue to assign to DRG 483 those patients who have a principal diagnosis unrelated to disease of the face, mouth, or neck and a tracheostomy. We proposed to retitle DRG 483 ''Tracheostomy/Mechanical Ventilation 96+ Hours Except Face, Mouth, and Neck Diagnosis.''

In the proposed rule, we indicated that we would give future consideration to modifying DRGs 482 and DRG 483 based on the presence of code 96.72, and specifically invited comments on this area.

Comment: Several commenters representing hospital associations and medical groups supported the proposed modification to DRG 483. Some commenters strongly supported using code 96.72 as a determining factor for assigning ventilator patients to DRG 483. Another commenter indicated that the proposal was a more accurate means of identifying high-cost ventilator patients.

One commenter representing medical coders opposed the proposed modification. The commenter expressed concern that there were no supporting data to justify the revision. The commenter pointed out that it was not clear to which DRG tracheostomy patients with mechanical ventilation of less than 96 hours and with out a face, neck, or mouth diagnosis would be classified, since no modification to DRG 482 was proposed. The commenter did note that CMS was encouraging the reporting of code 96.72, but believed that this might be a problem when a number of other significant operative procedures are performed, given the limited spaces available on the claim form to report ICD–9–CM procedure codes.

Response: The proposed change was a first attempt to refine DRGs 482 and 483 so that those patients who receive long-term (> 96 hours) mechanical ventilation are separated from those patients who receive mechanical ventilation of less than 96 hours. The proposed change to DRG 483 was partially in response to concern that hospitals could omit diagnosis codes indicating face, mouth, or neck diagnosis in order to have cases assigned to DRG 483 rather than the much lower paying DRG 482. It also was an attempt to improve the classification of patients on mechanical ventilation by identifying those who receive long-term use of a ventilator. By making the GROUPER recognize long-term mechanical ventilation and assigning those patients to the higher weighted DRG 483, we hoped that hospitals would be more aware of the importance of reporting code 96.72 when, in fact, patients had been on the ventilator for greater than 96 hours. Therefore, hospitals would appropriately increase the reporting of this code. This reporting would allow us to continue to refine DRGs 482 and 483 to better reflect the resource utilization of these cases.

We agree with the commenter that hospitals frequently are faced with cases where more than six procedures are performed during the inpatient stay and that there are limited spaces available on the claims form for reporting procedure codes. The proposed change encourages hospitals to begin to report code 96.72, since it will effect DRG assignment.

The commenter was correct; we were not completely clear in the proposed rule about the effect that the addition of code 96.72 would have on DRG 482. The change will have an impact on DRG 482. All cases involving a tracheostomy and a diagnosis of face, mouth, and neck diagnosis that also have been on continuous mechanical ventilation for greater than 96 hours (code 96.72) will be moved out of DRG 482 and into DRG 483. The effect is that the expensive, long-term mechanical ventilation cases will be moved out of DRG 482 and into the higher-weighted DRG 483. As mentioned earlier, we did not propose any DRG modification involving patients who receive a tracheostomy, have mechanical ventilation of less than 96 hours, and do not have a face, neck, or mouth diagnosis. These cases will continue to be assigned to DRG 483.

Should future data indicate a need for further refinement of DRGs 482 and 483, we would propose these changes at that time. The public would be given an opportunity to comment on these proposals through the normal notice-and-comment rulemaking process.

In this final rule, we are adopting as final the proposed change in the definition of DRG 483 and the proposed change to add code 96.72 to DRG 483. To further clarify this change, we are changing the title of DRG 483 to ''Tracheostomy with Mechanical Ventilation 96 + Hours or Principal Diagnosis Except Face, Mouth, and Neck.''

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.

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 or have not been utilized 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 proposed 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 final rule under the discussion of MDC 5 changes with regard to the remodeling of DRGs 14 and 15.

We received two comments in support of this proposal. However, one of the commenters noted that code 436 is not just limited to use in smaller hospitals, as we stated in the proposed rule. We acknowledge the commenters remarks that code 436 is widely used in hospitals of all sizes and is not exclusively used in smaller hospitals. However, our rationale for removing code 436 from the MCE because it is frequently used, still holds. Accordingly, we are adopting as final the proposed removal of code 436 from the MCE ''nonspecific principal diagnisis'' edit, effective with discharges occurring on or after October 1, 2002.

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.

In the May 9, 2002, we proposed 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 proposed to reorder DRG 495 (Lung Transplant) above DRG 512 (Simultaneous Pancreas/Kidney Transplant).
- In MDC 5, we proposed 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).

In the proposed rule, we were unable to test the effects of the proposed revisions to the surgical hierarchy and to reflect these changes in the proposed relative weights because the revised GROUPER software was unavailable at the time the proposed rule was completed. Rather, we simulated most major classification changes to

approximate the placement of cases under the proposed reclassification, and then determined the average charge for each DRG. These average charges served as our best estimate of relative resources used for each surgical class. We have now tested the proposed surgical hierarchy changes after the revised GROUPER was received and are reflecting the final changes in the DRG relative weights in this final rule. Further, as discussed in section II.C. of this preamble, the final recalibrated weights are somewhat different from the proposed weights because they were based on more complete data.

Based on a test of the proposed revisions using the April 2002 update of the FY 2001 MedPAR file and the revised GROUPER software, we have found that the revisions are still supported by the data, and no additional changes are indicated except those discussed below pertaining to the implementation of two new cardiac drug-eluting stent DRGs. (For a complete description of this change, see the discussion under ''Other Issues'' in section II.B.14. of this preamble.) Due to the implementation of two new DRGs pertaining to cardiac drug-eluting stents, DRGs 526 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with AMI) and 527 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without AMI), we also are reordering the following DRGs in MDC 5: DRGs 115 (Permanent Cardiac Pacemaker Implant with AMI, Heart Failure or Stroke, or AICD Lead or and Generator Procedure) and 116 (Other Permanent Cardiac Pacemaker Implant) above DRG 526; DRG 526 above DRG 516 (Percutaneous Cardiovascular Procedures with Acute Myocardial Infarction (AMI)); DRG 516 above DRG 527; DRG 527 above DRG 517 (Percutaneous Cardiovascular Procedure without AMI, with Coronary Artery Stent Implant); DRG 517 above DRG 518 (Percutaneous Cardiovascular Procedures without AMI, without Coronary Artery Stent Implant); and DRG 518 above DRGs 478 (Other Vascular Procedures with CC) and 479 (Other Vascular Procedures without CC).

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. In the May 9, 2002 proposed rule, we did not propose 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.

In this final rule, we are making limited revisions of the CC Exclusions List to take into account the 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 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 final rule contain the revisions to the CC Exclusions List that will 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 will not be recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

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

Copies of the original CC Exclusions List applicable to FY 1988 can be obtained from the National Technical

Information Service (NTIS) of the Department of Commerce. It is available in hard copy for $133.00 plus shipping and handling. A request for the FY 1988 CC Exclusions List (which should include the identification accession number (PB) 88–133970) should be made to the following address: National Technical Information Service, United States Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161; or by calling (800) 553–6847.

Users should be aware of the fact that all revisions to the CC Exclusions List (FYs 1989, 1990, 1991, 1992, 1993, 1994, 1995, 1996, 1997, 1998, 1999, 2000, and 2002) and those in Tables 6F and 6G of this FY 2003 final rule 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.

We received no comments on our proposed changes to the CC list, and we are adopting the changes as final.

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

MOVEMENT OF PROCEDURE CODES FROM DRG 468—Continued

Procedure code	Description	Included in DRG	Description
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.
MDC 11—Diseases and Disorders of the Kidney and Urinary Tract			
0492	Implantation or replacement of peripheral neuro-stimulator.	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.
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.

We did not receive any comments on the proposed movement of procedures codes from DRG 468. Accordingly, we are adopting, as final, the movement of the codes as outlined above.

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 move cases to keep the DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data. Based on our review this year, we are not moving 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 adding 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 ICD–9–CM Manual contains the list of valid diagnosis and procedure codes. (The ICD–9–CM Manual is available from the Government Printing Office on CD–ROM for $22.00 by calling (202) 512–1800.) The NCHS has lead responsibility for the ICD–9–CM diagnosis codes included in the *Tabular List* and *Alphabetic Index for Diseases,* while CMS has lead responsibility for the ICD–9–CM procedure codes included in the *Tabular List* and *Alphabetic Index for Procedures of the Manual.*

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.

We described our plans to expedite the implementation of coding changes in the September 7, 2001 **Federal Register**, including moving the dates of the ICD–9–CM Coordination and Maintenance Committee to December and April of each year. We also established the possibility of implementing procedure codes discussed in the April meeting as part of the October update in the same year. This reduces the time for activating a new code from a minimum of 11 months to a minimum of 6 months.

Because the changes would not be included in the proposed rule published in the spring, the public would be given less opportunity to consider the merits of the proposals. Decisions from the spring meeting must be finalized by early June in order to be included in changes in the GROUPER software and be effective October 1. The addenda must also be published on the homepage and distributed to publishers so that both paper versions of the ICD–9–CM code book and software applications can be ready in time for use by health care providers. Only those issues from the April meeting that could be quickly resolved and that received support from the public would be able to be included in the October addendum. Those that could not be quickly resolved would continue to be addressed as part of the addendum for October 1 of the next year.

The ICD–9–CM Coordination and Maintenance Committee met on April 18 and 19, 2002. Two code title issues discussed during that meeting were approved in time to be included in the Addendum of this final rule, to be effective October 1, 2002. These codes are new code 89.60 (Continuous intra-arterial blood gas monitoring) which is shown in Table 6B in the Addendum of this final rule, and revised code title 02.41 (Irrigation and exploration of ventricular shunt) which is shown in Table 6F in the Addendum of this final rule.

For a report of procedure topics discussed at the April 2002 meeting, see the Summary Report at: *http://www.cms.hhs.gov/medicare/icd9cm.asp.* This site also includes the Final Addendum for ICD–9–CM Procedures, which will be effective October 1, 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.asp.* 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 final rule. As we stated above, the code numbers and their titles were presented for public comment at the ICD–9–CM Coordination and Maintenance Committee meetings. Both oral and written comments were considered before the codes were approved. In the proposed rule, we only solicited comments on the proposed DRG classification of these new codes.

For codes that have been replaced by new or expanded codes, the corresponding new or expanded diagnosis codes are included in Table 6A (New Diagnosis Codes) in the Addendum of this final rule. New procedure codes are shown in Table 6B. Diagnosis codes that have been replaced by expanded codes or other codes or have been deleted are in Table 6C (Invalid Diagnosis Codes). These invalid diagnosis codes will not be recognized by the GROUPER beginning with discharges occurring on or after October 1, 2002. 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).

Comment: One commenter expressed concern about making procedure code changes discussed at the April ICD–9–CM Coordination and Maintenance Committee effective the following October. The commenter had concerns with the fact that these coding changes would not be discussed in the proposed rule, but would appear in the final rule. The commenter indicated that hospitals need time to comment on all proposed changes to the DRGS and to analyze changes for budgeting, train staff on coding changes, and implement software changes. The commenter also endorsed movements toward replacing ICD–9–CM with ICD–10–PCS and believed this would improve coded data. In addition, the commenter suggested that consideration be given to using Alpha-numeric HCPCS codes to report the use of drugs, supplies, and devices used for inpatients, instead of trying to make ICD–9–CM serve this purpose.

Response: We discussed the issue of consideration of coding changes at the April meeting of the Committee in the final rule on Payment for New Medical Services and New Technologies Under the Acute Care Hospital Inpatient Prospective Payment System published in the **Federal Register** on September 7, 2001 (66 FR 46902). We were responding to section 533 of Public Law 106–554, which provided for expediting the incorporation of new services into the coding system. While we recognize the commenter's concern, we also are responding to repeated requests to expedite our process of updating codes. We will carefully evaluate requests for new codes that are discussed at the April ICD–9–CM Coordination and Maintenance Committee to determine which codes can and should be included in the addendum on ICD–9–CM effective October of each year. We encourage the commenter to continue to participate in the process by attending these public meetings and offering its opinions.

On the issue of the movement to ICD–10–PCS and the possibility of using HCPCS codes for inpatient reporting, we note this issue is currently under review by the National Committee on Vital and Health Statistics (NCVHS). This committee advises the Secretary on coding standards issues under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The committee is currently conducting public meetings on the issues raised by this commenter. We will defer issues involving changes to the HIPAA standards to the NCVHS. For more information on this committee, please see its web site at: *http://www.ncvhs.hhs.gov/.*

14. Other Issues

In addition to the specific topics discussed in section II.B.1. through 13. of this final rule, we addressed a number of other DRG-related issues in the May 9, 2002 proposed rule. In the proposed rule, we did not propose any changes to the DRGs relating to the issues. Below is a summary of the issues that were addressed, any public comments we received, and our responses to those comments.

a. Intestinal Transplantation

We examined our data to determine whether it is appropriate to add a new intestinal transplant DRG. Our data revealed that nine intestinal transplantation cases were reported by two facilities. Of the nine cases, two cases involved a liver transplant during the same admission and, therefore, would be assigned to DRG 480 (Liver Transplant). As we stated in the proposed rule, we do not believe that the remaining seven cases provide a sufficient number to warrant the creation of a new intestinal transplant DRG.

Comment: Commenters supported the proposal not to create a separate new DRG for intestinal transplants and pointed out that this procedure is not being widely performed.

Response: We will continue to monitor intestinal transplantation cases to determine whether it may be appropriate in the future to establish a new DRG for the intestinal transplant procedure.

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 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.

Comment: Commenters supported the creation of a new diagnosis code so that Myasthenia Gravis in crisis patients can be uniquely identified and the mild and severe forms of the disease is distinguished.

Response: This topic was addressed at the April 18, 2002 ICM–9–CM Coordination and Maintenance Committee meeting. NCHS proposed two new codes to capture Myasthenia Gravis not in crisis and Myasthenia Gravis in crisis. If the Committee approves these two codes, they would not become effective until October 1, 2003. At that point, we would be able to assess the charges associated with Myasthenia Gravis in crisis patients receiving plasmapheresis.

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. For the proposed rule, 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.

We received one comment in support of our proposal not to make DRG changes to the cardiac mapping and ablation codes. Accordingly, in this final rule, we will not make any changes relating to the DRG assignment of codes 37.20, 37.26, and 37.34

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 did not propose to assign cases without CCs from DRG 111 to DRG 110. We reiterate that hospitals are responsible for coding their records completely and for recording and submitting all relevant diagnosis and procedure codes that have a bearing on the current admission (in particular, any secondary or additional diagnosis codes that may be recognized by the GROUPER software as codes describing complications or comorbidities associated with a case).

Comment: One commenter recommended a new DRG due to the significant costs associated with the device.

Response: The commenter submitted no data that would cause us to question our findings described above. Therefore, in this final rule, we are not changing the current DRG assignment of procedure code 39.71. e. Platelet Inhibitors.

In the August 1, 2001 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.

For the May 9, 2002 proposed rule, 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 we did not propose any changes to the assignment of the procedure code 99.20.

We received one comment in support of maintaining the current DRG assignments of code 99.20. Therefore, in this final rule, we are not making any changes to the DRG assignments of code 99.20.

f. Drug-Eluting Stents

The drug-eluting stent technology has been developed to combat the problem of restenosis of blood vessels previously treated for stenosis. The drug is coated on a stent with a special polymer, and after the stent is placed in the vessel, the drug is slowly released into the vessel wall tissue over a period of 30 to 45 days. The drug coating on the stent is intended to prevent the build-up of scar tissue that can narrow the reopened artery.

In Table 6B of the Addendum to this final 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 adding code 00.55 (Insertion of drug-eluting noncoronary artery stent).

A manufacturer of this technology 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). The manufacturer requested that code 36.07 be assigned to DRG 516 (Percutaneous Cardiovascular Procedure with Acute Myocardial Infarction (AMI)) even without the presence of AMI.

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.

The FDA has not yet approved this technology for use. In the May 9, 2002 proposed rule, we specifically solicited comments on our proposal to treat the new codes cited above consistent with the current DRG assignment for coronary artery stents. We also stated that 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.

Comment: Several commenters supported the development of new ICD–9–CM codes 36.07 and 00.55 for drug-eluting stents, citing the need for identification of this new technology. Several commenters supported the creation of new ICD–9–CM codes in order to ensure this technology would receive payment under Medicare.

Response: We created two new ICD–9–CM codes for use with cases

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

involving discharges occurring on or after October 1, 2002. These codes can be found in Table 6B. ''New Procedure Codes'' in the Addendum of this final rule. However, we emphasize that it is not necessary to assign new technologies a new ICD–9–CM code in order for Medicare payment to commence. In the absence of a new code, technologies are assigned to the nearest similar existing code and, consequently, to the relevant DRG for payment.

Comment: Numerous comments opposed our proposed DRG assignment of code 36.07 to DRG 517. One commenter noted that, while this technology is not yet approved, it has shown promise to significantly advance the treatment of coronary artery disease, and encouraged CMS to consider the available data to determine the most appropriate paying DRG. This commenter supported the reassignment of code 36.07 to another DRG or, if necessary, the modification of all affected DRGs, once verifiable data on the costs associated with drug-eluting stents become available.

Many of the commenters who supported higher payment for this technology were clinical practitioners and hospitals who expressed great anticipation for the potential benefits of this technology. In addition, commenters referred to the likelihood that, once these new drug-eluting stents are approved, patients would demand to have them inserted. This demand would put tremendous financial strain on hospitals.

Commenters also argued there should be long-term cost savings to the Medicare program and the health system generally from this technology after approval by the FDA. Specifically, if dramatically fewer patients require restenting, savings will result from fewer repeat angioplasty procedures. Also, to the extent bypass surgeries are also reduced (as suggested by the article footnoted above), savings will result from that outcome as well.

Response: We note that, at this point, the FDA has not approved this technology for general use. However, we also note that public presentation of the results from recent clinical trials have found virtually no in-stent restenosis in patients treated with the drug-eluting stent. Therefore, we recognize the potentially significant impact this technology may conceivably have on the treatment of coronary artery blockages.

As we have previously stated, new technology is generally assigned to the same DRG as the predecessor technologies. In this way, hospitals can receive payment immediately for the new technology. As use of the new technology diffuses among hospitals, we have gradually and largely automatically recalibrated DRG payment rates based on hospital claims data to reflect increasing or decreasing costs of cases assigned to the DRG. Generally, it takes 2 years for claims data to be reflected in the DRG weights.

Section 533 of Public Law 106–554 added sections 1886(d)(5)(K) and (d)(5)(L) to the Act (as implemented by §§ 412.87 and 412.88) to reduce the time needed for the DRG system to recognize the higher costs of new technologies that meet certain criteria (see section II.D. of this final rule). However, drug-eluting stents did not meet the cost threshold criterion. Therefore, we proposed to assign cases involving code 36.07 to DRG 517. Although this DRG assignment would be consistent with our prior practice of assigning new technology to the same DRGs to which its predecessor technologies were assigned, further consideration of this issue persuades us that a different approach is needed, given the extraordinary circumstances in this particular instance.

We are concerned that, if the FDA does approve this technology and the predictions of its rapid, widespread use are accurate, this action will result in a significant strain on hospital financial resources. In particular, we are concerned that the higher costs of this technology would create undue financial hardships for hospitals due to the high volume of stent cases and the fact that a large proportion of these cases could involve the new technology soon after FDA approval. Therefore, in this final rule we are creating two new DRGs that parallel existing DRGs 516 and 517, to reflect cases involving the insertion of a drug-eluting coronary artery stent as signified by the presence of code 36.07: DRG 526 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with AMI); and DRG 527 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without AMI). We understand the earliest date that a decision from the FDA is anticipated is late 2002. To further ensure that payments for the new DRGs 526 and 527 will not be made prior to FDA approval, we will activate these DRGs effective for discharges occurring on or after April 1, 2003. If the FDA approves the use of drug-eluting stents prior to April 1, 2003, cases coded with procedure code 36.07 will be paid using the DRG relative weights for DRG 517. New DRGs 526 and 527 will be temporary DRGs. By creating separate new DRGs, we are able to ensure that higher payments will only be made after a positive decision by the FDA. We expect that when claims data are available that reflect the use of these stents, we will combine drug-eluting stent cases with other cases in DRGs 516 and 517.

Although one manufacturer of this technology submitted data to us that included charges, hospital provider numbers, and admission and discharge dates on the Medicare patients for whom hospital bills were collected under the trial in order to demonstrate the higher average charges of cases included in the trial, much of the data submitted to us included only estimated charges for the new technology. Therefore, it was necessary to undertake several calculations to establish the DRG relative weights for these two new DRGs. First, based on prices in countries where drug-eluting stents are currently being used, and the average price of currently available stents, we calculated a price differential of approximately $1,200. Assuming average hospital charge markups for this technology (based on weighted average cost-to-charge ratios), the anticipated charge differential between old and new stents would be approximately $2,664 per stent. However, we recognize that some cases involve more than one stent. Using an average of 1.5 stents per procedure, the net estimated incremental charge for cases that would receive a drug-eluting stents is $3,996.

In order to accurately determine the DRG relative weights for these two new DRGs relative to all other DRGs, we must also estimate the volume of cases likely to occur in them among discharges occurring on or after April 1, 2003 and by September 30, 2003. To approximate the number of cases that would likely receive the drug-eluting stent between April 1, 2003 and September 30, 2003 (and thus would be assigned to new DRGs 526 and 527), we first identified cases in DRGs 516 and 517 with procedure code 36.06 (Insertion of non-drug-eluting coronary artery stent). Of these cases, we estimated what percentage would be likely to receive the drug-eluting stent after April 1, 2003. The manufacturer estimated that as many as 43 percent of current stent patients will receive drug-eluting stents during FY 2003. However, this estimate assumes 9 months of sales of the new stents during FY 2003, from January to September. Because these two new DRGs will only be valid for 6 months during FY 2003, from April through September, we estimated that 21.5 percent of all stent cases will be assigned to new DRGs 526 and 527 (43 percent of stent cases for 6 months instead of 9 months).

In determining the DRG relative weights, we assumed that 21.5 percent of coronary stent cases (those with code 36.06) from DRGs 516 and 517 would be reassigned to new DRGs 526 and 527 (with code 36.07), and the charges of these cases would be increased $3,996 per case, to approximate the higher charges associated with the drug-eluting stents in DRGs 526 and 527. The relative weights for DRGs 516 and 517 are calculated based on the charges of the cases estimated to remain in these two DRGs.

We note that this unprecedented approach is in response to the unique circumstances surrounding the potential breakthrough nature of this technology. We anticipate that the vast majority of new technologies in the future will continue to be routinely incorporated into the existing DRGs.

New DRG 526 (Percutaneous Cardiovascular Procedure With Drug-Eluting Stent With AMI) will have the following principal diagnoses:

- 410.01, Acute myocardial infarction, anterolateral wall, initial episode of care.
- 410.11, Acute myocardial infarction, other anterior wall, initial episode of care.
- 410.21, Acute myocardial infarction, inferolateral wall, initial episode of care.
- 410.31, Acute myocardial infarction, inferoposterior wall, initial episode of care.
- 410.41, Acute myocardial infarction, inferior wall, initial episode of care.
- 410.51, Acute myocardial infarction, other lateral wall, initial episode of care.
- 410.61, True posterior wall infarction, initial episode of care.
- 410.71, Subendocardial infarction, initial episode of care.
- 410.81, Acute myocardial infarction of other specified sites, initial episode of care.
- 410.91, Acute myocardial infarction, unspecified site, initial episode of care.

And operating room procedures:

- 35.96, Percutaneous valvuloplasty.
- 36.01, Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy without mention of thrombolytic agent.
- 36.02, Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy with mention of thrombolytic agent.
- 36.05, Multiple vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent.
- 36.09, Other removal of coronary artery obstruction.
- 37.34, Catheter ablation of lesion or tissues of heart.

Or nonoperating room procedures:

- 37.26, Cardiac electrophysiologic stimulation and recording studies.
- 37.27, Cardiac mapping.

And nonoperating room procedure:

- 36.07, Insertion of drug-eluting coronary artery stent(s).

The principal diagnosis will consist of any principal diagnosis in MDC 5 except AMI:

- 410.01, Acute myocardial infarction, anterolateral wall, initial episode of care.
- 410.11, Acute myocardial infarction, other anterior wall, initial episode of care.
- 410.21, Acute myocardial infarction, inferolateral wall, initial episode of care.
- 410.31, Acute myocardial infarction, inferoposterior wall, initial episode of care.
- 410.41, Acute myocardial infarction, inferior wall, initial episode of care.
- 410.51, Acute myocardial infarction, other lateral wall, initial episode of care.
- 410.61, True posterior wall infarction, initial episode of care.
- 410.71, Subendocardial infarction, initial episode of care.
- 410.81, Acute myocardial infarction of other specified sites, initial episode of care.
- 410.91, Acute myocardial infarction, unspecified site, initial episode of care.
- And operating room procedures:
- 35.96, Percutaneous valvuloplasty.
- 36.01, Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy without mention of thrombolytic agent.
- 36.02, Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy with mention of thrombolytic agent
- 36.05, Multiple vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent
- 36.09, Other removal of coronary artery obstruction
- 37.34, Catheter ablation of lesion or tissues of heart

Or nonoperating room procedures:

- 37.26, Cardiac electrophysiologic stimulation and recording studies
- 37.27, Cardiac mapping

And nonoperating room procedure:

- 36.07, Insertion of drug-eluting coronary artery stent(s).

Comment: One commenter expressed concern that this technology will be used to treat lesions that are not clinically indicated. This commenter suggested that there should be clear language stating that drug-eluting stents should only be used in patients who are symptomatic from coronary artery disease as documented by noninvasive stress tests and imaging to locate the ischemia.

Response: We appreciate the commenter's concern that this new technology be used only where it is clinically indicated. We note that our treatment of this technology should in no way be construed to circumvent the ongoing FDA review. We expect that the technology, if approved, would be used in accordance with any labeling guidelines issued by the FDA, and we reserve the right to evaluate the need for Medicare coverage limitations or restrictions in the future.

Comment: One commenter applauded our recognition of the potential advance in peripheral vascular care by creating a code for noncoronary artery stents, code 00.55 (Insertion of drug-eluting noncoronary artery stent(s)). However, the commenter indicated it could not discern from Table 6B (67 FR 31630) the DRG to which code 00.55 was assigned.

Response: Our usual practice is to assign a new code to the DRG to which the predecessor code had been assigned. For example, in 1995, when we added additional fourth digits to 60.2 (Transurethral prostatectomy) and created 60.21 (Transurethral (ultrasound) guided laser induced prostatectomy (TULIP)) and 60.29 (Other Transurethral prostatectomy), we assigned the two new codes to the DRGs in which 60.2 had been located. (In version 12.0 of the GROUPER, those DRGs were 306 and 307 and DRG 336 and 337; the two newer codes continue to be assigned to the same DRGs today.) We have followed this precedent with code 00.55, which is patterned after code 39.90 (Insertion of non-coronary artery stent or stents). Code 39.90 is not a code recognized by the GROUPER software as a procedure code that causes DRG assignment, and therefore it is not assigned to a DRG or DRGs by itself. The GROUPER will recognize the main procedure in which a stent is inserted in order to make the DRG assignment for that case. We recognize that insertion of stents in noncoronary vessels has the potential to occur in many MDCs and DRGs. We will monitor the new stent code in noncoronary vessels in our MedPAR data to determine if the DRG placement in which it is reported is appropriate.

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.

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). 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. The manufacturer 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 also 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 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.

We proposed to assign code 00.51 to DRG 514 or 515 and to assign code 00.50 to DRG 115 and 116. However, we solicited comments on these proposed DRG assignments and indicated that we would carefully consider any relevant evidence about the clinical efficacy and costs of this technology.

Comment: Numerous commenters responded to our statement that we would further consider evidence on the costs and clinical efficacy of the cardiac resynchronization technology. Commenters noted that, on average, patients with moderate to severe heart failure (New York Heart Class III/IV), for whom the CRT is indicated, are more physically compromised and need the support of additional personnel such as physical assistants and clinical heart failure coordinators. Data were submitted showing that heart failure cases have significantly longer average lengths of stay than average stays for other cases. These cases also have higher average charges (approximately $11,000 to $13,000 higher, according to one commenter). The commenters acknowledged that DRG 115 does specifically account for heart failure cases, but noted that DRGs 514 and 515 do not.

Commenters also argued there are additional costs associated with the additional surgical supplies required to perform these procedures (as well as the price differential of the new technology itself). Examples of supplies include a special left ventricular coronary sinus lead, a special pulse generator device, and a special electrical lead. One manufacturer estimated the incremental difference in the charges of the device and the additional surgical supplies to be $23,500.

Commenters further noted the additional surgical procedure time associated with CRTs. They noted that the implant procedure itself is much more complex than a conventional pacemaker or implanted cardioverter defibrillator, and generally requires additional staff, anesthesia, and other specialized services and supplies. The insertion of the left ventricular lead is estimated to require an additional 2 hours beyond a conventional procedure. Commenters pointed out that typically a venogram is required to navigate the coronary venous system. The additional time and resources were estimated to increase costs to the hospitals by $7,500.

Finally, commenters also cited data and anecdotal evidence to demonstrate the clinical benefits of this technology. The commenters noted that FDA approved CRT–D on May 2, 2002, which provides further evidence of the clinical efficacy of this technology. One commenter provided information to show that CRT–D improves peak oxygen uptake, translating to an increased ability to perform activities of daily living. Another commenter noted that pacing therapy offers the potential to increase blood pressure and heart rate.

On the basis of these higher costs and clinical improvements, these commenters generally recommended that CRT–Ds should be assigned to DRG 104. This DRG has a higher relative payment weight than either DRGs 514 or 515 (7.9615, compared to 6.3288 and 5.0380, respectively, based on the FY 2003 proposed DRG weights). One commenter suggested that if CRT–D cases are not assigned to DRG 104, they should only be assigned to DRG 514, not DRG 515. Several commenters suggested that CRT–Ps be assigned only to DRG 115, and not to DRG 116, since DRG 115 is the higher paying DRG. Other commenters suggested that all DRT–Ps be assigned to DRG 515 since DRG 515 pays more.

One commenter suggested that CRT–Ds are more clinically coherent to cases now assigned to DRG 104 based on: (1) The similarity of the diagnosis (for example, congestive heart failure); and (2) the similarities in clinical procedures used to implant a left ventricular lead and other cardiac catheterizations included in DRG 104. The commenter also suggested that the operating room preparation and procedure time for CRT–D cases was similar to that for other major cardiovascular procedures included in DRG 104, which supports the commenter's contention that CRT–Ds are more clinically consistent with DRG 104 than DRG 514 and 515.

Several commenters, including a national and a State hospital association, supported the assignment of new code 00.51 to DRG 514 or 515. Some commenters also supported the assignment of new code 00.50 to DRG 115 and DRG 116. The commenters added that cardiac resynchronization therapy is a new technology that recently received FDA approval and is still not widely used in hospitals in the United States. The commenters indicated that even though there is limited information at this time with regard to the clinical efficacy and costs of these devices, the technology seems to be similar to pacemakers and defibrillators, so the proposed DRG grouping is logical.

Response: We have carefully evaluated the information provided to us by the commenters. With respect to the cost data provided, we note that it is our previously stated preference to review actual data reflecting the total costs per case from patients treated with a particular new technology. Because the DRG payment is intended to cover all of the care provided during the course of an inpatient hospitalization, it is necessary to evaluate the impact a new technology may have on other aspects of patients' hospitalization. For example, many new technologies allow patients to be discharged sooner, actually reducing the total costs of the stay. While there is no indication that

this is the case with the CRT–D technology, we are unable to make an assessment based on the segregated data that were provided.

With respect to the suggestion that CRT–D cases should be assigned to DRG 104, we note that the DRG system groups cases that are similar clinically and in terms of costs. DRG 104 includes procedures performed on cardiac valves such as valve replacement and repair. Our clinical advisors disagree with the suggestion that the implantation of a CRT with or without defibrillation is clinically related or similar to procedures such as valve repair or replacement, which are assigned to DRG 104. We believe that, based on the nature and function of the devices, they are more appropriately classified as either pacemakers for the CRT–P or implantable cardioverter-defibrillators (ICDs) for the CRT–D devices. The additional lead is not, in our view, sufficient justification for classifying the CRT–Ds differently from all other debibrillators.

Furthermore, although chronic heart failure, for which these CRTs are used, is a common diagnosis, the etiology of the heart failure may vary significantly. Heart failure due to a faulty valve may be treated with valvuloplasty or valve replacement, and would be classified to DRG 104. On the other hand, heart failure due to ischemic events, such as a myocardial infarction, usually requires a completely different therapeutic approach involving other DRG assignments. Therefore, we do not believe it would be appropriate to classify cases receiving CRT–Ds to DRG 104.

With respect to the fall-back recommendation of the commenter that, if CRT–D cases are not assigned to DRG 104, they should all be assigned to DRG 514, we considered and rejected this suggestion. We note that a fundamental assumption underlying the DRGs is that the hospital has the responsibility for deciding what technology and process to employ in treating a particular type of patient. As hospitals in the aggregate make treatment decisions, these decisions are reflected in the DRG payment weights. This allows the payment rates to evolve in response to changing practice patterns.

The decision to treat CRT–D technology similarly to existing defibrillator technology is affected by our opinion that substantial improvement in health outcome benefits of adding the cardioverter-defibrillator component have not been fully established through clinical research. There are no published articles that have shown an improvement in survival from CRT. Although we appreciate the information provided by the commenters in this regard, we note there is not a significant body of evidence that CRT–D technology will supplant existing treatments for large numbers of patients. Because the DRG payment system is an average-based system wherein hospitals are expected to offset the higher costs of some cases with below-average costs in others, we anticipate that hospitals will be able to adequately finance this new technology as it is utilized. To the extent hospitals move to adopt this technology more widely over time, appropriate adjustments will be reflected in the DRG weights.

With respect to the recommendation that all CRT–P cases be assigned to DRG 115, CRT–Ps are inserted into patients with congestive heart failure. Therefore, when the code for CRT–P is reported in a patient with congestive heart failure, the case will be assigned to DRG 115. Only if the CRT–P were inserted in a patient who does not have congestive heart failure would the case be assigned to DRG 116. Since all the commenters agree that only patients with congestive heart failure would be candidates for the CRT–P, the end result will be that all of these cases would be assigned to DRG 115 as the commenters recommended. With respect to the recommendation that all CRT–Ps be assigned to DRG 515, our response is the same as for rejecting the assignment of DRT–Ds to DRG 515. Assignment of CRT–Ps to DRG 515 is not clinically appropriate.

Accordingly, we are adopting as final our proposed classification of code 00.50 to DRGs 115 and 116, and code 00.51 to DRGs 514 and 515. These changes will be effective for discharges occurring on or after October 1, 2002.

Comment: Many commenters mentioned that when the CRT–Ds are inserted, a coronary sinus venogram is often performed. The commenters stated that a venogram is a procedure that is similar to an arteriogram, which is classified as a non-O.R. procedure that affects the DRG assignment in some cases. The commenters stated that the additional time and resources of the venogram for a CRT–D should be accounted for by assignment of these cases to DRG 104.

Response: Coronary arteriograms and angiocardiograms do effect the DRG assignment in some cases. Arteriograms and angiograms of other sites that are not of the heart do not affect the DRG assignment. Venograms are not currently on the list of non-O.R. procedures that affect the DRG assignment. While the commenters are not suggesting that we add venograms to the list of non-O.R. procedures that affect the DRG assignment, they are recommending that the comparison of venograms to angiocardiograms be used as a justification for assigning CRT–Ds to DRG 104. Our medical consultants advise us that venograms are not as difficult to perform as are the coronary arterigrams and angiocardiograms. Venograms also have fewer associated risks than coronary arterigrams and angiocardiograms. Therefore, we would not reclassify venograms and make them affect the DRG assignment. In short, we do not believe that the performance of a venogram is justification for moving CRT–Ds to DRG 104.

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.

Comment: Two commenters addressed this issue. One commenter stated that additional data review was needed to determine the variation in charges and length of stay to determine if this recommendation should be pursued. Another commenter stated that using charge data is incorrect. Hospitals are under increased pressure and scrutiny to keep their charges low and would not increase the charges of the revision prosthetic because it does not influence the amount of payment received. The commenter suggested that revisions of the hip and knee procedures should have their own DRG.

Response: Hospital charges have been the basis for recalibration of the DRG weights since FY 1986. Therefore, it is in the hospitals' best interest to submit accurate billing data. We utilize charge data in our analysis of the DRGs to ensure that each DRG contains patients with a similar pattern of resource intensity. To the extent that the markup of charges over cost varies from one particular device or procedure to another, the relative weights will be impacted. However, due to the relativity of the DRG weights, a low markup associated with one device or procedure will be offset by relatively higher markups associated with another device or procedure, leading to higher relative weights, and thus higher payments, for the latter device or procedure.

i. Multiple Level Spinal Fusions

We received correspondence suggesting that we create new spinal fusion DRGs that differentiate by the number of discs that are fused in a spinal fusion. The correspondents 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 explored the possibility of creating codes to differentiate cases by the number of discs fused during a spinal fusion procedure at the April 18 and 19, 2002 meetings of the ICD–9–CM Coordination and Maintenance Committee. Because the topic proved to be quite challenging and will require additional discussion, the Committee will consider it further at its scheduled December 5 and 6, 2002 meeting.

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 did not propose DRG changes for multiple level spinal fusions in the May 9, 2002 proposed rule.

Comment: Commenters representing national and state hospital associations supported the proposal to not make DRG changes for multiple level spinal fusions at this time. The commenters agreed that ICD–9–CM historically has not been used to differentiate among cases by the number of repairs or manipulations performed during a single procedure. Also, the commenters wrote that developing a coding methodology for multiple level spinal fusions will require careful consideration because it will be introducing a new concept into ICD–9–CM coding. The commenters offered to work with CMS to examine whether such a methodology could be developed in the future.

One commenter urged CMS to carefully examine the issue of providing separate codes and payment for multiple level spinal procedures. The commenter stated that increased costs were incurred in this type of surgery and may warrant recognition within the DRGs.

Response: We appreciate the comments on what has evolved as a challenging coding issue. We look forward to working with the commenter and other groups as we attempt to develop an efficient way to capture multilevel spinal fusions. The topic will be discussed at the next meeting of the ICD–9–CM Coordination and Maintenance Committee, which will be held on December 5 and 6, 2002. The agenda for this meeting will be posted in November 2002 at: *www.cms.hhs.gov/medicare/icd9cm.asp.* Once new codes are developed, we will evaluate the DRG assignments.

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 >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.

We received comments in support on our proposed decision that the current DRG assignments for code 882.0 are appropriate. Accordingly, in this final rule we are not making any modifications of the DRG assignments for cases with code 882.0 at this time.

k. Cavernous Nerve Stimulation

As discussed in the August 1, 2001 final rule (66 FR 39845), we reviewed data in MDC 12 (Diseases and Disorders of the Male Reproductive System) to look 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 assigned. Therefore, we did not propose any DRG assignment changes to procedures code 89.58 or any changes to DRGs 334 and 335.

We received one comment in support of our proposal not to change the DRG assignment of code 89.58 or DRGs 334 and 335. Accordingly, in the final rule we are making no changes to DRGs 334 and 335 with regard to procedure code 88.58. We anticipate that procedure code 89.58 will be performed in conjunction with radical prostastectomy, which is an operative code(s) describing the major surgical procedure.

1. Additional Issues Raised by Comments

We received a number of comments on additional specific DRG assignment issues that were not raised in the proposed rule. We are not responding to them individually here because they were not raised in the proposed rule. We will be considering each issue raised for consideration in the FY 2004 DRG reclassifications. We also note that we previously described a process for submission of non-MedPAR data for consideration in evaluating the DRG assignment issue (64 FR 41499).

C. Recalibration of DRG Weights

We are using 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 recalibrate the weights based on charge data for Medicare discharges. For the proposed rule, we used 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.

The final recalibrated DRG relative weights are constructed from the FY 2001 MedPAR data, which include discharges occurring between October 1, 2000 and September 30, 2001, based on bills received by CMS through March 31, 2002, 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 11,483,663 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.

The 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.
- 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. (See section II.B.14.f. of this preamble for a discussion of the special adjustment used in calculating the FY 2003 DRG relative weights for DRGs 526 and 527.)
- 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 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 new weights are normalized by an adjustment factor (1.43889) 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.

We did not receive any comments on DRG recalibration.

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

D. Add-On Payments for New Services and Technologies

1. Background

Section 533(b) of Public Law 106–554 amended section 1886(d)(5) of the Act to add subparagraphs (K) and (L) to establish a process of identifying and ensuring adequate payment for new medical services and technologies under Medicare. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that the process must apply to a new medical service or technology if, ''based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges * * * is inadequate.'' Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered ''new'' if it meets criteria established by the Secretary (after notice and opportunity for public comment).

In the September 7, 2001 final rule (66 FR 46902), we established that a new technology would be an appropriate candidate for an additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries (§ 412.87(b)(1)).

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

Table 10 in the Addendum of this final rule lists the qualifying criteria by DRG based on the discharge data that we are using to calculate the FY 2003 DRG weights. These thresholds 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 requiring applicants for FY 2004 to submit a significant sample of the data no later than early October 2002. The complete request also must include a full

description of the clinical applications of the technology and the results of any clinical evaluations demonstrating that the new technology represents a substantial clinical improvement. Subsequently, we are requiring that a complete database be submitted no later than mid-December 2002.

Applications for consideration under this provision for FY 2004 should be sent to the following address: Centers for Medicare & Medicaid Services, c/o Inpatient New Technology Applications, Mail Stop C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244.

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 FY 2003 DRG weights in this final rule.

Technology may be considered ''new'' for purposes of this provision within 2 or 3 years after the point at which data begin to become available reflecting the 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 Food and Drug Administration (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.

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

Because any additional payments directed toward new technology under this provision must be offset to ensure budget neutrality, it is important to consider carefully the extent of this provision and ensure that only technologies representing substantial advances are recognized for additional payments. In that regard, we indicated that we 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 balance appropriately 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 the target limit is exceeded, we would reduce the level of payments for approved technologies across the board, to ensure estimated payments do not exceed the limit. Using this approach, all cases involving approved new technologies that would otherwise receive additional payments would still receive special payments, albeit at a reduced amount. Although the marginal payment rate for individual technologies would be reduced, this would be offset by large overall payments to hospitals for new technologies under this provision.

Comment: Numerous commenters expressed concern that the method by which payments are made—in a budget neutral manner—reduces the amount of DRG payments for other cases. The commenters noted that shifting money around within the prospective payment system leaves hospitals without the additional money they need to ensure beneficiaries have access to the newest medical tests and treatments. Many of the commenters believed that reducing payments for other services in order to increase payments for new technology is inappropriate, as the costs associated with all other inpatient procedures are not declining. The commenters noted that they will continue to urge Congress to adopt an appropriate adjustment to hospital payments without redistributing payments from elsewhere in the system.

Some commenters also wrote that the new technologies listed in the proposed rule are worthy of additional funding, but, since budget neutrality would reduce payments for all other inpatient procedures, even though costs for these procedures are not declining, the applications should not be approved. However, if the applications are approved, the commenters stressed the need to maintain the requirement that no more than 1 percent of total acute inpatient prospective payments may be used for new technology payments. Furthermore, if actual total add-on payments were less than estimated in calculating the budget neutrality adjustment, the commenters argued that unspent funds should be restored to the standardized amount.

Response: As stated above, the Congressional Report language accompanying section 533 of Public Law 106–554 clearly indicated Congress' intent that this provision is to be implemented in a budget neutral manner. Therefore, the commenters are correct that Congress is the appropriate body to consider concerns about the budget neutrality of this provision. We

also agree with the commenters about the need to limit the total payments made under this provision. In the September 7, 2001 final rule, we established a target limit of 1 percent of total acute inpatient prospective payment system payments for new technology. This target is intended to limit the redistributional impact of these higher payments for new technology relative to payments for other services.

Although our estimates are influenced by past experience, it has been our longstanding practice not to adjust our budget neutrality calculations retroactively on the basis of actual payments. We note that hospitals may either benefit or lose in any given year, depending on whether we underestimate or overestimate the budget neutrality factor. We would note that, in years when hospitals benefited from an underestimate of the budget neutrality factor, we did not recoup any payments resulting from the underestimate.

Comment: Some commenters criticized our implementation of the add-on payment provision for new technology. They claimed that the criteria we set make it impossible for technologies to qualify for add-on payments and suggest that many companies did not apply for new technology add-on payments because the threshold and other criteria were set so high. As proof, the commenters pointed to the small number of applications we received for new technology add-on payments for FY 2003, and to the apparent denial of all applicants. The commenters argued that our criteria operate to nullify the effect of the provision and, therefore, go against Congress' intent.

Response: Unlike the commenters, we believe the limited number of applications lends support to the appropriateness of the criteria. It was our intention to implement this provision without fundamentally disrupting the prospective payment system. A substantial number of cases receiving extra cost-based payments, (or substantial disaggregation of the DRGs into smaller units of payment) would undermine the efficiency incentives of the DRG payment system. This system, is founded on the theory that, by paying for patients with similar clinical characteristics based on the average resources needed to treat those patients, the system creates an incentive for physicians and hospitals to evaluate the most appropriate treatment approach for an individual patient, knowing that the payment to the hospital will, on average, reflect the average resources utilized across all patients in the DRG. Add-on payments for specific new technologies influence the financial incentives faced by the physician and the hospital, and, because these payments are implemented in a budget neutral manner, they impact the average payments for all DRGs.

While we recognize Congress' intent that Medicare beneficiaries have faster access to new technologies that may be introduced more slowly otherwise due to payment concerns, we believe Congress also did not intend to fundamentally disrupt the incentives of the prospective payment system. We will continue to carefully evaluate whether our criteria appropriately balance these two objectives.

Comment: Many commenters repeated objections to policies proposed in the May 4, 2001 proposed rule (66 FR 22646). These comments are listed here.

Several commenters argued that the one standard deviation threshold was too high for most new technologies to qualify. Commenters also wrote that the substantial clinical improvement criterion should be removed, and that the 50-percent pass-through payment does not adequately reimburse hospitals for the cost of new technologies. Many commenters suggested that we use the 80-percent standard that we use for outlier thresholds.

One commenter objected to our requirement of a ''significant sample'' of ''verifiable'' external data. This commenter wrote that any economic data required should be reasonably derived from the clinical trials conducted in conjunction with submissions to the FDA. In addition, our data requirements should not be overly burdensome and should recognize the difficulties faced by hospitals, such as compliance with patient confidentiality regulations.

Some commenters suggested that we incorporate new technologies directly into the DRG system and adjust the weights to reflect the increased costs of the item(s) as data become available. They argued that this method would be more consistent with the fundamental structure of the acute care hospital inpatient prospective payment system and would avoid the complexity of coding and billing for new technology cases.

Some commenters suggested that the ICD–9–CM Coding System cannot continue to be expanded to create new codes to identify new technologies in the long term, and the ICD–10–Procedure Coding System (ICD–10–PCS) would be an appropriate long-term solution. One commenter, a national hospital association, referred to ICD–10–PCS as ''the system of choice with appropriate attention given to implementation, education and system related issues.'' This commenter recommended that the approval process be revised to include a requirement that the applicant must barcode each item for ease of hospital reporting and billing, based on Universal Product Numbers.

Response: We discussed our positions on each of these issues in detail in the September 7, 2001 final rule (66 FR 46905). We appreciate the interest of the many stakeholders in ensuring that Medicare beneficiaries have full access to improvements in medical technology. Our rationales for these policies have not changed since we discussed them in that final rule, and we did not propose changes to these policies in the May 9, 2002 proposed rule. Therefore, readers are referred to the September 7, 2001 final rule for our responses to these comments. However, we will continue to assess each of these policies as we gain more experience with this provision, and would appreciate the commenters' continued input.

Comment: MedPAC agreed with the approach that we have taken in implementing this provision. MedPAC stated that our approach is ''a reasonable compromise between the need to provide quick access to important new technologies for Medicare beneficiaries and not spending more than necessary.''

Response: We appreciate the supportive comments submitted by MedPAC.

Comment: In conjunction with concern regarding overall payment decreases as a result of the requirement that add-on payments for new technology be budget neutral, several other commenters indicated that they agreed with our proposed denial of all of the new technology applications.

Response: We want to clarify the misunderstanding expressed by some new technology applicants that we proposed to deny all of the applications. In the May 9, 2002 proposed rule, we stated that, for two of the applicants, Xigris™ and the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device, we were withholding a final determination on whether these technologies represented a substantial clinical improvement or met the cost threshold until the final rule. We did propose to deny the other two applicants, Zyvox™ and Renew™ Radio Frequency Spinal Cord Stimulation Therapy.

Comment: One commenter believed that the cost threshold for a new technology to qualify for add-on payments is too high, but also expressed

concern that recent proposed legislation, which would establish that the cost of new technology must exceed the lesser of the current threshold or 50 percent above the standardized amount (about $2,100), was too low. This commenter urged us to amend our regulations to continue to allow the threshold to vary by DRG (currently, the threshold is based on the DRG's geometric mean charge plus the DRG's standard deviation of charges), but at a lower level than at present.

However, another commenter argued in favor of the alternative lower threshold. This commenter wrote that the current cost threshold was the primary reason that many technology manufacturers determined that submission of an application for an add-on payment would be fruitless.

Response: We agree with the commenter that the alternative threshold proposed in the legislation is too low. Reducing the threshold to such an extent would lead to many more technologies qualifying for add-on payments, which would be contrary to the bundling theory of the DRG system and would be inflationary. Under these lower thresholds, technology sponsors would have a strong incentive to establish prices for otherwise low-cost technologies at marginally higher levels that would meet this minimal threshold. In contrast, market forces prevent otherwise low-cost technologies being priced at a level sufficient to meet our present, higher threshold. Even though the add-on payments are budget neutral, this price inflation would eventually be reflected in the market basket. On the other hand, the current thresholds greatly limit inflationary pressures by targeting technologies that have extraordinarily high costs. However, we will continue to assess the adequacy of our current criteria as we continue to gain experience implementing the provision for add-on payments for new technologies.

Comment: One commenter argued that the evaluation of an application for the substantial clinical improvement criteria should focus on the potential for the new technology to result in a substantial improvement over currently covered therapies. The commenter noted that very few medical devices are approved by the FDA on the basis of clinical trials that directly compare the new technology to other Medicare-covered alternatives. Data demonstrating a clear advantage in clinical outcomes are often not available until several years after FDA approval.

The commenter believed this approach would be beneficial to CMS, noting that the current process suggests a coverage-type analysis, potentially limiting CMS' ability to undertake any later coverage review after a substantial improvement determination is made. The commenter added that denying a request on the basis that a technology does not represent a substantial improvement could lead local Medicare contractors to restrict coverage based upon such a denial.

Response: We disagree that data needed to evaluate whether new devices are a substantial improvement over current therapies are unavailable until years after the technology is introduced. Our experience evaluating the applications discussed below, as well as under the outpatient prospective payment system pass-through policy, demonstrates that the sponsors of new technologies generally do collect data that can be used to assess whether a new technology is a substantial improvement over previously available technologies. Further, we believe it would be difficult, if not infeasible, to assess objectively the validity of an unsupported claim about potential outcomes. Rather, we believe it is appropriate and reasonable to expect applicants to present verifiable data demonstrating a substantial improvement of any applicant new technology relative to available alternatives.

We also do not believe that denial of an application on the grounds that the new technology is not a substantial improvement over existing technologies would lead to Medicare's contractors denying coverage. The criteria for substantial improvement determinations are quite different from coverage determinations, and we do not believe our contractors are likely to confuse the two.

Comment: One commenter wrote that it would be inappropriate to apply the budget neutrality adjustment to the hospital-specific payments to sole community hospitals (SCHs) and Medicare-dependent hospitals (MDHs). The commenter's argument appears to be based on the presumption that the add-on payments would not be available to hospitals paid using the hospital-specific rates.

Response: The commenter has correctly pointed out that we did not address whether add-on payments would be made to SCHs or MDHs paid on the basis of their hospital-specific amount in accordance with § 412.92(d) and § 412.108(c), respectively. We believe these additional payments for new technologies should be available to SCHs and MDHs paid on the basis of their hospital-specific amounts. These hospitals' payments under the hospital-specific amount methodology are adjusted by the DRG weight for each discharge. Because the costs of new technology would not be reflected in the base years used to calculate the applicable hospital-specific amounts, it is appropriate to provide for these hospitals to receive the add-on payments under this provision. Therefore, we are amending § 412.88(a)(1) to reflect this oversight.

Because SCHs and MDHs will be eligible to receive add-on payments in addition to their hospital-specific amounts, it is also appropriate to apply the applicable budget neutrality adjustments to the hospital-specific amounts.

Comment: Some commenters requested a payment calculation, showing that the add-on payment is made before the outlier adjustment. The commenters also were confused about the add-on payments in transfer situations. They wanted clarification on whether the transferring hospital would get the full add-on payment or if it would receive a prorated payment, and requested an example.

In addition, one commenter asked whether payments for indirect medical education (IME) or the disproportionate share hospital (DSH) adjustment are included in the ''DRG payment amount'' that is compared against costs to determine whether an individual case qualifies for the add-on payment. The commenter argued that if the add-on payment amount is calculated before outlier payments, it would logically follow that they would also be calculated before IME and DSH payments.

Response: The commenters are correct that the add-on payment is made prior to calculating whether the case qualifies for outlier payments (see § 412.80(a)(3)). In response to the request for a payment example, consider a new technology estimated to cost $3,000, in a DRG that pays $20,000. A hospital submits three claims for cases involving this new technology. After applying the hospital's cost-to-charge ratio, it is determined that the costs of these three cases are $19,000, $22,000, and $25,000. Under the proposed approach, Medicare would pay $20,000 (the DRG payment, including any IME or DSH payments) for the first claim. For the second claim, Medicare would pay one half of the amount by which the costs of the case exceed the DRG payment, up to the estimated cost of the new technology, or $21,000 ($20,000 plus one half of the amount by which costs of the case exceed the standard DRG payment). For the third claim, Medicare would pay $21,500 ($20,000 plus one half of the

total estimated costs of the new technology). In the event the hospital had a fourth case with extraordinarily high costs, the fixed-loss outlier threshold would be applied to the total DRG payment plus the add-on payment for new technology ($21,500), for comparison with the actual costs to determine whether the case would qualify for outlier payments.

With respect to the comment requesting clarification regarding the amount of the add-on payment made to a transferring hospital where the new technology eligible for add-on payments is provided prior to the transfer, the amount of the new technology add-on payment is not adjusted, but is paid up to 50 percent of the full cost of the new technology. This is appropriate because the hospital is likely to incur the full cost of the new technology when it is used. We are amending § 412.88(a)(1) to reflect this clarification.

With respect to whether IME and DSH payments are excluded from the comparison between the full DRG payment for the case and the costs for purposes of computing the add-on payment, § 412.88(a)(1) states that the full DRG payment ''includes indirect medical education and disproportionate share.'' This amount is then compared to the costs of the discharge to compute the amount of the add-on payment § 412.88(a).

Comment: One commenter, representing a national hospital association, recommended against approving new technologies with very limited utilization because these technologies should already be receiving additional funds as outlier cases, and the added administrative burden of including these items negates any benefit. This commenter also suggested that we limit the number of applications that can be approved by setting a minimum of $30 million in projected payments for each new technology.

This commenter argued that this limitation would reflect the added burden and administrative expense for hospitals associated with each additional new technology item that is approved. The commenter stated that training and operational and behavioral changes in response to specific coding requirements were examples of such additional costs.

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

Comment: Commenters requested further guidance for future applications.

Response: We are developing more detailed instructions for applicants, based on our experience in processing the FY 2003 applications. In the meantime, individuals interested in obtaining more information about the application process should call the Division of Acute Care at (410) 786–4548.

2. Applicants for FY 2003

We received five applications for new technologies to be designated eligible for inpatient add-on payments for new technology. One of these applications was subsequently withdrawn. In the proposed rule, we proposed that two of the applicants, Zyvox™ and Renew™ Radio Frequency Spinal Cord Stimulation Therapy, did not meet our criteria. We withheld a final determination on two other applicants, Xigris™ and the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device, pending further review to determine whether they met the substantial clinical improvement criteria.

Comment: A few commenters noted that, according to the final rule last year (66 FR 46914), we indicated we would propose our determination regarding new technology applications in the proposed rule. The public would then have the opportunity to comment on the proposed determinations. Because the FY 2003 proposed rule did not include specific proposed determinations for two technologies, the commenters argued that we did not give the public and the provider community an appropriate notice and comment period before the decisions take effect on October 1, 2002. These commenters urged us to allow for additional public comments on our final decisions announced in this final rule.

Response: We presented the results of our analysis of the available data in the May 9, 2002 proposed rule, including the budget neutrality implications, to provide an opportunity for those interested to submit specific comments on the applications. In fact, we did receive comments on specific aspects of the applications, as noted below. In addition, we clearly indicated in the proposed rule we were continuing to evaluate Xigris™ and the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device for possible approval in the final rule (67 FR 31428 and 31429). Therefore, we believe interested parties had sufficient information to evaluate our proposed decisions and to provide informed comments. For these reasons, we are not extending the period for providing public comment on the decisions on applicants announced below.

We also noted in the May 9 proposed rule that, due to the very limited timeframe between enactment of this provision, its implementation through the final rule, and the deadlines to submit applications for consideration for FY 2003, it was necessary to be more flexible this first year in working with the applicants to ensure that they were given every opportunity to demonstrate that their new technology qualified for add-on payments. Insofar as possible, we intend in the future to announce our proposed determinations in the annual proposed rule updating the acute care hospital inpatient prospective payment system.

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).

Xigris™ was approved by the FDA in November 2001. In its approval letter, the FDA wrote that this biologic ''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 (for example, as determined by APACHE II [acute physiology and chronic health evaluation]).'' In the May 9, 2002, proposed rule, however, we indicated that we were 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. Specifically, because the reduction in mortality in the published data was the result of a treatment effect in a relatively small number of patients and mortality was examined for only 28 days after treatment, we indicated that we planned to review unpublished data on all-cause mortality at the time of hospital discharge for all patients enrolled in the study.

Subsequent to the publication of the proposed rule, Lilly submitted additional data in response to our request. The major endpoint of the PROWESS study was a reported reduction in 28-day all-cause mortality of 6.1 percent. At the time the study ended, many of the participants were still hospitalized and whether they would ultimately recover was unknown. We requested data about those hospitalized patients to determine if the reported advantage in mortality from Xigris™ use persisted for all study participants. These data are now available and show an overall decrease in mortality for all patients, including patients over 65 years of age.

Therefore, we have concluded that, when used in accordance with the following FDA-listed indications and contraindications, Xigris™ meets the substantial improvement criteria for additional payment for new medical services and technologies under § 412.87(b)(1):

- Active internal bleeding;
- Recent (within 3 months) hemorrhagic stroke;
- Recent (within 2 months) intracranial or intraspinal surgery or severe head trauma;
- Trauma with an increased risk of like-threatening bleeding;
- Presence of an epidural catheter;
- Intracranial neoplasm or mass lesion or evidence of cerebral herniation.

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. 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.[2] Of course, the data submitted do not represent a random sample of all cases in these DRGs across all hospitals.

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.

We noted in the May 9, 2002 proposed rule (67 FR 31429) that, due to the passage of Public Law 106–554 in December 2000, and the publication of the final rule in September 2001, it was understandable that the data requirements that were included in the final rule in order to ensure that we would receive the information necessary to analyze applicants for new technology add-on payments were not accommodated in the design of the PROWESS trial. Therefore, in this case, it was necessary for CMS to work with Lilly to verify independently the data in order to determine whether Xigris™ represents a substantial clinical improvement.

After publication of the proposed rule, we analyzed our MedPAR data to develop a cohort group of patients in order to assess the validity of the charges reported for the patients in the PROWESS trial. Using the same methodology as Lilly, we were able to identify a cohort group of cases in the MedPAR data with similar criteria as the patients who were screened for the PROWESS trial and were discharged from the hospitals included in the trial. We calculated that the average total charges for these cases closely approximated the total charges that Lilly sent with its analysis. Based on this analysis, we have determined that the average standardized charges of $86,184 described above exceeds the cost threshold criteria of $82,882 for the DRGs involved. Therefore, we are approving Xigris™ for add-on payments under § 412.88, to be effective for FY 2003 and FY 2004.

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

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

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 (24µg/kg/hr for 96 hours for a 70kg person).'' Therefore, cases involving the administration of Xigris™ as identified by the presence of code 00.11 are eligible for additional payments of up to $3,400 (50 percent of the average cost of the drug).

For purposes of budget neutrality, we have estimated the additional payments that would be made under this provision during FY 2003. Lilly had estimated that, initially, 25,000 Medicare patients would receive Xigris™. However, Lilly's estimate does not fully reflect severe sepsis patients who may not have multiple organ failure, but for whom Xigris™ is indicated nonetheless due to APACHE II scores in the third and fourth quartiles. Therefore, for purposes of our budget neutrality estimates, we are projecting 50,000 Medicare patients will receive Xigris™ during FY 2003. We believe this projection reflects modest growth in FY 2003 from $35 million in sales reported by Lilly through February 2002 (since the drug was approved in November 2001). (At $6,800 per patient, $35 million in sales equates to just over 5,000 cases for the first 4 months since FDA approval.) We note that some analysts project sales of Xigris™ as high as approximately 100,000 cases annually. We believe our estimate reflects the potential for growth beyond the current usage since FDA approval in November 2001, and for the use of Xigris™ in treating patients without multiple organ failure for whom the drug is indicated but who were not included in Lilly's estimate.

If the maximum $3,400 add-on payment is made for all 50,000 of these patients, the total amount that would be paid for these cases would be an additional $170 million. However, comparing the total standardized charges for the 274 patients age 65 or older, we calculated that 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 Xigris™ would be $74.8 million (44 percent of $170 million).

Comment: Numerous commenters recommended that we approve Xigris™. Many of the commenters described Xigris™ as a major advance in the treatment of patients with severe sepsis. However, some commenters indicated that its use has substantially increased the costs of caring for these patients. One commenter reported rationing of this drug at some institutions due to cost considerations. Another commenter submitted an article from a pharmaceutical newsletter recommending the ''best method for patient selection is to use the criteria for enrollment in the PROWESS trial.''

Response: We are pleased to approve Xigris™ for add-on payments under this provision. As described above, we believe this drug represents a substantial improvement over currently available therapies for the treatment of severe sepsis in patients who have a high risk of death. We note that our finding that Xigris™ represents a substantial clinical improvement is limited to the indications and contraindications listed in the approved FDA labeling guidelines.

Comment: Some commenters, including the applicant, objected to CMS' request for additional data and endpoints beyond those requested by the FDA for its approval of Xigris™. The commenters argued that the FDA has the regulatory responsibility to monitor safety and efficacy of drugs and medical devices and provides rigorous review and oversight to the approval of drugs. They further contended that the placement of drugs under FDA ''priority review'' process for approval should be given weight when determining whether a drug meets the CMS ''substantial improvement'' criteria.

According to the commenters, by asking manufacturers for additional data to determine if an applicant meets our substantial clinical improvement criteria, CMS has inappropriately substituted its judgment for that of the FDA. The commenters suggested that we implement policies to ensure that these ''improprieties'' will not be repeated. One commenter argued that, if we plan to ask for unpublished data from future sponsors, we should amend our rulemaking to specify the conditions under which unpublished data may be required.

Response: Although we are affiliated with the FDA and we do not question the FDA's regulatory responsibility for decisions to approve drugs, we are not using FDA guidelines to determine what drugs, devices, or technologies qualify for new technology add-on payments under Medicare. Our criteria do not depend on the standard of safety and efficacy that the FDA sets for general use, but on a demonstration of substantial clinical improvement in the Medicare population (particularly patients over age 65).

To clarify this distinction, we offer the following example. The FDA approves a drug for general use to control the effects of seasonal allergies. This drug works well and has minimal side effects, but it makes some people feel nauseous if they take it without food. Two years later, another company creates a new allergy medicine that does not cause nausea. This drug also gets approval from the FDA. This does not necessarily mean that the new drug represents a substantial clinical improvement over the existing drug. The new drug may be better for some patients to take, but it is only an equivalent treatment, or another option, to the first drug. Therefore, the new drug would not meet the CMS substantial clinical improvement criteria.

We also disagree with the suggestion that the FDA priority review process should be the standard by which CMS should approve new technologies for add-on pass-through payments. We do not want to accept a priority review determination by the FDA as a *de facto* substantial improvement determination by us because: (1) The FDA decision is made prior to reviewing all the clinical data about the product (the decision to review the marketing application as a priority review is made at the beginning of the review process); (2) if the FDA changes its criteria for priority review, it would change the criteria for substantial improvement; (3) the current criteria used by the FDA for priority review are not the same across product types; (4) the criteria for priority review are not exactly the same as CMS substantial improvement in all instances; and (5) it would mean that the FDA would be making a *de facto* reasonable and necessary determination, since a product that offers a substantial improvement is certainly reasonable and necessary.

With respect to the comments regarding the request for submission of unpublished data, we note that the September 7, 2001 final rule indicated that we would require applicants to submit evidence that the technology does provide a substantial clinical improvement over existing technologies (66 FR 46914). Therefore, we disagree with the commenter that it is necessary to amend our regulatory process in this regard.

Comment: The applicant commenter made several additional points in addition to the previous comment. The

applicant objected to the suggestion in the proposed rule that payment would likely be limited to patients meeting the FDA labeling guidelines. The applicant also objected to the statement in the proposed rule that the charge data submitted did not represent a random sample. The applicant reiterated its estimate that 25,000 Medicare beneficiaries would receive Xigris™ in FY 2003.

Response: We are approving Xigris™ for add-on payments on the basis that it represents a substantial clinical improvement over other treatments for patients consistent with the FDA-listed indications. We do not have an administrable mechanism to identify patients who may receive this drug without having the FDA-listed indications. We will review potential options to enable us to more precisely make such distinctions in the future. We reserve the right to reexamine the issue of limiting the types of patients for which add-on payments are made for FY 2004.

In determining whether a new technology is eligible for add-on payments, we compare the average standardized charges of cases involving the applicant technology to the weighted threshold of the relevant DRGs, which reflects the charges of all cases in those DRGs that are discharged from all hospitals (weighted by the number of cases in each DRG). Thus, our statement that the data submitted did not represent a random sample was made in the context of measuring whether the average standardized charge of the PROWESS trial data was statistically significantly higher than the threshold. In order for such a significance test to be truly valid, the trial cases would have to have been drawn randomly from all cases and all hospitals with cases in the relevant DRGs. Clearly, the PROWESS trial was not designed in this manner, nor would we expect it to be. Thus, we were attempting to approximate a standard using a methodology that requires certain assumptions that were not met by the data at hand, and we were merely acknowledging it was only an approximation.

As stated above, we believe the applicant's estimate of 25,000 Medicare patients receiving Xigris™ during FY 2003 does not reflect cases without multiple organ failures but with APACHE II scores in the third and fourth quartiles.

Comment: Some commenters noted that ICD–9–CM codes do not distinguish between dosage amounts for drugs. They recommended (at least until ICD–10–PCS becomes available) relying on ICD–9–CM for identifying new procedures such as a new pancreas implant or a minimally invasive hip replacement; and incorporating the HCPCS Level II codes. (HCPCS stands for Health Care Financing Administration [recently renamed the Centers for Medicare & Medicaid Services] Common Procedure Coding System) for new drugs or supplies.

One commenter indicated that ICD–9–CM codes appear to be sufficient at this time, but, as new technologies proliferate, they will become overwhelming. However, the commenter did request guidance from us about using ''nontraditional'' ICD–9–CM codes, as well as information about reporting these codes in instances where more than six procedure codes (the maximum spaces provided on the bill) are involved.

Response: We appreciate the insight provided by this commenter regarding future coding options and will take it into consideration as we look to future refinements to this policy. However, for the reasons addressed at length in the September 7, 2001 final rule, we are using the ICD–9–CM codes at this time to identify cases eligible for the new technology add-on (66 FR 46909–10). However, because of limited space available for new ICD–9–CM codes, we are unable at this time to differentiate the volume of drugs that are administered. Therefore, as described above, we will pay on the basis of an average dose per patient.

As stated above, add-on payments for Xigris™ will be calculated for cases identified by use of the ICD–9–CM code 00.11 (when other conditions are met). In relation to guidance on the use of this code, we believe the documentation requirements are straightforward: consistent with the definition of the code, the medical record must indicate infusion of drotrecogin alfa (activated). With respect to situations where more than six procedure codes may be involved, hospitals should follow normal coding guidelines for selecting which codes to include.

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.

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

At the time of the proposed rule, this technology was not approved for general use by the FDA. Therefore, we indicated that if the FDA approved the product for general use prior to our issuance of the final rule, we would issue a determination whether this technology represents a substantial clinical improvement under the criteria outlined in the September 7, 2001 final rule.

On July 2, 2002, the FDA approved this technology. The approval was for spinal fusion procedures in skeletally mature patients with degenerative disc disease at one level from L4–S1. Therefore, based on the FDA's approval, multilevel usages of this technology would be off-label. As noted above, this technology would meet the cost threshold only if the added costs of multilevel fusions are taken into account. Because the FDA has not approved this technology for multilevel fusions, and the applicant has not submitted data to demonstrate this technology is a substantial clinical improvement for multilevel fusions (as described above, the clinical trial upon which the application was based was a single-level fusion trial), we cannot issue a substantial clinical improvement determination for multilevel fusions. Therefore, because the average charges for this new technology, when used for single-level spinal fusions, does not exceed the threshold of $37,815 noted above, we are denying this application for add-on payments during FY 2003. Because the new technology did not qualify on the basis of charges above the thresholds, we did not make a substantial improvement determination.

Comment: A few commenters were very supportive of approving Medtronic Sofamor Danek's InFUSE™ Bone Graft technology. These commenters note that this rhBMP–2 technology is a substantial clinical improvement as it obviates the need for a second surgical procedure to harvest autogenous iliac crest bone. The commenters noted that this substantial improvement focuses mostly on relief of pain in patients because many patients who undergo bone harvesting have pain at the donor site up to 10 years after the surgery.

Several other commenters, however, recommend that we not approve this application for add-on payments. These commenters stated that ''the clinical trial results solidly counter the claim of significant improvement.'' Commenters also objected to the data that the manufacturer provided, stating that in order for the threshold to be met, the manufacturer provided estimates for procedures that would involve multilevel fusions. At the time of the proposed rule, the FDA had not approved the treatment, and commenters noted that the FDA could not approve the treatment for multilevel surgeries because it had been given no clinical evidence for these procedures. The commenters pointed out that FDA's approval (which came on July 2, 2002) could (and does) only indicate approval for use of the product for single-level fusions. Therefore, the commenters strongly opposed the approval of the BMP applicant because it does not meet our financial threshold. The commenters also were concerned that, if approved for new technology payments, the technology may be used inappropriately off label and for indications that have not been approved by the FDA.

Response: We stated in the September 7, 2001 final rule that we believe the technologies approved for add-on payments should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology (66 FR 46913). Further, we stated that we believe it is in the best interest of Medicare beneficiaries to proceed very carefully with respect to the incentives created to quickly adopt new technology.

As noted above, we are denying this application for add-on payments during FY 2003 because it does not meet our cost threshold when used for single-level spinal fusions, and there is no available evidence upon which to determine whether it represents a substantial improvement for multilevel uses.

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, in the May 9, 2002 proposed rule, we did not propose any changes to the DRG assignment of these cases. We indicated that 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.

Comment: Several commenters, including the applicant, strongly objected to our denial of Zyvox™ for new technology payments. They criticized our decision not to approve it on the grounds that payments for this expensive drug are already incorporated into the DRG recalibration for FY 2003. The commenters argued that, based on the recent assignment of an ICD–9–CM code, the drug still qualifies for add-on payments under the Congressional intent of the law.

The commenters referenced the language of section 1886(d)(5)(K)(ii)(II) of the Act in support of their claim that this technology qualifies as new. They believed the 2-year to 3-year period ''beginning on the date on which an inpatient hospital code is issued with respect to the service or technology'' applicable to Zyvox™ should begin October 1, 2002, when new code 00.14 becomes effective. They argued that this new code will allow data to be accumulated to track the costs of these cases.

Response: Again, we do not believe it would be appropriate to consider technologies that have been on the market for 2 or 3 years for approval under this provision on the basis that a new, more precise, procedure code is subsequently issued. Allowing technologies that have already been in use to attain higher payments as a result of the assignment of a new, more specific ICD–9–CM code would open the door for the sponsors of any medical device or technology to consider whether they might qualify their product for add-on payments by requesting and receiving a new code from the ICD–9–CM Coordination and Maintenance Committee. We do not believe it was Congress' intent that this provision should be interpreted that way.

Therefore, it is necessary to establish a point after which previously existing technologies are not eligible to qualify for add-on payments under this new provision. We believe it is reasonable to establish the cutoff point such that those technologies with data available in the FY 2001 MedPAR to be included in the calculation of the FY 2003 DRG weights will not be eligible for new technology payments. We note that this process of incorporating new technologies into existing DRGs, where they eventually affect the weights depending on their utilization, was how all new technologies have been introduced since 1984. While we recognize Congress' intent to revise this process to expedite the introduction of new technologies, there was no indication in the legislation that the new policy was to apply to technologies whose costs were already reflected in the DRG weights.

Comment: The applicant criticized CMS for delaying the implementation of the provision. The commenter noted that the provision was to be implemented, ''[n]ot later than October 1, 2001'' and stated that CMS failed to implement the law by October 1, 2001. They argued that, by delaying the implementation, CMS effectively prevented Zyvox™ from ever meeting the ''new'' criteria, even though the drug got approval only 8 months before the provision was passed.

Response: We disagree that we delayed implementation of this provision. In the September 7, 2001 final rule, we stated that, although we did not approve any new technologies for add-on payments effective October 1, 2001, we did carefully evaluate all technologies that were brought to our attention, either as a result of our internal analysis or by the public, including those submitted for consideration during the public comment period on the May 4, 2001 proposed rule. Zyvox™ was not among the technologies submitted for consideration at that time.

Comment: Commenters argued that, although Zyvox™ was available and used during FY 2001, and therefore would be reflected in hospitals' charges used to set the FY 2003 DRG relative weights, due to the high cost of the drug, it is far from clear that hospitals prescribed the product for the majority of Medicare patients for whom it would be most appropriate. Therefore, the impact of the costs of the drug on the DRG weights is understated.

Response: We cannot assess whether the utilization of Zyvox™ was hampered by Medicare payments during FY 2001. However, we would note that Zyvox™ was treated in the same manner as other new technologies have been over the years. Further, we will continue to evaluate the appropriateness of payment for these patients as we do all other technologies and patient categories.

Comment: One commenter objected to the reference to Zyvox™ sales figures as evidence of expanding general access to the drug. The commenter stated that we provided no evidence to indicate this sale growth is the result of expanding use in the treatment of Medicare beneficiaries. The commenter went on to argue that ''sales reports and other company financial data must be considered outside the scope of the review process.''

Response: We disagree that we should ignore sales reports related to a product seeking additional payments to promote its expansion into the medical market. This market analysis was certainly not the basis for our decision not to approve this applicant, as described above. The sales reports were simply a portion of data we considered in our evaluation of the effects of our decision. We also note

that we received no evidence during the comment period to document that the sales growth referenced above did not pertain to Medicare beneficiaries.

Comment: The applicant expressed concern that, during discussions and meetings with CMS, no mention was made that there might be an issue related to the application meeting the ''new'' criterion.

Response: The criteria to qualify for add-on payments were specified clearly in the September 7, 2001 final rule. Clearly, the applicant believed it met the criteria, as evidenced by the fact that it applied and its subsequent comments on our proposed decision. The facts regarding the point at which Zyvox™ was approved by the FDA and when it became available for use are agreed upon. The difference of opinion centers on the criteria for ''new''. The commenter has described its interpretation, with which we disagree, as discussed above. The public comment process is part of the review and approval process. We believe the public comment process is the most appropriate avenue to consider the interpretation of legislative and regulatory criterion. As discussed above, we do not believe that it would be appropriate to allow technologies that have already been in use to attain higher payments as a result of the assignment of a new, more specific, ICD–9–CM code.

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)	$2,750.00
One Extension (8 Electrode)	695.00
Receiver (8 Channel)	4,995.00
Transmitter (8 Channel)	4,995.00
Total System	13,435.00
16 Channel/Electrode System:	
Two Leads (16 electrode)	5,550.00
Two Extensions (16 electrode)	1,390.00
Receiver (16 Channel)	7,295.00
Transmitter (16 Channel)	7,295.00
Total System	21,480.00

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 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 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.

Comment: Several commenters objected to our proposed decision to not approve this application because the technology does not meet our criterion for ''new'' designation.

Response: We continue to believe that this technology does not meet the criterion for the reasons given in the proposed rule, as elaborated on in our response to comments discussed above in relation to Zyvox™.

III. Changes to the Hospital Wage Index

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts ''for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.'' In accordance with the broad discretion conferred under the Act, we currently define hospital labor market areas based on the definitions of Metropolitan Statistical Areas (MSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs) issued by the Office of Management and Budget (OMB). OMB also designates Consolidated MSAs (CMSAs). A CMSA is a metropolitan area with a population of one million or more, comprising two or more PMSAs (identified by their separate economic and social character). For purposes of the hospital wage index, we use the PMSAs rather than CMSAs 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.

Comment: Commenters strongly encouraged us to take the time needed to develop the most appropriate survey instrument for collecting occupational mix data and to provide adequate time for hospitals to have available the required information. One commenter wrote that neither CMS nor the hospital industry is ready to implement an occupational mix adjustment. The commenter believed that, when the law was passed requiring occupational mix data to be collected by the end of September 2003, Congress did not understand the burden and complexity of collecting and using the information. The commenter noted that, over 10 years, CMS encountered many problems when it first tried to collect occupational mix data and believed that, today, hospitals are in no better position to provide the necessary information.

A commenter also requested that we publish a rule for comment that delineates our proposed occupational mix methodology and illustrates how the index mix would be calculated and used to adjust the overall wage index. The commenter expressed interest in continuing to work with us on this effort.

MedPAC has recommended that CMS collect the occupational mix data as part of the Medicare cost report, just as the wage data are currently collected. MedPAC notes that a separate survey usually has a lower initial response rate, and incorporating the survey as part of the cost report should minimize reporting burden on hospitals, enhance data accuracy, and help to achieve a 100-percent response rate. MedPAC recommended that we modify the cost report form and instructions as soon as possible to enable the collection of this data during the second round of data collection. MedPAC also recommended that we provide detailed information as soon as possible to hospitals regarding the specific occupational mix data they will be required to report in order to allow hospitals time to modify their information systems to collect the necessary wage and hours data. Although, MedPAC acknowledges it may not be possible to collect accurate data for FY 2002, it believes that it still may be feasible to collect the data for FY 2003 and meet the Congressional mandate to implement an occupational

mix adjustment for the FY 2005 wage index.

A few commenters expressed concern that an occupational mix adjustment would only recognize geographical differences in the price hospitals pay for a particular employee category and would not reflect that a hospital, such as a teaching hospital, may have higher labor costs because its patient population requires a larger number of highly skilled, highly priced employees. The commenters noted that a previous MedPAC study showed that an occupational mix adjustment would lower the wage index values for many areas where teaching hospitals are located. The commenters also expressed concern that Medicare's current DRG payment system does not adequately recognize patient severity and the higher resource costs that are associated with treating complex patients. The commenters believed that the current wage index methodology more appropriately reflects a higher employee skill mix, as reflected in higher wage indices where teaching hospitals are located, allowing teaching hospitals to recoup some of the losses they incur under the current DRG system. The commenters suggested that, if we include an occupational mix adjustment in the wage index, we should also refine the DRG system to ensure that more complex cases are adequately reimbursed.

Response: We appreciate all the comments we received and the continued support and assistance of hospitals in developing the occupational mix adjustment. Before implementing the adjustment, we will publish the details of the occupational mix methodology in the **Federal Register** and provide for public comment.

B. FY 2003 Wage Index Update

The FY 2003 wage index values in section V. of the Addendum to this final 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 final 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 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

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, in the May 9, 2002 proposed rule, we proposed to remove 100 percent of GME and CRNA costs from the FY 2003 wage index.

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 used the final wage index file. We found that the majority of labor market areas, both rural and urban, would benefit by the removal of all of these costs (304 out of 373). Only one rural labor market area would be negatively impacted by this change (New Hampshire by -0.09 percent). We note that, as part of its Report to the Congress on Medicare in Rural America (June 2001), 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 decreases range from .01 to 1.0 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 proposed to remove 100 percent of GME and CRNA costs beginning with FY 2003 wage index.

Comment: Several commenters stated that, although the early elimination of GME and CRNA costs from the wage index calculation is not as significant as some other payment reductions, the proposed policy represents a net reduction in payments for some hospitals compared to payments using a wage index with 80 percent of GME and CRNA costs removed. Based on CMS' analysis presented in the proposed rule, the commenters noted that excluding 100 percent of these costs from the FY 2003 wage index would negatively affect hospitals in more than 20 percent of the labor market areas. Commenters also noted that the affected areas are primarily urban, where large teaching hospitals are more likely to be located. In addition, the commenters noted that urban hospitals have to absorb increased indigent care costs.

The commenters believed that our current 5-year phaseout policy was the result of a good-faith agreement negotiated with a hospital industry workgroup. They further believed that adoption of the proposed accelerated phaseout for the FY 2003 wage index would establish an unfortunate

precedent that questions the rationale for hospital associations to enter into any future negotiations with CMS. The commenters request us to adhere to our original 5-year phaseout schedule.

One commenter supported our proposal to remove 100 percent of GME and CRNA costs from the FY 2003 wage index.

Response: We implemented changes to the FY 1995 cost report (used to calculate the FY 1999 wage index) in order to separately identify the wage data associated with GME and CRNAs. However, due to data reporting problems, we were unable to remove these costs until the FY 2000 wage index. In the meantime, the hospital industry established a workgroup that developed a compromise agreement on the removal of these data from the wage index, including a 5-year phaseout to alleviate the negative impact this change would have on some areas. The recommendations of the workgroup were presented to CMS, and most (but not all) of them were accepted (see the July 30, 1999 final rule, 64 FR 41505). However, we note that CMS was not a party to the industry workgroup that developed the compromise agreement.

As noted above, Medicare pays hospitals for GME and CRNA costs separately from the acute care hospital inpatient prospective payment system. CMS is responsible for ensuring the accuracy and fairness of the wage index and it is our assessment at this time that, due to the small impact as described above, of removing GME and CRNA costs from the wage index, and because hospitals that are negatively impacted by this change are in areas that have benefited from the inclusion of these costs over the years, it is in the interest of improving the overall fairness of the wage index to accelerate the phaseout. Therefore, we are proceeding with removing 100 percent of GME and CRNA costs beginning with the FY 2003 wage index.

Comment: One commenter representing CRNAs requested that we continue to include in the wage index the costs of contract CRNAs who are used by hospitals to address staffing shortages. The commenters noted that our proposal recognizes the fact that hospitals are increasingly reliant upon contract labor for providing direct and indirect patient care. The commenter believed that hospitals should not be penalized for having to use contract CRNAs to meet staffing needs.

Response: As explained above, we believe the wage index should, to the extent possible, reflect those costs for which hospitals receive payment under the acute care hospital inpatient prospective payment system. Because hospitals are not paid under this system for CRNAs' services, we continue to believe that CRNA costs are appropriately excluded from the 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 the May 9, 2002 proposed rule, we proposed 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 proposed 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).

Comment: Several commenters supported our continuing efforts to examine contract labor costs for inclusion in the wage index and to ensure that the wage index is not manipulated to distort an area's wage level. MedPAC commented that ''excluding contract labor costs may affect the accuracy of the wage index and introduces undesirable incentives that may affect hospital employment decisions.'' However, some commenters cautioned that it will be challenging for hospitals to provide the required detailed data and documentation for the appropriate costs and hours and to exclude nonlabor expenses, such as equipment and supplies, from total contract expenses. The commenters believed that, for most housekeeping and dietary services contracts,

meaningful data regarding hours are nonexistent. For management contracts, some commenters believed that the collection of cost and hours data may be more feasible. However, the contract itself may not provide enough detail to be a sufficient source of documentation. One commenter disagreed with the inclusion of contract labor costs in the administrative and general cost center because the commenter believed that the types of costs reported in that center vary too widely across hospitals to be comparable.

The commenters advised that it is important for us to ensure consistency among fiscal intermediaries in their auditing of supporting documentation for contract labor. Further, some commenters supported a delay in including the additional contract labor costs until we develop clear definitions and acceptable methods for tracking the costs and hours. A delay would also allow hospitals more time to assure the appropriate and accurate collection of the required data. One commenter also requested that CMS make the new data regarding contract labor costs available for review, analysis, and comment prior to including these costs in the wage index.

Response: Due to, among other things, the general support we received for our proposal to include costs for contract indirect patient care services in the wage index, we are proceeding as proposed. We will revise the cost report form and instructions, as early as it is feasible to do so. We also will monitor the hospital industry for information regarding hospitals' ability to provide the data. Further, we will work with hospitals and intermediaries to develop acceptable methods for tracking the costs and hours. Finally, before including these additional costs in the wage index, we will provide a detailed analysis of the impact of including these additional costs in the wage index values in the **Federal Register** and provide for public comment. Our final decision on whether to include contract indirect patient care labor costs in our calculation of the wage index will depend on the outcome of our analyses and public comments.

Comment: One commenter believed that, in order to be a true measure of labor market differences, the wage index should reflect only those jobs and employment practices that are the same in every geographic area. In addressing the disparity in the current wage index policy that excludes the costs for contracted low paying jobs from the wage index, while the costs for the same services under direct hire are included, the commenter suggested that we consider excluding from the wage index all labor costs that are obtained under different methods across hospitals.

Response: The use of contract labor is widespread among hospitals, and the practice of hiring under contract exists to some degree in virtually every service a hospital provides. Under the commenter's proposal, the resulting wage index would reflect too few categories of services to be representative of hospitals' labor force. Therefore, we believe it would not be feasible to exclude from the wage index all services that are obtained by hospitals using different employment methods.

D. Verification of Wage Data From the Medicare Cost Report

The data for the 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 July 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. The unresolved data elements that were included in the calculation of the proposed FY 2003 wage index have been resolved and are reflected in calculation of the final FY 2003 wage index.

The final rule we removed data for 36 hospitals that failed edits. For 14 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, or are in bankruptcy status, and supporting documentation is no longer available. We identified 22 hospitals with incomplete or inaccurate data resulting in zero or negative, or otherwise aberrant, average hourly wages. Therefore, the hospitals were removed from the calculation. As a result, the final FY 2003 wage index is calculated based on FY 1999 wage data for 4,797 hospitals.

Comment: One commenter requested that we remove the data from the FY 2003 wage index calculation for a specific hospital that closed in 2001. According to the commenter, the hospital had a major accounting and recordkeeping problem dating back several years.

Response: We have always maintained, subject to limited expectations, that any hospital that is in operation during the data collection period used to calculate the wage index should be included in the database, since the hospital's data reflect conditions occurring in that labor market area during the period surveyed (59 FR 45353). While we also believe it is appropriate to eliminate data for terminated hospitals when there is reason to believe that the data are incorrect, and the data cannot be verified due to the hospital's closure, if the wage data for a terminated hospital does not fail any of our edits for reasonableness, the hospital's data are included in the calculation of the area's wage index.

During FY 1999, the period used to calculate the FY 2003 wage index, the hospital in question was the second largest hospital in its MSA. We find the hospital's FY 1999 Worksheet S–3 wage data to be consistent with hospitals of similar size in the MSA. Therefore, we will retain the wage data for the closed hospital in the FY 2003 wage index. We also note that removing the hospital's data from the wage index calculation would actually lower the MSA's wage index value.

Comment: One commenter representing a national hospital association requested that CMS add a fatal edit to the cost reporting systems to eliminate obvious errors that are difficult or impossible to correct 4 years later when we use the data for the wage index. Examples of such errors are negative average hourly wages or a line item that includes salaries but no associated hours. Currently, we delete the problematic data elements, but the commenter believed that this does not necessarily make the reported data better, nor does it make the data consistent with data reported by other hospitals. The commenter recommended that we include a fatal edit that will not allow the cost report to be filed by the hospital until all required wage data have been entered.

Response: We agree with the commenter that these obvious errors should be corrected by the hospital before the cost report is filed. The cost reporting system currently has an edit that prevents the reporting of negative adjusted salaries. Therefore, no line item should have a negative average hourly wage. However, due to the complexities of the cost report software, a hospital is unable to simply adjust Worksheet S–3, Part II salaries to zero, if hours are missing or inaccurate, without also triggering a necessary adjustment to the trial balance (Worksheet A), as most salary items reported on Worksheet S–3, Part II are directly transferred from Worksheet A. Because Worksheet S–3, Part II wage

data are only used for wage index purposes, we believe it is preferable for both CMS and hospitals not to have the entire cost report rejected, and risk an untimely submission of the cost report, because the hours on Worksheet S–3, Part II are problematic.

We are working on revising the intermediaries' software to improve their edits and give them more flexibility to make adjustments directly to Worksheet S–3, Part II when the adjustments are necessary for wage index purposes only. We acknowledge that this revision would not help hospitals to detect obvious errors as early as possible, that is, before they file their cost reports with their intermediaries. However, improved intermediary edits would allow the errors to be identified and corrected before the data are submitted to us to be used in developing the wage index.

E. Computation of the FY 2003 Wage Index

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

Step 1—As noted above, we based the 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	01/15/00	1.00710
01/14/00	02/15/00	1.00358
02/14/00	03/15/00	1.00000
03/14/00	04/15/00	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 $23.2295.

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 $11.0086 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 180 hospitals in 39 MSAs. The MSAs affected by this provision are identified by a footnote in Table 4A in the Addendum of this final rule.

Comment: Two commenters opposed our use of 3-year-old data for developing the wage index. The commenters believed that the FY 2003 wage index does not reflect current market conditions for nurses. For example, one commenter stated that, due to the current nursing shortage, her facility's average hourly wage has increased 10 percent over the past 18 months. However, the wage index does not adequately reflect the increased wage costs. The commenter noted that rural hospitals have been severely impacted by the nursing shortage. Since rural hospitals are reliant upon Medicare reimbursement, the commenter suggested that we revise the wage index methodology to allow the wage index to reflect labor cost increases sooner.

Response: The wage index is a relative measure, which compares area average hourly wages to the national average hourly wage. The nursing shortage and increased nursing wages are a national phenomenon. We believe the wage index is minimally impacted by inflationary effects of increased nursing costs. Increases in hospital wages overall would be reflected in the market basket.

In computing the wage index, we use data from cost reports beginning during the most recent Federal fiscal year for which we have a complete year's worth of data. For the FY 2003 wage index, that is cost reports that began during FY 1999. Because hospitals' cost reports may end as late as August or even September of the following year, it would not be feasible for us to use cost reports that began during FY 2000 (many of which would not close until the latter part of 2001). Due to the time period allowed for: (1) Hospitals to complete and submit their cost reports to their intermediaries; (2) intermediaries to perform a separate, detailed review of all hospitals' wage data and submit the results to CMS; and (3) CMS to compile a complete set of all hospitals' wage data from a given Federal fiscal year, it would not be possible to use FY 2000 cost report data to calculate the FY 2003 wage index. As described in the proposed rule (67 FR 31434) and section III.E. of this final rule, we adjust the wage index to a common period that reflects the latest cost reporting period for the filing year. For the FY 2003 wage index, this period is September 1, 1999 to August 31, 2000.

Comment: One commenter recommended that, to reflect the labor markets in which rural hospitals compete more accurately, the wage index value for a rural area should be the average of the three lowest MSA rates in the geographic area.

Response: We note that the statute requires that we apply wage indexes that reflect ''the relative hospital wage level in the geographic area of the hospital'' (section 1886(d)(3)(E) of the Act). Furthermore, in some States, there are some MSAs for which the calculated wage index value is actually lower than the rural area of the state. As we discussed in the proposed rule (67 FR 31435) and in section III.E. of this final rule, for those urban areas, we assign the statewide rural wage index value. We are uncertain as to whether the commenter considered this policy in its recommendation. While the commenter did not provide details of its rationale for the recommended change, we appreciate the commenter's suggestion and welcome a more detailed discussion and analysis.

Comment: One commenter wrote that CMS' instructions for developing wage-related costs using Generally Accepted Accounting Principles (GAAP) are inconsistently communicated by CMS staff and inconsistently applied by the fiscal intermediaries. The commenter urged us to ensure the credibility of the wage index by requiring that our staff and contractors understand and consistently apply our wage index policies to eliminate variations in interpretation and application of the wage data.

Response: In an effort to clarify our instructions and to promote consistency in hospitals' reporting and CMS' and the intermediary's handling of wage-related costs that are developed using GAAP, we have revised the cost report instructions (in Transmittals 8 and, soon to be released, 9) and the intermediary's desk review program. Because of the wide variation in GAAP methodologies, we continue to emphasize that it is the responsibility of the hospitals to be able to provide adequate support for the GAAP methodologies they apply. In addition, if a hospital believes that an intermediary may be incorrectly handling a particular issue, the hospital is encouraged to bring it to our attention. We will continue our efforts to ensure uniform reporting of the wage data.

Comment: One commenter, representing the District of Columbia,

indicated that the Washington, DC–MD–VA–WV MSA includes 16 Virginia hospitals, 13 Maryland hospitals, 12 District of Columbia hospitals, and 2 West Virginia hospitals. The commenter was concerned about the negative impact of the West Virginia and Maryland hospitals on the Washington, DC–MD–VA–WV MSA wage index (although the commenter did not specify a particular issue with the West Virginia hospitals). Unlike hospitals in all other States and the District of Columbia, Maryland hospitals, which are under a waiver from the acute inpatient prospective payment system, do not rely on the wage index adjustment factor to adjust their inpatient Medicare payments. Therefore, the commenter wrote, Maryland hospitals have no incentive to accurately report their wage costs on the Medicare cost report or to review and request corrections to CMS' wage index public use files. The commenter requested us to carefully review the impact of Maryland's all-payor system on hospitals within the same MSA.

Response: As the commenter notes, Maryland hospitals are paid under a program waiver (section 1814(b)(3) of the Act), in which the State establishes hospital inpatient and outpatient payment rates for Medicare, Medicaid, and private payors. The Medicare wage index is not a factor in the State's ratesetting methodology. However, in recent years the wage index has been applied to the Medicare payment rates for other providers that are not under the State's waiver, such as SNFs, hospices, and home health agencies. Many Maryland hospitals own, or are members of systems that own, facilities or entities that are now directly impacted by the quality of the hospitals' reported data.

As with all hospitals in the wage index, we edited the FY 1999 wage data for the Maryland and West Virginia hospitals. We found no significant problems in their wage data. We believe that the Maryland hospitals' wage data are reasonable for the State and the MSA. The lower average hourly wages for the West Virginia hospitals are comparable to other hospitals in that State. Furthermore, under OMB's definition of the Washington, DC–MD–VA–WV MSA, these Maryland and West Virginia hospitals are part of that MSA. Therefore, the wage data for these hospitals will continued to be used in the calculation of the area wage index for the Washington DC–MD–VA–WV MSA.

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. In accordance with section 1886(d)(8)(B)(ii)(II) of the Act, in the May 9, 2002 proposed rule, we proposed 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 wage index values for FY 2003 are shown in Tables 4A, 4B, 4C, and 4F in the Addendum to this final 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 final rule list the 3-year average hourly wage for each labor market area before the redesignation of hospitals, based on FYs 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 final 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) 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.

We indicated in the proposed rule that, at the time the proposed wage index was constructed, that the MGCRB had completed its review of FY 2003 reclassification requests. Table 9 of this final rule 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. This table also includes hospitals reclassified for purposes of the standardized amount and hospitals located in urban areas that have been designated rural in accordance with section 1886(d)(8)(E) of the Act. There are 54 hospitals reclassified for the wage index beginning during FY 2003. In addition, 367 hospitals are reclassified for FY 2003 based on their 3-year reclassification that became effective during FY 2001, and 181 hospitals are reclassified for FY 2003 based on their 3-year reclassification that became effective during FY 2002. There are 24 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 34 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 59 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 FY 2003 wage index values incorporate all of these hospitals. Since publication of the May 9 proposed rule, the number of reclassifications has changed because some MGCRB decisions were still under review by the Administrator and because some hospitals decided to withdraw their requests for reclassification.

Applications for FY 2004 reclassifications are due to the MGCRB by September 3, 2002. We note this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under § 412.273(d) (as added by this final rule). At the time of publication the May 9, 2002 proposed rule, the internet site for reclassification (*http://www.hcfa.gov/regs/mgcinfo.htm*) was not operational. To obtain an application for MGCRB reclassification, call the MGCRB at (410) 786–1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244–2670.

Changes to the wage index that resulted from withdrawals of requests for reclassification, wage index corrections, appeals, and the Administrator's review process have been incorporated into the wage index values published in this final 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.

In the May 9, 2002 proposed rule, we proposed 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, including any comments received and our responses to those comments.

We receive several comments pertaining to the FY 2003 or FY 2004 MGCRB reclassification process. These are addressed below.

Comment: One commenter expressed concern that the methodology used for wage index reclassification for FY 2003 reclassification applications does not include a process by which corrections to 1996 and 1997 cost reporting data may be submitted. The commenter suggested that we allow for the correction of inaccurate data from prior years as part of a hospital's bid for geographic reclassification, and that not to allow corrections to the data results in inequities in the calculation in the average hourly wage for purposes of reclassification.

Response: Effective with reclassifications for FY 2003, section 1886(d)(10)(D)(vi)(II) of the Act provides that the MGCRB must use the average of the 3 most recent years of hourly wage data for the hospital when evaluating a hospital's request for reclassification. To evaluate applications for wage index reclassifications for FY 2003, the MGCRB used the 3-year average hourly wages published in Table 2 of the August 1, 2001 **Federal Register**. These average hourly wages are taken from data used to calculate the wage indexes for FY 2000, FY 2001, and FY 2002, based on cost reporting periods beginning during FY 1996, FY 1997, and FY 1998, respectively.

In the August 1, 2001 **Federal Register**, we revised the Medicare regulations at § 412.230(e)(2)(ii)(A) to specify that hospitals seeking reclassification must provide a 3-year average hourly wage using data from the hospital wage survey used to construct the wage index in effect for prospective payment purposes (66 FR 39934).

Hospitals have ample opportunity to verify the accuracy of the wage data used to calculate their wage index and to request revisions, but must do so within the prescribed timelines. We consistently instruct hospitals that they are responsible for reviewing their data and availing themselves to the opportunity to correct their wage data within the prescribed timeframes. Once the data are finalized and the wage indexes published in the final rule, they may not be revised, except through the mid-year correction process set forth in the regulations at § 412.63(x)(2). Accordingly, it has been our consistent policy that if a hospital does not request corrections within the prescribed timeframes for the development of the wage index, the hospital may not later seek to revise its data in an attempt to qualify for MGCRB reclassification.

Allowing hospitals the opportunity to revise their data beyond the timelines required to finalize the data used to calculate the wage index each year would lessen the importance of complying with those deadlines. The likely result would be that the data used to compute the wage index would not be as carefully scrutinized because hospitals would know they may change it later, leading to inaccuracy in the data and less stability in the wage indexes from year to year.

Comment: Several commenters requested that we clarify whether we intend to utilize OMB's new MSA standards and, if so, how we intend to incorporate the changes into the Medicare program. Relatedly, one commenter requested that we specify in the text of the final rule whether or not a hospital that was treated as a rural referral center (RRC) as of October 1, 2000, will continue to qualify for the RRC exception if their physical location becomes urban as a result of subsequent updates to metropolitan areas issued by the OMB. The commenter is concerned that the absence of a clear statement in the regulations text indicating that the grandfathered status of RRCs will continue into subsequent years could possibly result in a loss of their special status. The commenter referenced the instance when many RRCs located in areas that were redesignated as urban by OMB lost their RRC status. (See the August 29, 1997 final rule (62 FR 45999) for a more detailed explanation.)

Response: At this time, it is our understanding that OMB is not expected to announce changes to the new MSA standards until after we have published the proposed rule for FY 2004. Even if the new standards are announced in advance of the publication of our FY 2004 proposed rule, we would need time to assess their implications for payment purposes (for example, how will the new Micropolitan Areas designated by OMB, which will encompass counties currently considered rural, interact with other statutory and regulatory requirements for special hospital designation, such as an RRC).

Therefore, we intend at this time to continue to use the current MSA standards for FY 2004 acute inpatient prospective payment system payments. Hospitals applying for MGCRB reclassification for FY 2004 must apply based on the existing MSA definitions. With respect to the commenter's concern regarding the implications of the revised MSA definitions on RRCs, we are not prepared at this time to address this issue. We intend to evaluate this and other issues related to the new MSA definitions when they become available next year.

Comment: One commenter requested clarification as to whether Table 9, Hospital Reclassifications and Redesignations by Individual Hospital, is an official list and whether the wage index calculation is affected by errors in omission. The commenter indicated that the list in the proposed rule includes hospitals that have withdrawn their FY 2002 reclassifications and subsequently cancelled the withdrawal for FY 2003 and FY 2004, as well as omits hospitals that have received approval letters from the MGCRB reinstating the remaining years of the 3-year appeal.

Response: We indicated in the proposed rule that, while Table 9 shows hospitals that have been reclassified under either section 1886(d)(8)(B) or section 1886(d)(10)(D) of the Act, it may not reflect all withdrawals from reclassifications approved by the MGCRB or decisions of the CMS Administrator if those withdrawals were made subsequent to the preparation of the proposed rule. Similar to the other provisions and tables included in the proposed rule, publication of Table 9 in the proposed rule provided an opportunity for affected hospitals to review and verify the accuracy of the data. In situations such as those described by the commenter, we encourage affected providers to furnish us with specific feedback regarding the information contained in the proposed rule. Any changes that result from withdrawals of requests for reclassification, wage index corrections, appeals, and the Administrator's review process are incorporated into the wage index values and Table 9 published in the final rule.

Comment: Several commenters requested that the wage data for urban hospitals redesignated as rural under section 1886(d)(8)(E) of the Act, be included both in the MSA where the hospital is physically located and the rural area to which they are redesignated for purposes of the wage index. Commenters cited section 1886(d)(8) of the Act and section 152(b) of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) in support of their request. The commenters asserted that section 1886(d)(8) of the Act protects nonreclassified hospitals from being negatively impacted by reclassifications. They also pointed out that in implementing the statutory reclassifications required by section 152(b) of Public Law 106–113, CMS calculated the wage index values of the MSAs that contain the counties specified in section 152(b) by ''including the wages of hospitals that were reclassified out of the MSA by section 152(b).'' The commenters stated that the exclusion of hospitals redesignated under section 1886(d)(8)(E) of the Act in calculating the wage index is contrary to the expectations of the hospitals prior to the enactment of this provision (by section 401 of Public Law 106–113).

Response: Section 1886(d)(8)(E) of the Act permits 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. A hospital granted redesignation under section 1886(d)(8)(E) of the Act is therefore treated as a rural hospital for all purposes of payment under the Medicare acute inpatient prospective payment system, including standardized amount, wage index, and disproportionate share calculations, as of the effective date of the redesignation. Therefore, for purposes of calculating the wage index as a result of the redesignation to a rural area, the wage index data of the redesignated hospital is treated as though the hospital were located in the rural area of the State. That is, its data are excluded from the wage index calculation for the urban area where the hospital is geographically located and included in the wage index calculation for the rural area to which the hospital is designated. This is consistent with the statutory language requiring that a hospital be treated as though it is located in a rural area.

In the case of section 1886(d)(8) of the Act, Congress specifically acted to provide special protection for rural hospitals negatively impacted by reclassifications. Section 1886(d)(8)(C) of the Act provides that rural areas are held harmless for decisions resulting from the application of section

1886(d)(8)(B) of the Act, or of decisions of the MGCRB or the Secretary. Redesignations under section 1886(d)(8)(E) of the Act are not covered under this provision.

In the case of section 152(b) of Public Law 106–113, Congress specifically directed the Secretary to treat these statutorily mandated reclassifications as decisions by the MGCRB. Section 1886(d)(8)(E) of the Act directs the Secretary to treat the redesignated hospitals as being located in the rural area of the State in which the hospital is located. We did not exclude the wages of the hospitals reclassified under section 152(b) in calculating the FY 2001 wage index for the affected areas because we believed that this approach appropriately reflected the expectations of the hospitals that had applied to reclassify into the areas affected by this provision prior to enactment of this provision. Because section 1886(d)(8)(E) of the Act has been in place for well over a year, hospitals applying for reclassification for FY 2003 could not reasonably have expected, in light of the language of that section, that they would benefit from the inclusion of the wage data of the redesignated hospitals in two different areas.

We note that the commenters' suggestion would not uniformly benefit hospitals remaining in or reclassified into the urban area from which the now rural hospital was reclassified. Our analysis indicates several such areas would be negatively impacted. The greatest positive impact would occur in the area of concern to the commenter.

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. 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-Holland, 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 amended section 1886(d)(8)(B) of the Act by adding clause (ii). This clause 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 for redesignation under the January 3, 1980 standards elected to use those older standards so they would not receive the urban designation accorded to them under section 402 because they would lose their special rural designation (that is, an RRC, a sole community hospital (SCH), or a Medicare-dependent hospital (MDH)). Under section 1886(d)(8)(B)(ii) of the Act, the option to make such an election was available only for FY 2001 and FY 2002. Effective for FY 2003, as we proposed, we are providing that hospitals located in counties qualifying for redesignation under section 1886(d)(8)(B) of the Act based on the 1990 standards will 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 under section 1886(d)(8)(B) of the Act unless the counties again qualify when the standards based on the 2000 census data are available.

Comment: One commenter expressed concern that the reclassification based on 1990 standards disadvantages hospitals classified as RRCs, SCHs, or MDHs by taking away their special status classification because they are no longer considered rural. The commenter was concerned that the provision is not in keeping with Congressional intent. As an alternative, the commenter suggested that an affected hospital should be allowed to request reclassification as a rural hospital under § 412.103(a)(3), which allows hospitals to be treated as rural if they qualify as either a rural referral center or a SCH.

Response: Because the law does not provide for an election on the part of the hospital for FY 2003, while specifying such an election for FYs 2001 and 2002, hospitals in affected counties are reclassified as urban. Therefore, consistent with our longstanding policy that hospitals reclassified as urban for purposes of the standardized amount are considered urban and lose their eligibility for special rural hospital status, the commenter is correct that a hospital becoming urban under section 1886(d)(8)(B)(ii)(II) of the Act would lose its special status as a result. With respect to the commenter's request that, in the event an affected hospital is not permitted the option to decline reclassification to an urban area that it may apply to be redesignated rural under § 412.103, we agree with the commenter that a reclassified hospital may seek rural redesignation under § 412.103. We will then determine whether the hospital meets the criteria for reclassification under this regulation. However, any such reclassification would be subject to the limitations on reclassification at § 412.230(a)(5)(iv), which prohibit a hospital that has been granted redesignation as a rural hospital under § 412.103 from receiving an additional reclassification by the MGCRB.

We also note that it has been brought to our attention that the reclassifications applicable under section 1886(d)(8)(B)(ii) of the Act are applicable for cost reporting periods beginning in the relevant Federal fiscal year. Therefore, in applying such reclassifications for FY 2003, they are effective as of the beginning of the hospital's cost reporting period beginning during FY 2003. This effective date has no impact on hospitals that are reclassified to the same MSA under this provision as they were reclassified into for FY 2002. Such

hospitals will be paid in accordance with the FY 2003 wage index value of the area to which they are reclassified effective with discharges on or after October 1, 2002. However, hospitals whose reclassification changes as a result of applying the 1990 standards for FY 2003 will be paid in accordance with the wage index applicable to the area to which they would otherwise have been classified were it not for section 1886(d)(8)(B)(ii) of the Act at the start of FY 2003. Then, for discharges occurring on or after the date of the start of their cost reporting period beginning during FY 2003, they will be paid in accordance with the wage index applicable to the area they are reclassified into under section 1886(d)(8)(B)(ii).

G. Requests for Wage Data Corrections

In the May 9, 2002 proposed rule, we stated that, to allow hospitals time to construct the proposed FY 2003 hospital wage index, in May 2002 we would make available a final public data file containing the FY 1999 hospital wage data.

The final wage data file was released on May 10, 2002. As noted above in section III.D. of this preamble, this file included hospitals' cost report data obtained from Worksheet S–3, Parts II and III of their FHY 1999 Medicare cost reports. In addition, Table 2 in the Addendum to this final rule contains each hospital's adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 1999 data used to construct the final FY 2003 wage index.

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 were discussed in section IX.A. of the preamble of the May 9, 2002 proposed rule, ''Requests for Data from the Public.''

In addition, Table 2 in the Addendum to the proposed rule contained 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. We noted that the hospital average hourly wages shown in Table 2 only reflected 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, were reflected in the final public use wage data file made available on May 10, 2002.

We believe hospitals had 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 were 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 provided an opportunity to submit corrections along with complete, detailed supporting documentation to its intermediary by February 8, 2002.

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 notified 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 noted that the April 5, 2002 deadline also applied to these requested changes. During this review, we did 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 were necessary to allow sufficient time to review and process the data so that the final wage index calculation could be completed for development of the final FY 2003 prospective payment rates published in this final rule.

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 did not meet the procedural deadlines set forth above were not 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 are not permitted to challenge later, 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)).

As stated above, the final wage data public use file was released on May 10, 2002. Hospitals had an opportunity to examine both Table 2 of the proposed rule and the May 2002 final public use wage data file (which reflected revisions to the data used to calculate the values in Table 2) to verify the data CMS used to calculate the wage index.

As with the file made available in January 2002, CMS made 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 was 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 were encouraged to review their hospital wage data promptly after the release of the May 2002 file. Data presented at that time could not be used by hospitals to initiate new wage data correction requests.

If, after reviewing the May 2002 final file, a hospital believed that its wage data were incorrect due to a fiscal intermediary or CMS error in the entry or tabulation of the final wage data, it was provided an opportunity to send a letter to both its fiscal intermediary and CMS, outlining why the hospital believed an error existed and providing all supporting information, including relevant dates (for example, when it first became aware of the error). These requests had to be *received* by CMS and the fiscal intermediaries no later than June 7, 2002.

Changes to the hospital wage data were only 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, at this stage of the process, neither the intermediary nor CMS accepted the following types of requests:

- Requests for wage data corrections that were submitted too late to be

included in the data transmitted to CMS by fiscal intermediaries on or before April 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) are incorporated into the final wage index in this final rule, to be 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 had access to the final wage data by early May 2002, they have had 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 in this final rule, and the implementation of the FY 2003 wage index on October 1, 2002. If hospitals availed themselves of this opportunity, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified after publication in the final rule, 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 had the opportunity to verify its data, and the fiscal intermediary notified 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 will be 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 in the May 9, 2002 proposed rule we proposed 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 in the May 9, 2002 proposed rule we proposed to delete it as well.

Finally, we proposed 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.

Comment: One commenter disagreed with the proposed revision to clarify § 412.63(x)(2). The commenter stated that the clarification 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 is illogical. The commenter believed that we should allow all potentially affected hospitals to report what they believe to be errors that they failed to correct before the beginning of the Federal fiscal year.

Response: We frequently instruct hospitals that they are responsible for reviewing their data and notifying the intermediary if there is an error or omission.

The proposed revision is consistent with the current rules in that it reinforces for hospitals the responsibility they have for assuring the accuracy of the wage data they submit.

The wage index is recalculated each year based on wage data from acute care hospitals nationwide. Since this calculation must be carried out on a nationwide basis, it is critical that we have the necessary data from all hospitals in a timely fashion so that the wage index values can be calculated prior to the beginning of the upcoming fiscal year. Accordingly, we set out well in advance a detailed timetable for reviewing and revising the data that hospitals, fiscal intermediaries, and CMS must follow. In this way, all hospitals are given an equal opportunity to review and correct their data within the established process. To further assist in the wage data review process, we require that fiscal intermediaries notify state hospital associations when a hospital fails to respond to issues raised during the wage data review process. The purpose of the notification is to inform the hospital association that its member hospital's failure to respond to matters raised by the fiscal intermediary can result in data being disallowed, thereby possibly lowering an area's wage index value. Consistent with out efforts to finalize the data used to construct the wage index prior to publication of the final rule, we make mid-year data revisions in only very limited circumstances, so that the disruptive effects of such changes can be avoided to the greatest extent possible. In turn, consistent with that principle, we think it is appropriate to limit such mid-year revisions to those pertaining only to the data of the requesting hospital. We do not believe this revision will unduly restrict the ability of hospitals to bring to our attention the need for revisions in a neighboring hospital's data; under our wage data revision process, hospitals have an ample opportunity to do this prior to the publication of the rule. Therefore, we disagree with the commenter that it is necessary or advisable to allow other hospitals an opportunity to request changes to a hospital's wage data after the final rule is published, and we are adopting our proposed changes as final.

Comment: One commenter representing Medicare fiscal intermediaries recommended that we revise the wage index development process to provide an incentive for hospitals to submit accurate wage data with their as-filed cost reports. The

commenter noted that, in the August 1, 2001 **Federal Register** (66 FR 39871), we implemented procedural changes that allow the intermediaries additional time to review hospital's wage data. In that rule, we indicated that wage data were revised between the publication of the proposed and final rules for 30 percent of the hospitals. To reduce this percentage, and the number of ''second'' desk reviews that intermediaries must perform when hospitals revise their wage data, the commenter recommended the following changes:

- CMS should publish an initial wage index public use file in September based on provider as-filed wage data.
- Hospitals should be allowed 4 weeks to review and submit to their intermediaries requests for corrections to the initial wage index public use file.
- After the hospitals 4-week review and correction request period, intermediaries should perform a single desk review of each hospital s wage data and make the appropriate requested corrections.
- After CMS publishes the reviewed final wage index file, hospitals should submit only corrections due to CMS' or the fiscal intermediary's mishandling of the wage data.

Response: We appreciate the commenter's recommendation, and we agree that revisions to the current wage index process should be considered to reduce duplicative review efforts. We will carefully explore options and their associated risks before making further refinements to the wage index development process.

IV. 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. 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. For FY 2003, payment rates will be updated by the projected increase in the hospital market basket minus 0.55 percentage points.

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 that 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 for use in providing inpatient care, 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 in the market basket. 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, 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 combined.

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, the base year cost structure for the prospective payment system hospital index shifts from FY 1992 to FY 1997). Revising means changing data sources, cost categories, or price proxies used in the input price index.

We used a rebased and revised hospital market basket in developing the FY 2003 update factor for the prospective payment rates. The rebased and revised market basket reflects FY 1997, rather than FY 1992, cost data. 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, analysis of FYs 1998 and 1999 Medicare cost report data showed little difference in comparable cost shares from FY 1997 data.

In developing the rebased and revised market baskets set forth in the May 9, 2002 proposed rule (67 FR 31438) and adopted in this final rule, we used hospital operating expenditure data in determining the market basket cost weights. We relied primarily on Medicare hospital cost report data for the 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. We are providing the following detailed discussion of the process for calculating cost share weights.

Cost category weights for the FY 1997-based market baskets were developed in several stages. First, base weights for several of the operating cost categories (Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, and Blood and Blood Products) were derived from the FY 1997 Medicare cost reports. 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 of the hospitals' cost centers are utilized for both inpatient and outpatient care. Health Economics Research (HER), under contract with CMS, just recently completed a feasibility study on the construction of a separate outpatient market basket for our outpatient hospital prospective payment system. While this research provided some insight about ways to separate inpatient and outpatient costs, HER also found that substantially more data would need to be collected from hospitals in order to accomplish this. Furthermore, 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 payor. 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 operating expenses to obtain a portion for all other expenses.

Finally, 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 are unable to incorporate these data in this final rule.

Comment: Several commenters mentioned the need for an improved market basket, where the composition of the market basket is a more contemporary reflection of the cost pressures hospitals are facing. They suggest that we rebase more frequently than the current interval of approximately every 5 years.

Response: As explained in the May 9, 2002 proposed rule (67 FR 31439), FY 1997 was selected as the base year for the revised and rebased hospital market basket because it is the most recent year for which relatively complete data are available.

It is important to realize that the Medicare cost reports were used as the primary source of data because these data were supplied directly from hospitals. The independent secondary sources such as the BES and the input-output table fill in where cost report data were not available or appeared to be incomplete. While the major cost categories are available for a more recent year from the cost reports, the additional detail derived from the input-output tables and the BES was not, as the Bureau of the Census only publishes these data for 5-year intervals. In addition, the major cost category weights determined using the FY 1997 Medicare cost reports were compared to weights calculated using FY 1998 and FY 1999 Medicare cost reports. These results were then compared to the weights calculated from the 1997 Medicare cost reports. The results were very similar to those calculated using FY 1997 Medicare cost report data. Thus, 1997 data are the most recent, complete, and consistent data readily available for our rebasing work this year, and using more recent data woud not produce dissimilar results.

Below, we further describe the sources of the six main category weights and their subcategories in the FY 1997-based market basket while noting 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 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 we used the 1992 Current Population Survey to break out various occupational subcategories. These subcategories were not broken out for the 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 FY 1997-based 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 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 the national level. The 1997 proportion as calculated by ANASYS was compared to limited data for FYs 1998 and 1999 contained in the Medicare Cost Reports System. 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.

Comment: A few commenters indicated that the explanation provided for the derivation of the professional liability insurance weight does not convey a full understanding of the methodology and data used; they would like additional information. They also questioned the appropriateness of assuming a constant level of malpractice coverage at a national level across time when updating this weight.

Response: We believe the method for calculating the weight for professional liability insurance in the hospital market basket is reasonable given the alternatives we examined. The weight for professional liability insurance was derived from a survey conducted by ANASYS for CMS called the National Hospital Malpractice Insurance Survey (NHMIS). This survey was designed to collect hospital malpractice insurance costs of primary and excess coverage as well as deductible and other costs for 1996 and 1997. The survey collected malpractice information directly from a representative sample of hospitals derived from a universe defined as all non-Federal short-term acute care prospective payment system hospitals. The hospitals were sent a questionnaire derived from a 1986 General Accounting Office Survey. Follow-up phone calls were made where necessary resulting in a total response rate to the survey was 67 percent. After the data were collected, several edits were run to test the validity and reasonableness of the data. The total malpractice cost was derived by adding the adjusted primary and excess premiums, deductible costs, and other costs. The survey hospitals were then matched to the corresponding Medicare cost reports to derive a total hospital cost using the malpractice insurance policy year and hospital fiscal year as matching variables. The total professional liability insurance cost for each hospital calculated from the survey was then divided by the total hospital costs calculated from the Medicare cost reports to arrive at a weight for professional liability insurance for the hospital. The mean cost weight of all of the hospital weights was then used as the professional liability insurance weight.

Other methods, such as using the Medicare cost reports or trending 1992 data forward, presented significant data limitations. We were unable to use the Medicare cost report data in the development of a weight because 1997 data were incomplete, with very few hospitals submitting information on professional liability insurance. We compared weights derived from 1998 and 1999 cost report data, which were much more complete than 1997 data, and found that they produced results very similar to the weight calculated in the ANASYS report. We were also unable to use the prior method of calculating a professional liability insurance weight by trending 1992 data forward. This method would only capture the effect of price changes over time and would not reflect increases or decreases in the quantities of professional liability insurance purchased that should be reflected in the cost category weight. In the development of the 1992-based market basket, the method used was the only available option. Therefore, given the data available from ANASYS and the limitations of other methods we considered, we believe that the method of calculating a weight chosen was reasonable.

To address the commenters' second point, we feel that it is appropriate to assume a constant level of malpractice coverage at a national level. By doing so, we are able to capture only the 'pure' price change in professional liability premiums and not the additional effect of increasing or decreasing liability coverage. This method is consistent with the methods used by Bureau of Labor Statistics (BLS) in constructing its Producer Price Indexes (PPIs).

Comment: Several commenters believe that we should explicitly account for other insurance categories such as property and general liability insurance in the market basket and not just professional liability insurance because of large premium increases in those categories. In addition, the commenters believe that we should adjust the weight given to insurance, blood products, and other items that experience extraordinary price increases.

Response: The market basket implicitly accounts for increases in other insurance categories under the All Other-Labor Intensive Services category. We are unable to separate out other detailed insurance categories in the market basket due to data limitations. A publicly available data source that meets our criteria for developing weights for these other insurance categories does not exist at this time. In addition, data for price proxies such as the BLS PPI for property and casualty insurance show similar price movements to those of the All Other-Labor Intensive category in the market basket.

In addition, we cannot inflate the weights of some categories and not others. This would violate the general principles of price index construction. We have compiled data for all of the cost categories in addition to total costs for a common base year and developed a set of weights that are consistent with respect to the principles of price index construction. Attempting to reflect more

recent trends in some categories and not in others would not accurately capture the entire cost structure that hospitals face at a given time. In addition, while expenditures for a category may be increasing, this may not necessarily lead to a greater weight for that category in the market basket. For example, property insurance expenditures could be increasing, but other categories could be increasing faster, so that the weight for property insurance in the market basket would be declining. Thus, it is necessary that all of the weights are reflective of a consistent base year.

• *Utilities:* For the FY 1997-based market baskets, the cost weight for utilities is 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. Even though the Business Expenditure Survey replaced the Asset and Expenditure Survey, the categories and results are still 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, photographic 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.

The shares for pharmaceuticals and blood and blood products are 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 are 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) (Pub. L. 106–554) required that we 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, we have 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. We studied four alternative data sources to possibly determine a weight for blood in the market basket. If none of these data sources were deemed acceptable, we could conclude that a component for blood should not be reintroduced in the hospital market basket. In its December 2001 report 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, we have 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 FY 1997 cost reports 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. In this final rule, we use the Medicare cost reports to determine a weight for blood and blood products in the hospital market basket given the consistency with these other sources, the representativeness of our estimate, and the stability of the cost share.

Overall, our work resulted in the identification of 23 separate cost categories in the 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 categories). The differences between the weights of the major categories determined from the Medicare cost reports for the FY 1997-based index and the previous FY 1992-based index are summarized in Table 1.

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

Expense categories	Rebased FY 1997-based 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	.....
All Other	32.053	34.448
Total	100.000	100.000

Table 2 sets forth all of the 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 FY 1997-BASED PROSPECTIVE PAYMENT HOSPITAL OPERATING COST CATEGORIES AND WEIGHTS

Expense categories	Rebased FY 1997-based 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

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

3. Selection of Price Proxies

After computing the FY 1997 cost weights for the rebased and revised hospital market basket, it was necessary to select appropriate wage and price proxies for each expenditure category. Most of the indicators are based on 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 changes at the final stage of production.

• Consumer Price Indexes—Consumer Price Indexes (CPIs) measure price changes 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 wholesale purchasers. 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 skill mix.

Table 3 sets forth the complete hospital market basket including cost categories, weights, and price proxies. For comparison purposes, we also list the respective FY 1992-based market basket price proxies. A summary outlining the choice of the various proxies follows the table.

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

Expense categories	Rebased FY 1997 hospital market basket weights	Rebased FY 1997 hospital market basket price proxy	FY 1992 hospital market basket price proxy
1. Compensation	61.656		
Wages and Salaries	50.686	ECI-Wages and Salaries, Civilian Hospital Workers.	CMS Occupational Wage Proxy
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 Commercial Natural Gas	PPI Commercial Natural Gas
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	30.749		
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 & Feeds	PPI Processed Foods & 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 & Equipment
(7.) Photographic Supplies	0.204	PPI Photographic Supplies	PPI Photographic Supplies
(8.) Rubber and Plastics	1.668	PPI Rubber & Plastic Products	PPI Rubber & Plastic Products
(9.) Paper Products	1.355	PPI Converted Paper & Paperboard Products.	PPI Converted Paper & Paperboard Products
(10.) Apparel	0.583	PPI Apparel	PPI Apparel
(11.) Machinery and Equipment.	1.040	PPI Machinery & Equipment	PPI Machinery & 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		

Note: Totals may not sum to 100 due to rounding.

a. Wages and Salaries

For measuring the price growth of wages in the FY 1997-based market basket, we 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 was 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. During the period from 1995 through 2000, this trend reversed; each year the ECI grew slower than the blended occupational wage proxy. 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 has again grown 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 through 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 few years, there has been a move back towards less restrictive plans, and a subsequent increase in the utilization of hospital services. This recent surge appears to reflect the true underlying effect of rising 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, our analysis has indicated that the hospital labor market is more competitive than before 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. For FY 2003, the hospital market basket is forecast to increase 0.2 percentage points faster (3.5 versus 3.3) than it would have if the occupational blend had been used. Based on this, we use the ECI for wages and salaries for hospitals as the proxy in the hospital market basket for wages. 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 quarterly.

b. Employee Benefits

The 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 an analysis similar to that 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) is 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) is 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) is 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 is 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. In addition, we continue to monitor a BLS PPI for medical malpractice premiums that in the future could be used as a proxy for this cost category.

Comment: Several commenters indicated that hospital malpractice costs are increasing much faster than the professional liability portion of the market basket and we should consider other alternatives.

Response: We believe that our price proxy for professional liability insurance adequately measures the increases in professional liability insurance costs facing hospitals. While anecdotal evidence suggests that malpractice costs are increasing at double-digit rates, actual data as measured by the CMS hospital professional liability insurance survey as well as data on insurance from the BLS Producer Price Index through 2001 do not reflect this. Since the FY 2003 market basket increase is based on a forecast from DRI–WEFA, the expected trends in hospital professional liability insurance premiums are indeed reflected. As is the case with all of our indexes, we regularly review all of the proxies in the index to verify that they are representative of current industry trends. In addition, as mentioned in the May 9, 2002 proposed rule (67 FR 31444), we are currently exploring alternatives to our price proxy for hospital professional liability insurance including possibly using the BLS Producer Price Index for medical malpractice. We are also working with our contractor to explore possible methods of improving our hospital professional liability proxy, though this research is not yet complete.

h. Pharmaceuticals

The percentage change in the price of prescription drugs as measured by the PPI (Commodity Code #PPI283D#RX) is 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 as measured by the PPI (Commodity Code #02) is 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) is 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) is applied to this component. While the chemicals hospitals use 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) is 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 use the PPI for blood and blood derivatives as the price proxy for the blood and blood products cost category. 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 are not widely available. The PPI for blood and blood derivatives was the only index we found that met all of our criteria.

Comment: Several commenters supported the separate expense category for blood and blood products in the market basket and the use of the PPI for blood and blood derivatives for human use as the price proxy for monitoring the rate of change in blood costs. However, the commenters indicated that it is important to ensure that the PPI for blood and blood derivatives is appropriately and timely updated by the BLS so that it adequately tracks changing blood technologies and safety initiatives. The commenters added that ensuring the safety of the nation's blood supply requires constant attention to developing disease states and testing technologies and creates changing costs that must be captured by the blood PPI to ensure adequate reflection in the prospective payment system market basket.

Response: We agree that the PPI for blood and blood derivatives should appropriately reflect the price of blood and blood products. We will continue to monitor the PPI to ensure that this is the case. We are supportive of efforts by the BLS to collect the necessary information on the price of blood and blood products so they are accurately reflected in the PPI for blood and blood derivatives. Organizations that represent blood providers are also encouraged to work with BLS to accomplish this goal.

Comment: One commenter suggested that we use data from the Red Cross, America's Blood Centers or Zeman and Company in developing a price proxy that reflects recent cost increases for blood products.

Response: We require that all price indexes used in our market baskets to be relevant, reliable, available, and timely. The BLS PPI for blood and blood derivatives is an independent estimate of prices for these products that are published on a regular schedule (monthly). It is based on sound statistical methods and meets our criteria listed above. The possible sources of data mentioned by the commenter are not available frequently enough and on a regular basis and, therefore, do not meet the criterion of timeliness. Also, it has not been determined if indexes based on these data would be relevant or reliable enough for use in the CMS market baskets. Furthermore, because of their method of construction, the BLS indexes that we use as price proxies in the market baskets reflect only the effect of price changes and not the effects of quantity or quality changes. Our market baskets are designed to measure only the price change effects on increases in costs and not the quantity or quality effects. It has not been demonstrated whether indexes from these other data sources would capture only price effects or whether they mix price and quantity/quality effects.

m. Surgical and Medical Equipment

The percentage change in the price of medical and surgical instruments as measured by the PPI (Commodity Code #1562) is 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) is 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) is 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) is 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) is 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) is 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) is 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) is 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) is 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 is 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) is 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 FY 1997-based and the FY 1992-based market baskets.

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

Fiscal year (FY)	Rebased 1997-based 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	4.3	4.1
Average FYs 1995–2001	2.8	3.0
Forecast:		
FY 2002	3.9	3.0
FY 2003	3.5	3.2
FY 2004	3.1	3.2
Average FYs 2002–2004	3.5	3.1

Source: Global Insights, Inc, DRI–WEFA, 2nd Qtr. 2002; @USMACRO/MODTREND @CISSIM/TL0502.SIM

As indicated by Table 5, switching the proxy for wages and benefits to the ECI for Civilian Hospitals has a minimal effect over time. While the FY 2003 update is 0.2 percentage points higher than using the previous blended occupational wage proxy, 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.—1997-BASED PROSPECTIVE PAYMENT SYSTEM HOSPITAL OPERATING INDEX PERCENT CHANGE, USING DIFFERENT WAGE AND BENEFIT PROXIES, 1995–2004

Fiscal year (FY)	Rebased 1997 hospital market basket using ECIs for wages and benefits	Rebased 1997 market basket using occupational wage and benefit proxies
Historical Data:		

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

Fiscal year (FY)	Rebased 1997 hospital market basket using ECIs for wages and benefits	Rebased 1997 market basket using occupational wage and benefit proxies
FY 1995	2.8	3.0
FY 1996	2.3	2.5
FY 1997	1.6	2.2
FY 1998	2.7	3.2
FY 1999	2.7	3.0
FY 2000	3.3	3.4
FY 2001	4.3	4.1
Average FYs 1995–2001	2.8	3.1
Forecast:		
FY 2002	3.9	3.3
FY 2003	3.5	3.3
FY 2004	3.1	3.3
Average FYs 2002–2004	3.5	3.3

Source: Global Insights, Inc, DRI–WEFA, 2nd Qtr. 2002; @USMACRO/MODTREND @CISSIM/TL0502.SIM

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 * * *.'' 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.

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 methodology, 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.

Our proposed methodology was 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. However, we noted that, while we did not propose to change the methodology for calculating the labor-related share in the proposed rule, we have begun the research necessary to reevaluate the current assumptions used in determining this share. This reevaluation is consistent with MedPAC's recommendation in their 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.

We also noted our concern that the result of our methodology (increasing the labor-related share from 71.066 percent to 72.495 percent) could have negative impacts that would fall predominantly on rural hospitals. In addition, we noted that we planned to conduct further research and would make the appropriate changes in the final rule if another methodology was found to be superior to our current methodology.

Comment: Commenters generally supported our expressed willingness to review this methodology, and emphasized the need for a full and careful study of any changes before adopting major changes. Comments on behalf of some national and State hospital associations recommended that we not make any change to the labor-related share calculation, while proceeding with market basket rebasing, until completing a more thorough examination of the proportion of labor costs influenced by the local labor market, noting that we included in our methodology costs related to, influenced by, or that vary with the local labor market, even if these services may be purchased at the national level.

MedPAC commented that it believes that certain expenditures identified in our methodology as locally purchased are in fact purchased, in whole or in part, in national markets. The Commission gave examples such as computing, legal, and accounting services. The Commission noted it has worked with us in the past to discuss these issues, and commented that continued use of our proposed approach is appropriate in the absence of a superior method. Several commenters referred to the difference between MedPAC's and CMS's methodologies and suggested that we should adopt MedPAC's methodology.

Other commenters argued the labor-related share must be decreased, noting that increasing the percentage will only exacerbate current flaws in the payment system. Some commenters referred to the fact that the outpatient prospective payment system labor-related share is only 60 percent. Another commenter suggested the labor-related share should be changed to a State-specific share.

Still other commenters, some of whom represent national and State hospital associations, supported the proposed methodology, and expressed their belief that any revised methodology from the one discussed in the proposed rule would need to be separately proposed with an opportunity for specific public comment. It was also noted that it has been our standard practice to empirically estimate the labor share in accordance with changes in the market basket, and it was recommended that we continue to follow our empirical estimate. Another commenter stated that our proposed methodology is consistent with both our past practice and statutory mandate.

Response: We have decided not to proceed with reestimating the labor-related share at this time. We will conduct further analysis to determine the most appropriate methodology before proceeding. Therefore, for FY 2003, the labor-related share applicable to the standardized amounts will remain at 71.066 percent. Any future revisions to the labor-related share or the methodology will be proposed and subject to public comment.

We appreciate the input from commenters on this issue, and look forward to continuing to work with MedPAC and the hospital industry on future refinements to the labor-related share methodology.

Comment: One commenter offered several specific refinements to the proposed methodology. The commenter agreed with our proposal to remove postage costs from the methodology and recommended that insurance costs and certain other wage-related costs also be removed.

Another commenter noted that we are adjusting the labor portion of the standardized amount using data that is not measured through the existing hospital wage index. The commenter reports estimating a labor share of 61.656 percent by excluding contract labor costs not included in the wage index.

Response: As noted above, we are not revising our estimate of the labor-related share at this time. We will take these comments into consideration in our future analysis.

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 HCFA (now 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 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 used for freestanding psychiatric hospitals. This is 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 6 compares major weights in the rebased FY 1997 market basket for excluded hospitals with weights in the 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 weight for the excluded hospital market basket was derived using the same data sources and methods as for the acute care prospective payment market basket which were outlined previously. Differences in weights between the 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 6.—FY 1997-BASED EXCLUDED HOSPITAL AND PROSPECTIVE PAYMENT SYSTEM HOSPITAL MARKET BASKETS, COMPARISON OF SIGNIFICANT WEIGHTS

Category	Rebased FY 1997-based excluded hospital market basket	Rebased FY 1997-based 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 7 lists the cost categories, weights, and proxies for the FY 1997-based excluded hospital market basket. For comparison, the FY 1992-based cost category weights are included. The proxies are the same as those used in the FY 1997-based acute care hospital inpatient prospective payment system market basket.

TABLE 7.—FY 1992-BASED AND FY 1997-BASED EXCLUDED HOSPITAL OPERATING COST CATEGORIES, WEIGHTS AND PRICE PROXIES

Expense categories	Rebased FY 1997-based excluded hospital market basket weights	FY 1992-based excluded hospital market 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 Hospital Workers
B. Employee Benefits	11.253	11.569	ECI-Benefits, Civilian Hospital Workers
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 & 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 and 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	

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

Table 8 shows the historical and forecasted updates under both the FY 1997-based and the FY 1992-based excluded hospital market baskets.

TABLE 8.—FY 1992-BASED AND FY 1997-BASED EXCLUDED HOSPITAL OPERATING INDEX PERCENT CHANGE, 1995–2004

Fiscal year (FY)	Rebased FY 1997-based 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	4.0	3.0
FY 2003	3.5	3.2
FY 2004	3.1	3.2
Average FYs 2002–2004	3.5	3.1

Source: Global Insights, Inc, DRI–WEFA, 2nd Qtr. 2002; @USMACRO/MODTREND @CISSIM/TLO502.SIM.

A comparison of the FY 1997-based index incorporating the new wage and benefits proxies (ECIs) and updated occupational wage proxies is included in Table 9. Like the FY 1997-based prospective payment hospital index showed, there is little difference in the index over time when different compensation proxies are used.

TABLE 9.—FY 1997-BASED EXCLUDED HOSPITAL OPERATING INDEX PERCENT CHANGE, USING DIFFERENT WAGE AND BENEFIT PROXIES, 1995–2004

Fiscal year (FY)	Rebased FY 1997-based excluded hospital market basket	
	Using ECIs for hospital wage and benefit	Using occupational wages and Benefits proxies
Historical Data:		
FY 1995	2.7	2.9
FY 1996	2.4	2.5
FY 1997	1.7	2.2
FY 1998	3.0	3.5
FY 1999	2.9	3.0
FY 2000	3.3	3.5
FY 2001	4.3	4.1
Average FYs 1995–2001	2.9	3.1
Forecast:		
FY 2002	4.0	3.4
FY 2003	3.5	3.3
FY 2004	3.1	3.3
Average FYs 2002–2004	3.5	3.3

Source: Global Insights, Inc, DRI–WEFA, 2nd Qtr. 2002; @USMACRO/MODTREND @CISSIM/TL0502.SIM

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 revising and rebasing the CIPI to a FY 1997 base year to reflect a 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 weights in order to calculate the FY 1997-based CIPI. The first set of weights identifies the proportion of hospital capital expenditures attributable to each capital expenditure category, while the second 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 using 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 90 percent of 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 10 presents a comparison of the rebased FY 1997 capital cost weights and the FY 1992 capital cost weights.

TABLE 10.—COMPARISON OF FY 1992 AND REBASED FY 1997 COST CATEGORY WEIGHTS

Expense categories	FY 1992 weights	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 base year is FY 1997.

In order to estimate capital purchases from AHA data for 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 FY 1997 CIPI are presented in Table 11.

TABLE 11.—1992-BASED AND 1997-BASED VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year (From farthest to most recent)	Building and fixed equipment		Movable equipment		Interest	
	FY 1992 22 years	FY 1997 23 years	FY 1992 10 years	FY 1997 11 years	FY 1992 22 years	FY 1997 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

TABLE 11.—1992-BASED AND 1997-BASED VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES—Continued

Year (From farthest to most recent)	Building and fixed equipment		Movable equipment		Interest	
	FY 1992 22 years	FY 1997 23 years	FY 1992 10 years	FY 1997 11 years	FY 1992 22 years	FY 1997 23 years
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 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 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. A more detailed explanation of our rationale for selecting the price proxies is in the August 30, 1996 final rule (61 FR 46196). The proxies are presented in Table 10.

Global Insights, Inc., DRIWEFA forecasts a 0.7 percent increase in the rebased FY 1997 CIPI for FY 2003, as shown in Table 12.

TABLE 12.—FY 1992 AND FY 1997-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, 1995–2004

Federal fiscal year	CIPI, FY 1992-based	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	0.6	0.9
Average: FYs 1995–2001	0.9	1.1
Forecast:		
2002	0.6	0.8
2003	0.5	0.7
2004	0.6	0.8

TABLE 12.—FY 1992 AND FY 1997-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, 1995–2004—Continued

Federal fiscal year	CIPI, FY 1992-based	CIPI, FY 1997-based
Average: FYs 2002–2004	0.6	0.8

Source: Global Insights, Inc, DRI–WEFA, 2nd[t] Qtr. 2002; @USMACRO/MODTREND @CISSIM/TL0502.SIM.

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 3.0 percent increase in other capital expense prices, partially offset by a 2.3 percent decrease in vintage-weighted interest rates in FY 2003, as indicated in Table 13.

TABLE 13.—CMS CAPITAL INPUT PRICE INDEX PERCENT CHANGES, TOTAL AND COMPONENTS, FISCAL YEARS 1995–2005

Fiscal Year	Total	Total depreciation	Depreciation, building and fixed equipment	Depreciation, movable equipment	Interest	Other
Weights 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	4.3
2003	0.7	1.3	2.7	−0.1	−2.3	3.0
2004	0.8	1.3	2.6	−0.1	−2.0	2.8
2005	0.7	1.3	2.4	−0.1	−2.1	2.8

Source: Global Insights, Inc, DRI–WEFA, 2nd Qtr. 2002; @USMACRO/MODTREND @CISSIM/TL0502.SIM.

Rebasing the CIPI from FY 1992 to FY 1997 increased the percentage change in the FY 2003 forecast by 0.2 percentage points, from 0.5 to 0.7 as shown in Table 12. 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. We did not receive any public comments on the rebasing and revising of the capital input price index.

V. Other Decisions and 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 a discharge to postacute home health services to constitute a transfer 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 care 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 care 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 care transfer situations. For these 3 DRGs, hospitals receive 50 percent of the full DRG payment plus the per diem for the first day of the stay and 50 percent of the per diem for the remaining days of the stay, up to the full DRG payment. 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 current 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 potential expansion of 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
- Eliminate disparities between hospitals that happen to be disproportionately treating the current 10 DRGs and hospitals with an aggressive, short-stay, postacute care transfer policy for other DRGs.

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

In the May 9, 2002 proposed rule, we stated that, consistent with HER's findings, we believed expanding the postacute care transfer policy to all DRGs might be the most equitable approach, since a policy that is limited to certain DRGs may result in disparate payment treatment across hospitals, depending on the types of cases treated. 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 could 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 hospitals than for rural hospitals (34 percent compared with 25 percent through 1999), presumably due to earlier discharges to postacute care settings. Although the MedPAC report 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 care 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 Medicare Trust Fund expenditures for patients who are transferred to a postacute care setting after a very short acute care hospital stay would improve the program's overall financial stability.

As noted in the proposed rule, we believe that the current policy may create payment inequities among patients and among hospitals. By expanding the postacute care transfer policy, we would expect to reduce or eliminate these possible inequities. Therefore, in the May 9, 2002 proposed rule, we announced two options that we might use to expand the postacute care transfer provision and solicited comments and additional methodologies from commenters. The first method we proposed was to expand the postacute care transfer provision to all DRGs. The second proposal was to expand the provision to an additional 13 DRGs (We selected 10 DRGs using the same methodology we used in the July 31, 1998 final rule. Three of these 10 additional DRGs were paired, making the total 13.). However, expanding the postacute care transfer policy in this limited manner would retain many of the potential inequities of the current system.

As discussed further in the specific comments and responses that follow, we are not expanding the discharge to postacute care provision to additional DRGs for FY 2003. We believe the commenters have raised many issues regarding the impact of expanding this policy that we need to consider carefully before proceeding. In particular, due to the limited time between the close of the comment period and the required publication date of August 1, we were unable to completely analyze and respond to all of the points that were raised. However, we will continue to conduct research to assess whether further expansion of this policy may be warranted for FY 2004 or subsequent years and, if so, how to design any such refinements.

Comment: Many commenters argued that, in a system based on averages, expansion of the postacute care transfer policy negatively influences, and in fact penalizes, hospitals for efficient care. They claimed that this policy indiscriminately penalizes hospitals for efficient treatment and for ensuring that patients receive the right care at the right time in the right place. They believed that the postacute care transfer provision creates a perverse incentive for hospitals to keep patients longer.

Commenters also stated their concern that the expansion of the transfer provision violates the fundamental principle of the Medicare DRG payment system. The system is based on payments that will, on average, be adequate. These commenters argued that expansion of the transfer policy would give the system a per-diem focus and would mean that hospitals would be paid less for shorter than average lengths of stay, although they would not be paid more for the cases that are longer than average (except for outlier cases). One commenter suggested that if we expand the transfer rule, we should adopt a policy to pay more for long-stay cases.

Response: The Conference Agreement accompanying Public Law 105–33 states 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 [prospective payment system] payments in a manner that accounts for reduced hospital lengths of stay because of a discharge to another setting.'' The current postacute care transfer policy adjusts payments to hospitals to reflect the reduced length of stay arising from the shift of patient care from the acute care setting to the postacute care setting. In addition, because Medicare also often pays for the postacute care portion of beneficiaries' care, the transfer policy appropriately adjusts hospitals' payments to avoid duplicate payments for the care provided during a patient's episode of care.

However, we are not expanding the postacute care transfer policy in this final rule because we are not able to completely respond to all of the points raised by commenters prior to publication of the final rule. Specifically, we intend to undertake a more comprehensive analysis of the impact on the averaging aspects of the prospective payment system if this policy were to be expanded. We agree with the commenters that the transfer policy should not hamper the provision of effective patient care, and any future expansion will consider both the need to reduce payments to reflect cost-shifting due to reductions in length of stay attributable to early postacute care transfers and the need to ensure that payments, on average, remain adequate to ensure effective patient care.

Comment: Commenters believed that the proposal to expand the postacute care transfer policy would place an additional administrative burden on hospitals and would expand the liability of hospitals for decisions that are not in their control, particularly after the patient has gone home. In cases where an acute care hospital is unaware that a patient has been sent to a postacute care facility or is receiving home health care, the commenters argued that it should not be the burden of the hospital to obtain that information.

Response: As stated previously, we are not expanding the postacute care transfer policy at this time. In response to the point raised by the commenter, with respect to our current policy, in those cases where the hospital discharges a beneficiary to home and the beneficiary subsequently receives postacute care, without the hospital's knowledge, the incorrect discharge code will not be considered fraudulent. However, if the hospital has knowledge of the beneficiary receiving postacute care after discharge, the hospital is responsible for submitting the claim as a transfer or submitting an adjustment bill.

Comment: Some commenters noted that, although the statute clearly states that the Secretary is authorized to expand the postacute care transfer policy to additional DRGs, the Secretary is not required to do so. These commenters pointed to the policy decisions made in FY 2001 and FY 2002 not to expand the policy and encouraged CMS to make the same policy decision for this and all subsequent years, calling the proposed expansion unjustified and unreasonable.

Several commenters argued that, although the Secretary does have authority to expand the postacute care transfer provision, the Secretary was not given the authority to expand the provision to all DRGs. Section 1886(d)(5)(J)(iv) of the Act provides that the Secretary may extend the policy to additional DRGs with high volumes of discharges to postacute care settings. Commenters noted that not all DRGs meet this criteria.

Response: We agree that we are not required by section 1886(d)(5)(J)(iv) of the Act to expand the transfer provision beyond the 10 DRGs currently covered under the policy. However, the statute clearly indicates that the policy may be expanded further, as appropriate. Whether the policy should be expanded to all DRGs or a few will be considered in future analysis.

Comment: Several commenters believed that the impact of the expansion of the postacute care transfer needs to be considered more thoroughly and noted that the impact of such an expansion was not included in the proposed rule impact tables. These commenters were concerned that the overall effect of implementing either of the two proposed expansions would result in an overall decrease in per case payments in FY 2003. Commenters believed this expansion would disproportionately harm teaching hospitals that treat the most costly and complex cases within each DRG. They further charged that this policy would interfere with good clinical decisionmaking.

Response: We did not analyze the postacute care transfer policy in the impact tables in the proposed rule because we did not propose a specific policy expansion. We did include overall savings estimates attributable to the provision in the preamble discussion. The full impact of any proposed expansion of this policy, including the impacts on specific categories of hospitals, would be considered fully before proceeding to expand the policy in the future.

Comment: Many commenters strongly opposed the proposal to expand the postacute care transfer policy to all DRGs. Several commenters suggested that we repeal the original 10 DRG postacute care transfer policy provision, on the grounds that, through experience, hospitals have learned to operate more efficiently and seek best practices in patient care management. Therefore, the prospective payment system has met its objectives and lengths of stay have been reduced. In addition, the commenters noted that the lower length of stay achieved is better for patients due to lower risk of acquiring a nosocomial infection and better recovery rates at home. Therefore, the commenters argued, hospitals that have shortened the length of stay across all DRGs should not be punished by a reduction in payment amounts to per diem rates. As such, the commenters argued that premature discharges should be identified through the Quality Improvement Organization review process and not by the prospective payment system.

Response: We agree that shorter lengths of stay are better for patients in general and that more efficient hospitals should not be penalized for greater than average efficiency. In the July 31, 1998 final rule implementing the policy for the current 10 DRGs, we included analysis showing that, across virtually all lengths of stay for each of the 10 DRGs, Medicare paid in excess of costs even after the implementation of this provision. We also note that we do not believe the intent of this policy was to require a change in physician clinical decisionmaking, nor in the manner in which physicians and hospitals practice medicine. Rather, it simply addresses the appropriate level of payments once those decisions have been made, so the intent of the policy was to avoid overpayments. We agree with the commenter that an appropriate mechanism to identify premature discharges is the quality review process. As we have noted above, we will consider fully all of the financial implications on hospitals before proceeding to expand the policy in the future.

Comment: Some commenters stated that there is no longer any justification to expand the postacute care policy, particularly to all DRGs. Commenters argued that expansion is unjustified because at the time the original policy was implemented, data showed that lengths of stay were dropping and that use of postacute care was increasing. The commenters indicated that, since that time, inpatient length of stay has stabilized and Medicare spending on postacute care has slowed. In addition, any incentive hospitals may have had to discharge patients early to a postacute care facility has been removed now that Medicare also pays these facilities under prospective payment systems.

In addition, commenters stated that neither CMS nor its contractor, HER, has provided data to support the assumption that hospitals are benefiting financially from short-stay postacute care transfer cases. In fact, commenters noted that the HER report included one table that suggests the opposite is true. As described by the commenters, Table 4–8 in the HER report shows the average cost of short-stay cases in the 10 DRGs currently subject to the payment reduction. As shown by this table, short-stay postacute transfer cases are 7.4 percent more costly than short-stay nonpostacute care transfer cases. As a result, the commenters asserted that postacute care transfer cases are significantly less profitable than the non-postacute care transfer cases.

Response: While it is true that postacute care providers such as skilled nursing facilities, home health agencies, and rehabilitation hospitals are now paid under prospective payment systems rather than cost-based payment systems, the acute hospital still has an incentive to discharge patients as soon as possible. The impact of expanding prospective payments to other settings is that it changes the incentives for those providers in terms of their willingness to continue to accept patients needing a more acute level of

care, because sicker patients are more likely to have above average costs. There is no impact on the incentives of acute care hospitals.

We point out that the analysis prepared by HER was undertaken as an evaluation of the original policy, conducted in 2000 based on partial FY 1999 data. With respect to HER's finding that patients transferred for postacute care are more expensive than cases discharged home, one would expect cases receiving followup care to be sicker and require more resources. In fact, the postacute care transfer policy was implemented out of concern that these patients were being transferred out of the acute care setting much earlier in the course of their treatment than had previously been the case, and that some of the acute care portion of the patients' hospitalization was being provided by the postacute care facility. Because the acute care hospital was receiving the full DRG payment and the postacute care facility was receiving higher cost-based reimbursement, the Medicare program was paying, in essence, two facilities for the acute care of the patient.

Comment: Commenters noted that in the proposed rule CMS quoted five points from the HER report that supported an expansion of the provision, but did not include the section of the HER report that lists the arguments against expansion. The commenters included this list of HER's arguments against expansion:

- Expansion to all DRGs would require multiple per-diem payment policies. The current ten DRGs require two distinct payment methodologies to ensure equitable reimbursement. A policy covering all DRGs might require many more methodologies.
- The policy would be irrelevant for many DRGs. Many DRGs have few or no cases that are discharged to postacute care.
- Expansion to all DRGs would have relatively high costs compared to the benefits. There is little benefit to extending the policy to the many DRGs with low postacute care volume. The cost of requiring that fiscal intermediaries implement and audit compliance with the policy for these DRGs would dilute the overall benefit to the program.
- It would be difficult to identify unrelated postacute care cases prior to admission. If a patient is under postacute care before admission and then returns to that care after an unrelated admission, the transfer policy does not apply. With many more DRGs, CMS and hospitals would have more work sorting out the unrelated admissions.
- Many DRGs are ''inhomogeneous.'' HER cautioned that payment under the postacute care transfer policy would be inequitable for ''inhomogeneous DRGs'' that contain two or more distinct types of cases with disparate lengths of stay.

Response: The negative points raised above were included in our report of HER's analysis in the August 1, 2000 final rule (65 FR 47081). We note that in the final rule we also referred readers to where they could obtain a copy of the complete report.

Comment: Commenters analyzed the 13 DRGs identified in the proposed rule for possible partial expansion of the postacute care transfer policy using information derived from the FY 2000 MedPAR data. The commenters reported that many of the DRGs are inhomogeneous, including a wide variety of cases, some of which may be susceptible to early transfer and some of which may not.

Response: We are not adopting either of the methodologies for expanding the postacute care transfer policy at this time. However, if in the future we should consider expanding the policy, we will consider the effect of inhomogeneity in any DRGs we select.

Comment: Some commenters believed that the current system is inequitable. However, they argued that targeting 13 additional DRGs would only worsen the problem, and extending the policy to all DRGs is not an acceptable response. Commenters urged us to work to have the policy repealed altogether or at least to revise the policy to make it more equitable. For example, commenters noted that DRG 483 (Tracheostomy except for face, mouth and neck diagnoses), which is included under the current policy, has an average length of stay of 35 days. Commenters noted that the variation around the average is quite high, and that patients requiring this procedure and level of care almost always require postacute care. Therefore, commenters contended, because the variation around the average is so large, and the per diem cost for this DRG is well above average, the postacute care transfer policy has a very significant impact on payment that is unrelated to the use of postacute care services. These commenters urged us to reconsider the current policy because they believed that the logic of applying the standard per diem methodology to this DRG is flawed. They urged us either toreplace this DRG with another one on its high-volume postacute care transfer list or change the payment method to one that addressed the length of stay volatility.

Response: We believe the current policy remains an appropriate response to reductions in length of stay resulting from shifting care out of the acute hospital setting. However, as noted above, we do have concerns about limiting it to 10 specific DRGs. We will continue to closely monitor the data to assess whether future expansions or refinements are needed. With respect to the inclusion of DRG 483 in the current 10 DRGs covered by the postacute care transfer policy, in the July 31, 1998 final rule we responded to a similar comment (63 FR 40981). Our analysis showed this DRG was appropriate to include under the policy. Over 45 percent of discharges from this DRG were to postacute care, and it was ranked ninth in terms of volume of cases receiving postacute care. These factors qualify it for inclusion in the postacute care transfer policy under section 1886(d)(5)(J) of the Act.

Comment: One commenter contended that expanding the postacute care transfer provision would distort the meaning of a transfer case. According to the commenter, a transfer is a case that has been admitted to one hospital and is stabilized there, but which is then sent to another acute care hospital for treatment that the first hospital was not equipped to provide. The commenter further explained that patients discharged to postacute care, in contrast, have completed the acute care phase of their treatment and need postacute care either to assist their convalescence or to manage a chronic illness. The commenter contended that these are very different concepts.

Response: Under the acute inpatient prospective payment system, payments to the transferring hospital are reduced to reflect the fact that the patient is transferred prior to receiving the full course of treatment from the acute hospital. When Congress established the postacute care transfer policy, it did so in recognition of the fact that hospitals were transferring patients who still had acute symptoms into the postacute care setting for the remainder of their care. Therefore, the principle that the transferring hospital did not provide the full course of treatment is consistent under both the preexisting policy and the postacute care transfer policy.

Comment: One commenter claimed that the special payment formula for a transfer from DRG 209, 210 and 211 often results in less payment than the flat per diem method. The commenters provided an example assuming that a DRG with a payment of $10,000 and an average length of stay of 5 days received a per diem rate of $2,000. For a transfer case with a stay of 4 days under the

standard per diem transfer payment, the payment rate would be $10,000 ($4,000 for the first day and $2,000 for each of the next 3 days). The commenter argued that, under the special transfer payment policy, the payment rate would be only $8,000 ($5,000 for the first day and $1,000 for each of the next 3 days). The commenter recommended that we increase the percentage of the per diem paid on days after the first day to 75 percent of the per diem under the special payment method.

Response: Under § 412.4(f)(2), payment for a postacute care transfer case from DRGs 209, 210, or 211 is equal to 50 percent of the appropriate prospective payment rate for the first day of the stay, and 50 percent of the amount the hospital would receive under the standard transfer payment methodology. Thus, the example provided by the commenter is not correct. The payment would be the full $10,000 if the patient was transferred on the fourth day. Rather than receiving $5,000 for the first day, the hospital in the example would receive $7,000 (50 percent of the full DRG payment equals $5,000, plus 50 percent of the standard transfer payment equals $2,000, because the standard transfer payment is double the per diem for the first day of a transfer stay). The hospital would receive $1,000 for each of the next 3 days, resulting in total payments under this special transfer payment rule equal to $10,000 on day 4.

This example also demonstrates that, if the patient stay is one day shorter than average, the hospital receives the full DRG rate. Using both postacute care transfer payment methodologies, the hospital would receive the full DRG amount if the patient stay is one day shorter than the national average.

Comment: One commenter suggested that we determine if the administrative resources we are using to recalculate a hospital's payment under this policy are actually saving the Medicare program money or if a greater amount of administrative resources are spent to recover the payment differential for the transferred beneficiary. The commenter stated that we should not expand a ''cost-savings'' policy that fails to result in true savings.

Response: Currently, the transfer payment calculation is made at the time a claim is processed based on the discharge status code assigned by the hospital to the patient at the time of discharge. Therefore, there is no recalculation, and thus the administrative costs associated with this policy are marginal, as long as hospitals appropriately code the patient's discharge status.

Comment: Another commenter recommended that the postacute care transfer issue be addressed from a total system perspective, centered on meeting the patients' needs and include referral dynamics from the new postacute care prospective payment systems. The commenter also suggested that there should be an analysis of the medical versus payment dynamics of the 3-day prior hospitalization requirement for postacute care coverage.

One commenter suggested that we expand the postacute care transfer policy to include swing beds. The commenter pointed to the ease with which hospitals may move these swing beds from one care setting to another, suggesting that it would be easy for hospitals with swing beds to get around the existing transfer policy.

Response: We will take these suggestions into consideration as we continue to monitor the transfer policy. With respect to expanding the policy to include transfers to swing beds, we indicated in the July 31, 1998 final rule that we elected not to include swing beds under this policy because of the potential adverse impact on small rural hospitals. At this time, we are not changing this policy, although we will continue to evaluate whether it is appropriate to exclude transfers to swing beds from the postacute care transfer policy.

Comment: One commenter recommended waiting at least 3 years before expanding the transfer policy to provide for sufficient time for the entire continuum of care to reach equilibrium. In addition, the commenter indicated that when independent groups analyzed internal data on the 10 DRGs initially identified in the existing postacute care transfer policy, they found only 3 where there were significant numbers of transfers to postacute care. The commenter recommended reanalyzing the current policy to determine whether volume and disposition of the DRGs still require the policy. Some commenters stated that the perceived ''gaming'' hypothesis does not exist, meaning that hospitals are not cutting short patient care in order to make more money. Another commenter suggested that we monitor the recalibration of DRG weights, noting that if patients are being discharged too soon, these premature discharges would be reflected in frequent readmissions to the hospital, would increase the acuity of postacute care providers, and would lower the charges for acute stays. Earlier discharges will ultimately result in lower weights for associated DRGs. The commenter indicated that we could then easily monitor readmissions and acuity of postacute care treatment to target problem providers.

Response: We will examine these and other issues in future analysis of this issue. With respect to the treatment of transfers in DRG recalibration, we note that a transfer case is counted as only a fraction of a case toward DRG recalibration based on the ratio of its transfer payment to the full DRG payment for nontransfer cases. This ensures the DRG weight calculation is consistent with the payment policy for these 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 excluded 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)) in the types of cases paid under the general rule for transfer cases. In the May 9, 2002 proposed rule, we proposed 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 proposed to correct this error by revising § 412.4(f)(1) to provide that only the circumstances described in paragraphs (b)(1) and (c) of § 412.4 are paid as transfers under the general transfer rule.

We did not receive any public comments on this proposal. Therefore, we are adopting the proposed revisions of the regulations text as final. This correction reflects 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 regarding 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 payment options will yield the highest rate of payment for an SCH.

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.

We did not receive any comments on this clarification.

2. SCH Like Hospitals

Section 1886(d)(5)(D)(iii) of the Act provides that, to qualify as an SCH, a hospital must be more than 35 road miles from another hospital. In addition, there are several other conditions under which a hospital may qualify as an 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 an 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, an 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, in the May 9, 2002 proposed rule, we proposed 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 SCH. We believe the percentage of overlapping services between the SCH and the limited service facility 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 proposed that this percentage be set at 3 percent.

In the May 9, 2002 proposed rule, we solicited public comments on alternate appropriate levels of service overlap, as well as on the overall proposed change to the definition of like hospitals.

In response to comments as discussed below, we are adopting inpatient days as the unit of measurement for determining whether a hospital applying for SCH status can exclude from consideration as a like hospital another hospital within its service area (rather than services, as discussed in the proposed rule). The threshold would be set so that a hospital with total inpatient days of 8 percent or less compared to an SCH (or SCH applicant) would not be considered a like hospital for purposes of SCH designation.

We believe that Medicare inpatient days are a good proxy for service overlap. However, we will assess the impact of the overall change to the definition of like hospital and the service overlap proxy on SCHs and the prospective payment system. This assessment will determine whether refinements to this policy may be necessary in future years.

Comment: Many organizations commented on this proposal. Most supported it, but to varying degrees, because there is additional information they believe they need in order to better evaluate the proposal. The commenters noted definitions are needed for terms such as ''services'', ''overlap'', and ''provided services''. They also indicated that the data source (such as hospital cost reports or actual claims experience) and the methodology for measuring the services need to be defined and requested clarification of these issues in the final rule.

For example, commenters asked how CMS will measure overlap of services between the specialty hospital and the SCH (or SCH applicant). Would there be a weighting for volume or the volume capacity of the limited service specialty hospital? Would it be 3 percent of service lines (for example, obstetrics, cancer care, or cardiac services), or discharges, or DRGs reported?

Response: We appreciate the many helpful comments we received on this proposal. We proposed a 3-percent threshold of service overlap in an attempt to strike a balance between the need to ensure that SCHs do not lose their special status due to specialty hospitals opening nearby and the need to ensure that only hospitals that are the sole source of short-term acute hospital services for their community qualify as SCHs. We were concerned not to set the threshold too high because we wanted to ensure that only hospitals that truly are the sole source of care for their community continue to qualify as SCHs. Based on the comments we received, we are adopting alternative criteria, as described below. Adoption of this alternative criteria, comparing inpatient days, renders moot many of the questions raised by the commenters discussed above.

Comment: Some commenters pointed out that specialty hospitals take away profitable services that subsidizes other critical services such as emergency room service, intensive care unit services, skilled nursing care, and home health and hospice care furnished by the hospitals that typically qualify as SCHs.

These commenters believed SCH status was instituted to allow these types of providers the ability to provide access to a full range of services for Medicare patients, and that, as a result, these SCHs need to be protected.

One commenter requested that we require a hospital, to be considered a like hospital for purposes of SCH determinations, to provide, on an ongoing basis, all of the services typically furnished by an SCH, such as 24-hour emergency service and surgery and obstetrics services.

Some commenters recommended that the services provided by a limited-service specialty hospital should be defined so that, if the hospital had the capability of providing a service such as emergency service but was not staffed for 24-hour emergency service, was staffed only to the extent of referring its emergency patients to the SCH, or provided only its specialty-related emergency service, the hospital would not be considered to be furnishing emergency services, and, as a result, the hospital would not be considered a like hospital.

Other commenters did not believe that percentages of specific DRGs or a similar calculation of limited services would be a fair and equitable method of determining SCH status, particularly when considering whether a hospital with SCH status should be permitted to retain such status.

One commenter supported the proposal to amend the definition of SCH like hospitals to exclude any hospital that offers a very limited range of services. However, the commenter did not support the percent-of-services methodology. The commenter stated that the administrative burden associated with making this determination would be too great for both providers and intermediaries.

Response: Our proposal was intended to measure the extent of overlapping services because this would seem to be a useful indicator to determine whether another hospital in the community offers a plausible alternative to the SCH for residents in the area seeking inpatient acute care. For example, the existing regulations contemplate situations where hospitals with fewer than 50 beds may become eligible for SCH status despite the location of an otherwise like hospital within 35 miles, if the community hospital would admit at least 75 percent of the area residents who become inpatients were it not for the fact that some beneficiaries or residents were forced to seek care outside the service area due to the unavailability of necessary specialty services at the community hospital (§ 412.92(a)(1)(ii)).

Section 2810.B.3.d. of the Provider Reimbursement Manual contains instructions for excluding services not offered by the SCH applicant from the determination of whether the applicant admits at least 75 percent of the area residents who become inpatients. Under this process, the hospital obtains information as to the diagnoses of and services furnished to those residents or Medicare beneficiaries who obtained care outside the SCH applicant hospital's service area during the survey period.

In connection with the policy we proposed in the May 9, 2002 proposed

rule, we contemplated using a similar process to determine whether a limited-service specialty hospital should be excluded from the definition of like hospitals. However, we recognize that this process would be labor and data intensive. As a result, we were interested in evaluating the recommendations submitted by commenters.

Comment: Several commenters suggested using Medicare inpatient days in hospital units subject to the acute care hospital inpatient prospective payment system to identify whether a limited-service specialty hospital is likely to offer many of the services also offered by the SCH. Thus, for example, a specialty hospital that only provides orthopedic surgery with a 1-day recovery period would have its service weighted to reflect the limited intensity of such services.

Commenters believe that using Medicare inpatient days would allow easy administration by both CMS and its fiscal intermediaries, because these data are readily available in hospital cost reports. They believed that by considering only inpatient days in units subject to the acute care hospital inpatient prospective payment system, the focus would be limited only to those services germane to the general acute care needs of the Medicare community. Other commenters suggested using actual gross payments for Part A services to Medicare beneficiaries as the unit of measurement for services provided.

Response: We agree with the commenters who proposed using inpatient days as the comparative statistic to determine whether a limited-service specialty hospital may be excluded from the like hospital definition. Although DRGs provide a comparison that more closely reflects service overlap, we believe that we will attain a similar outcome, with less administrative complexity, by comparing inpatient days. Accordingly, we are adopting patient days attributable to units that provide a level of care characteristic of the level of care payable under the acute care hospital inpatient prospective payment system as the unit of measurement for determining whether a hospital applying for SCH status can exclude from consideration as a like hospital another hospital within its service area. The number of inpatient days is readily available from all participating hospitals because it is already captured on the cost report.

We believe that Medicare inpatient days are a good proxy for service overlap. However, we will assess the impact of the overall change to the definition of like hospital and the service overlap proxy on SCHs and the prospective payment system. This assessment will determine whether refinements to this policy may be necessary in future years.

Comment: The commenters were in agreement that the overlapping services threshold of 3 percent was too low and would not accomplish our intent of distinguishing specialty hospitals from full-service acute care hospitals. Alternative suggestions included overlapping services thresholds of 8 percent, 10 to 15 percent, and setting the threshold after evaluating actual data. One commenter stated that adopting less than a 10-percent overlap threshold would not protect existing SCHs from losing their special status as a result of a limited-service specialty hospital opening in their community.

Commenters offered the example where a heart hospital or other niche provider may perform inpatient services that represent closer to 10 or 15 percent of the services performed by SCHs. In this situation the SCH continues to remain the sole source of the full range of acute care services in the community, including essential emergency services, and thus deserves to retain SCH status. However, if the specialty hospital is considered a like hospital, it would jeopardize the special status of the SCH.

One commenter referred to the regulations, where, to qualify for SCH status, a hospital with another like hospital within 25 to 35 miles cannot have more than 25 percent of the admissions of residents within its service area admitted to other hospitals (§ 412.92(a)(1)(i)). The commenter suggested that, where the focus is on specialty hospitals that are not like hospitals, a threshold on the order of one-third of that 25-percent threshold would seem appropriate. The commenter suggests that a specialty hospital with only 8 percent service overlap with the community hospital would not be able to service the community's acute care needs.

Response: As stated above, based on our evaluation of the public comments and the situations, of which we are aware, where an existing SCH's special status is being threatened by a nearby limited-service specialty hospital, we believe the best approach would be to revise our proposed definition of like hospital for SCH purposes to exclude any hospital where the inpatient services overlap compared to the SCH (or the SCH applicant) is less than 8 percent, as measured by inpatient days.

The inpatient services would be measured by total inpatient days as reported on the hospitals' cost report, and should include all days attributable to units that provide a level of care characteristic of the level of care payable under the acute care hospital inpatient prospective payment system. We believe setting the threshold at 8 percent would distinguish the specialty hospitals, which have very limited inpatient use and, therefore, limited inpatient days, from general, acute care hospitals typical of SCHs. Therefore, we are revising proposed § 412.92 (c)(2) to reflect this change.

To determine whether a hospital qualifies as an SCH, the fiscal intermediary would make a determination whether a nearby hospital paid under the acute care hospital inpatient prospective payment system is a like hospital by comparing the total acute inpatient days of the SCH applicant hospital with the total acute inpatient days of the nearby hospital. If the total acute inpatient days of the nearby hospital is greater than 8 percent of the total inpatient days reported by the SCH applicant hospital, the hospital is considered a like hospital for purposes of evaluating the application for SCH status. If the total acute inpatient days of the nearby hospital is 8 percent or less of the total acute inpatient days of the applicant hospital, the nearby hospital is not considered a like hospital for purposes of evaluating the application for SCH status under § 412.92.

Comment: Some commenters questioned the effective date of the proposal because they see the definition revision as a clarification of existing legislation that should be treated as such, applying to all open matters, not prospectively only.

Response: This change is a revision to our current policy for defining like hospitals. Therefore, it is being implemented prospectively, starting with cost reporting periods that begin on or after October 1, 2002.

Current regulations establish that an approved SCH classification remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved (§ 412.92(b)(3)). It will be necessary, therefore, in situations where a SCH's eligibility is contingent on a nearby hospital being excluded from the like hospital comparison under this provision, for the fiscal intermediary to reevaluate periodically whether the exclusion is still appropriate, based on the most current inpatient days data.

In the event that a new, limited-service specialty hospital opens within the service area of an existing SCH, the

fiscal intermediary will monitor the number of patient days at the two hospitals to ensure that the specialty hospital does not exceed the 8 percent threshold.

Comment: Some commenters stated that, without understanding how the test actually would be conducted, what data would be used, and why a 3 percent threshold was selected, interested parties could not provide us with thoughtful, helpful comments. Accordingly, they recommended that we not finalize our proposal at this time. Instead, we should clarify our proposal and resolicit comments. In the interim, these commenters believed that we should grandfather SCH status for all existing SCHs while it further developing this policy. Similarly, several commenters suggested we further evaluate and develop this proposal and present it for public review and comment before finalizing the proposal.

One commenter stated that we should also consider adopting an altogether different approach. Rather than implement an objective, one-size-fits-all approach, we should instead develop review guidelines for our Regional Offices, and allow these Regional Offices to make case-by-case, fact-specific determinations using the guidelines. Such guidelines could, for example, utilize a quantitative evaluation, similar to what we proposed. In addition, Regional Offices could be directed to examine whether area beneficiaries have a choice in the area for general-acute care hospital services.

Response: We believe that, based on our understanding of the situations of which we are aware involving an SCH whose special status is being jeopardized by the opening of a limited-service specialty hospital in its service area, and similar situations described in the comments we received, an 8-percent threshold for the comparison of inpatient days as described above is appropriate. We are concerned that a case-by-case approach would result in inappropriate disparities across geographic areas in terms of how applications are reviewed.

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, in the May 9, 2002 proposed rule, we proposed 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.)

We did not receive any comments on this technical change.

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.

As discussed in Federal Register documents at 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 considered as a rural referral center for FY 1998 and later years so long as that hospital continues to be located in a rural area and does not voluntarily terminate its rural referral center status. Otherwise, a hospital seeking rural referral center status must satisfy applicable criteria.

Also, effective October 1, 2000, if a hospital located in what is now an urban area was ever a rural referral center, it was reinstated to rural referral center status (65 FR 47089).

One of the criteria under which a hospital may qualify as a rural referral center is to have 275 or more beds available for use (§ 412.96(b)(ii)). A rural hospital that does not meet the bed size requirement can qualify as a rural referral center if the hospital meets two mandatory prerequisites (a minimum case-mix index and a minimum number of discharges) and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume) (§ 412.96(c)(1) through (c)(5)). 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 for FY 2003 in the May 9, 2002 proposed rule included all urban hospitals nationwide, and the proposed regional values for FY 2003 were 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 were 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.

In the May 9, 2002 proposed rule, we proposed 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. (See the table set forth in the May 9, 2002 proposed rule at 67 FR 31460).

Based on the latest data available (FY 2001 bills received through March 31, 2002), 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 2002 that is at least—

- 1.3225; 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 final 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)	1.2044
2. Middle Atlantic (PA, NJ, NY)	1.2247
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.3014
4. East North Central (IL, IN, MI, OH, WI)	1.2345
5. East South Central (AL, KY, MS, TN)	1.2418
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.1621
7. West South Central (AR, LA, OK, TX)	1.2595
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.3162
9. Pacific (AK, CA, HI, OR, WA)	1.2785

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). FY 2001 is the latest year for which we have complete discharge data available.

Therefore, in the May 9, 2002 proposed rule, we proposed 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. (See the table set forth in the May 9, 2002 proposed rule at 67 FR 31460.)

Based on the latest discharge data available for FY 2001, the final median number of discharges for urban hospitals by census region areas are as follows:

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	6,905
2. Middle Atlantic (PA, NJ, NY)	8,644
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	8,893
4. East North Central (IL, IN, MI, OH, WI)	7,890
5. East South Central (AL, KY, MS, TN)	6,953
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	5,696
7. West South Central (AR, LA, OK, TX)	6,226
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.

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

We did not receive any comments on the criteria for rural referral centers.

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) (to be redesignated as § 413.86(g)(9)) 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 a 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 final notice published in the **Federal Register** on 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 regulations provide for the cap on the number of residents to be 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 could 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 number of 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.

In the proposed regulation, we revisited this policy and explained 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 actual FTE count decreases as the displaced residents finish their training. Therefore, the receiving hospital would not need a higher resident-to-bed ratio in the prior year to accommodate the remaining FTEs. Consequently, the higher resident-to-bed ratio cap in fact would not benefit the receiving hospital. Thus, in the May 9, 2002 proposed rule, we proposed 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 proposed 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, as we explain below in response to a comment, in this final rule we are revising the proposed language of § 412.105(a)(1)(iii) to state that the exception to the resident-to-bed ratio cap for closed hospitals and closed programs applies only through the end of the first 12-month cost reporting period in which the receiving hospital trains the displaced FTE residents. We further 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 proposed 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 explained that because we proposed 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 proposed 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, which was reflected in proposed revised § 412.105(a)(1).

Comment: Numerous commenters expressed support for our proposal to allow an adjustment to the resident-to-bed ratio cap for residents displaced by the closure of another teaching hospital or another hospital's GME program. One commenter added that, although the proposed adjustment to the resident-to-bed ratio in the first year would equitably reimburse hospitals who commence training the displaced residents at the beginning of their respective fiscal year, this adjustment would result in the receiving hospital being under-reimbursed in the first full year of residency training when a hospital or program closes toward the end of the receiving hospital's fiscal year. The commenter requested that CMS correct this inequity by extending the resident-to-bed ratio cap adjustment to include both the first partial and the first full year of training displaced residents at the receiving hospital.

Response: We agree with the commenter that our proposal to limit the adjustment to the resident-to-bed ratio cap to the first (cost reporting) year in which the receiving hospital is training the displaced residents may result in reduced payments to the receiving hospital if the receiving hospital begins training those residents at some point other than the beginning of a full fiscal year. Therefore, in this final rule, we are revising the language proposed under § 412.105(a)(1)(iii) to state that the exception to the resident-to-bed ratio cap for closed hospitals and closed programs applies through the end of the first 12-month cost reporting period in which the receiving hospital trains the displaced FTE residents. We note that the effective date of this revised policy is for cost reporting periods beginning on or after October 1, 2002.

For example, if receiving Hospital A has a fiscal year end (FYE) of December 31, 2003, and it begins training 3 displaced residents on November 1, 2003, for purposes of applying the resident-to-bed ratio cap, receiving Hospital A may add a 2 months' proportion of the 3 FTEs to the numerator of the resident-to-bed ratio cap from the prior cost reporting period (FYE December 31, 2002). Receiving Hospital A may also add the FTEs that continue training at the hospital during its cost reporting period ending December 31, 2004 to the numerator of the resident-to-bed ratio cap from the FY 2003 cost reporting period. However, no adjustment may be made for purposes of applying the resident-to-bed ratio cap for subsequent years. Other than the allowance for applying the resident-to-bed ratio cap adjustment through the end of the first 12-month cost reporting period in which the receiving hospital trains the displaced

residents, the policy is the same as that in the proposed rule.

Comment: One commenter commended CMS for realizing that it would be appropriate to allow eligible hospitals to receive a temporary adjustment to the application of the IME resident-to-bed ratio cap. However, the commenter believed that in lieu of the rationale that CMS utilized in drafting the regulation published on August 1, 2001 and to avoid penalizing eligible hospitals, CMS should apply a retroactive effective date of October 1, 2001 to this policy.

Response: We understand the commenter's concerns, and in proposing this policy, we acknowledged the need to allow for the temporary adjustment to the resident-to-bed ratio cap. However, because we do not have explicit statutory authority to do so, we are unable to apply this policy retroactively. Therefore, the effective date of this policy will be prospective; that is, for cost reporting periods beginning on or after October 1, 2002.

Comment: Some commenters asserted that the proposal requiring that the resident-to-bed ratio cap be calculated in the cost reporting period following the departure of the last displaced residents as if the displaced residents had not trained at the receiving hospital in the prior year, adds more complexity to an already burdensome IME calculation. The commenters stated that the number of residents likely to be involved with this provision is minimal, and accordingly, CMS should not finalize this provision.

Response: As we have explained in the proposed rule, we believe that in light of the addition of FTEs to the resident-to-bed ratio cap in the first full cost reporting period, it is equitable to remove those FTEs when calculating the resident-to-bed ratio cap in the year following the departure of the displaced residents. We disagree that requiring that the resident-to-bed ratio cap be calculated in the cost reporting period following the departure of the last displaced residents as if the displaced residents had not trained at the receiving hospital in the prior year is overly burdensome. It requires only a simple subtraction of FTEs from the numerator of the prior year ratio, and in the next issuance of the Medicare cost report instructions, we will be making a revision to the instructions for line 3.19 of Worksheet E, Part A of the cost report to reflect this policy.

Comment: One commenter was concerned about our proposal to adjust ''the numerator of the prior year's resident-to-bed ratio *by the number of FTE residents that has caused the receiving hospitals to exceed its FTE cap''* (emphasis added) (67 FR 31461, May 9, 2002). The commenter stated that, by describing the increase in the numerator in relation to the hospital's FTE cap, the intent of the provision will not be fulfilled unless the hospital is already at its FTE cap. The commenter explained that if, for example, Hospital A has 4 residents in both cost reporting years 2002 and 2003, has a FTE cap of 5 FTEs, and accepts 3 displaced residents in 2003, it exceeds the FTE cap by only 2 residents. Therefore, as proposed, the adjustment to the prior year resident-to-bed ratio would result in a ratio cap of 0.06 ((4+2)/100). The current year resident-to-bed ratio would be 0.07 ((4+3)/100). Since this exceeds the hospital's prior year resident-to-bed ratio, the resident-to-bed ratio for Hospital A will be held to 0.06. The commenter concluded that since our intent is not to penalize hospitals that accept displaced residents, the adjustment to the prior year resident-to-bed ratio must not rely on the FTE cap for a reference point, but rather, must equal the number of displaced residents.

Response: The original regulations concerning temporary adjustments for hospital closure were written in response to requests from hospitals for an exception to the FTE cap, to allow the additional residents coming from a closed hospital to be counted by the receiving hospital (63 FR 26329 and 26329, May 12, 1998). Similarly, in the July 30, 1999 final rule (64 FR 41522), we explained that we adopted this provision because hospitals had indicated a reluctance to accept additional residents from a closed hospital without a temporary adjustment to their FTE caps. Accordingly, the existing regulations discussing hospital and program closure at § 413.86(g)(8) (§ 412.105(f)(1)(ix) for IME) state that ''a hospital may receive a temporary adjustment to its FTE cap to reflect residents added'' because of the closure of another hospital or another hospital's program. Furthermore, existing §§ 413.86(g)(8)(ii)(B) and (g)(8)(iii)(A)(*2*) require that, in order for a hospital to receive this temporary FTE cap adjustment, the hospital must document ''that it is eligible for this temporary adjustment by identifying the residents who have * * * *caused the hospital to exceed its cap.* * * *'' (emphasis added). These regulations are only applicable in instances where the training of displaced residents causes a hospital to exceed its FTE cap; if a hospital has room under its FTE cap to train these residents, no FTE cap adjustment is needed. Thus, in order for a hospital to qualify for an adjustment to its resident-to-bed ratio cap (or 3-year rolling average count), the hospital must first qualify for a temporary adjustment to its FTE cap. To qualify for a temporary FTE cap adjustment, the hospital must demonstrate that accepting some number of displaced residents has caused the hospital to exceed its FTE cap. Therefore, the proposed resident-to-bed ratio cap adjustment is necessarily linked to ''the number of FTE residents that has caused the hospital to exceed its FTE cap.'' Accordingly, we are not accepting the commenter's request at this time. However, we may consider in the future proposing to allow hospitals that are below their FTE caps and train displaced residents to also receive an adjustment for those displaced residents that are under the cap for purposes of applying the resident-to-bed ratio cap and the 3-year rolling average. As a final note, we would like to point out an error in the example that the commenter provided. In the example, a hospital that has 4 FTEs and an FTE cap of 5, accepts 3 displaced FTE residents. The commenter stated that the current year resident-to-bed ratio would be 0.07 ((4+3)/100). This is incorrect. Since, as explained above, the regulations prescribe that the receiving hospital's FTE count is only adjusted for those FTEs that have caused the receiving hospital to exceed its FTE cap, the current year numerator (as well as the prior year numerator) would be 6 (4+2), because only 2 of the 3 FTEs have caused the hospital to exceed its FTE cap of 5 FTEs.

Comment: One commenter requested CMS to allow hospitals that train displaced residents to receive permanent, not temporary, adjustments to their FTE caps.

Response: We are not addressing this comment in this final rule because it is outside the scope of what was specifically addressed in the proposed rule.

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

In the May 9, 2002 proposed rule, we discussed the regulations located at § 412.105(b) for determining the number of beds to be used in calculating the resident-to-bed ratio for the IME adjustment. Those 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.

We also discussed section 2405.3G of Part I of the Medicare Provider Reimbursement Manual (PRM), which further defines an ''available'' bed as a bed that is permanently maintained and is available for use to lodge inpatients.

These discussions were background for our proposal to clarify some of the uncertainty that had arisen concerning the application of the definition of ''available.'' For example, a question has arisen 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 proposed 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 stated that the 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 proposed 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 proposed to otherwise continue to determine a hospital's bed size using existing regulations and program manual instructions, including the application of the available bed policy.

We believe that the policy in the May 9, 2002 proposed rule more accurately indicates the size of a hospital's operations. We proposed to specify under § 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 proposed to make the proposed policy effective for discharges occurring on or after October 1, 2002.

Comment: Numerous commenters questioned why we were interested in applying an occupancy adjustment to counting beds for IME and DSH purposes. The commenters strongly opposed the proposed policy, which they indicated would serve to increase a hospital's IME payment but would limit a hospital's bed size for DSH payment purposes, if the hospital's occupancy is below 35 percent. In addition, the commenters believed that there are other reasons why a hospital may have excess capacity that may include patients utilizing the outpatient services instead of inpatient services, and that, due to cost, patients may be moved sooner from acute care settings to the next level of care.

The commenters contended that this proposal is contrary to the statutory language and congressional intent. The commenters further contended that the proposed policy would cause financial hardship to small urban hospitals that treat a disproportionate number of low-income patients.

MedPAC indicated that it believed that we are recognizing a real problem in maintaining integrity in the DSH payment procedures. However, MedPAC believed that the proposed policy illustrates the difficulties that arise when qualifying for DSH payments depends in part on the number of beds a hospital keeps in service. MedPAC recommended that a single formula apply to all hospitals regardless of location (urban/rural) or bed size. In addition, MedPAC recommended that the low-income shares used to determine each hospital's DSH adjustment reflect all low-income patients, which include patients receiving uncompensated care. MedPAC stated that a new DSH distribution formula will be needed when the uncompensated care data are complete, and that would be an opportune time to eliminate the use of a bed standard. Based on this information, MedPAC questioned whether it is worth changing the bed counting methodology now since a more fundamental change may occur in the next year or two.

Response: We believe our proposed policy represents a reasonable approach to addressing situations where hospitals appear to be maintaining excess capacity in order to qualify for higher DSH payments. With respect to our authority to implement such a change, we point out that we have broad authority under the statute in establishing the methodology for determining the number of available beds.

However, at this time, we have decided not to proceed with the proposed change. Instead, we will consider this issue as part of a future comprehensive analysis of our bed and patient day counting policies. That is, we believe there are other aspects of counting beds that need to be addressed as well and, upon further consideration, we have decided to proceed in a more comprehensive manner. We acknowledge MedPAC's comments as well and will take into account the potential that bed counting issues for DSH purposes may become less significant.

Accordingly, in this final rule, we are not adopting the proposed change of § 412.105(b)(3).

Technical Correction

Section 211(b) of Public Law 106–554 amended section 1886(d)(5)(F)(iv)(III) of the Act to revise the calculation of the DSH payment adjustment for hospitals affected by the revised thresholds as specified in section 211(a) of Public Law

106–554. These changes were effective for discharges on or after April 1, 2001, and no changes were made by section 211(b) for discharges prior to April 1, 2001. When we issued the June 13, 2001 interim final rule with comment period (66 FR 32172) to update the regulations to incorporate the changes made by section 211, we inadvertently changed the adjustment factor for rural hospitals with fewer than 100 beds from 4 percent to 5 percent under § 412.106(d)(2)(iv)(A) for discharges occurring before April 1, 2001. We are correcting this error in this final rule by revising § 412.106(d)(2)(iv)(A) to specify that, for discharges before April 1, 2001, the applicable DSH adjustment factor for rural hospitals with fewer than 100 beds was 4 percent.

This correction was not included in the May 9, 2002 proposed rule, as we were only made aware of it after publication of that proposed rule. The Administrative Procedure Act generally requires that agency rules be published in the **Federal Register** as a notice of proposed rulemaking with a period for public comment (5 U.S.C. 533(b)). This notice-and-comment procedure can be waived, however, if an agency finds good cause that the procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. Since this change is being made to correct a technical error, we find that the notice-and-comment procedure is unnecessary, and, therefore, find good cause to waive the notice of proposed rulemaking and issue the correction in this final rule.

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 (Pub. L. 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.

In the May 9, 2002 proposed rule, we proposed 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 proposed 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 included 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 proposed (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 proposed 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.

Comment: Three commenters addressed our proposal to conduct ongoing reviews of hospitals to determine whether or not they continue to meet the MDH criteria. The first commenter opposed the proposal for ongoing reviews of MDHs because this type of review is not specified in the law, but is an interpretation by CMS. The commenter supported its position by pointing out that a hospital qualifying based on the original criterion (that is, 1987 data) is allowed to retain this status despite any changes in subsequent years. The commenter also stated this may cause instability in individual hospital payments from year-to-year, which will be disruptive for a hospital whose revenue depends heavily on Medicare. The commenter suggested that, if the proposed reviews are found to be consistent with Congressional intent, CMS adopt a policy that does not penalize hospitals for small changes in patient mix and provides stability in the payment system from year to year. Moreover, the commenter suggested granting MDH status for a 3-year period before requiring requalification, similar to wage index reclassifications, or setting the level for requalification at a slightly lower level (perhaps 55 percent) so that a slight change in volume does not cause a loss of MDH status.

The second commenter supported the proposal but recommended that the requirement that hospitals apply for MDH status be removed, since the fiscal intermediaries will be conducting annual reviews.

The third commenter focused on the loss of MDH status effective 30 days after the intermediary provides written notification to the hospital that it no longer qualifies for MDH status. The commenter stated that mid-year MDH status changes provide a number of claims processing and cost report settlement problems. The commenter recommended that the effective date for the change in MDH status should be the first day of the cost reporting period following the intermediary's notification of the hospital.

Response: We agree that hospitals that qualify based on the original criteria were not required to requalify based on more recent data, since the original criteria, as dictated by law, was based on a specified period, here the 1987 data. However, the law was amended and specifies the new, additional criterion: ''two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report.'' We believe this language supports an interpretation that a hospital is to qualify as an MDH based on its most recent data, not based on a one-time qualification, as is the case with the original criteria (which was based on data from a set period of time, the hospital's FY 1987 cost reporting period).

With respect to the suggestion that the proposed ongoing reviews of hospitals MDH status should provide that, once approved, retention of a hospital's MDH status for a 3-year period, or that the level for requalification should be at a slightly lower percentage of inpatient days or discharges attributable to Medicare than 60 percent, the statute (section 1886(d)(5)(G)(iv)(IV) of the Act) does not provide such flexibility. Allowing hospitals to qualify using cost report data from other than two of the three most recently available cost reporting periods, or using a percentage less than 60 percent, would be inconsistent with the statutory language.

Regarding the effective date of a status change, the effective date of 30 days after the date of the notice from the fiscal intermediary is consistent with current policy for approval of both MDH and SCH status as well as notices that the hospital no longer meets such eligibility criteria. Concerning the commenter's request to not require hospitals to reapply for MDHs status since the intermediaries would already be reviewing that status on an annual basis, we wish to clarify that the ongoing reviews would be of hospitals with existing MDHs status only. Therefore, hospitals that had lost their MDH status would not be included in an automatic annual review to determine whether or not the hospitals continue to meet the eligibility criteria for MDH status. Instead, such hospitals must reapply for MDH status based on two of their three most recently audited cost reports.

Accordingly, we are adopting as final the proposed revised changes to the MDH policy under § 412.108(b).

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 the services of CRNAs.[1] 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:

[1] 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).

• 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 salary for a CRNA in rural areas in calendar year 2000 was $111,000, with a total annual compensation of $141,000. 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 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, in the May 9, 2002 proposed rule, we proposed to revise §§ 412.113(c)(2)(ii) and (c)(2)(iii) to raise the 500-procedure threshold to 800 procedures.

Comment: Several commenters supported our proposed changes and indicated that, without the proposed change in the regulations, rural hospitals will experience serious disruptions in their delivery of anesthesia services. CRNAs are the sole anesthesia providers in a number of rural hospitals. The commenters added that, without CRNAs, these rural hospitals will have difficulty in continuing to meet their patient's surgical and trauma stabilization services. Patients will be forced to travel outside of their communities, which could mean great distance.

One commenter suggested that the threshold should be reviewed every 3 years to ensure it continues to appropriately reflect market conditions for rural hospitals trying to maintain anesthetists services.

Response: We agree that the existing regulation providing for 500 procedures per year as a threshold could hinder the ability of some rural hospitals to sustain access to surgical procedures, which is the reason for our proposed change. We will continue to monitor this issue to determine whether future adjustments to the procedure threshold are warranted.

Comment: Several commenters raised an issue concerning the fact that some Medicare fiscal intermediaries include nonanesthesia ancillary services provided by the CRNAs when counting the total number of surgical procedures. They indicated that many rural hospitals are not able to qualify for the reasonable cost payment for their CRNAs as a result.

The commenters suggested a specific definition of surgical procedures that include cutting, abrading, suturing, and lasering of otherwise physically changing body tissues and organs. The commenters indicated that this suggested definition would clarify and eliminate the confusion in regulatory interpretation across fiscal intermediaries. One commenter indicated that anesthetists may provide therapeutic services for pain management unassociated with a surgical procedure.

Response: In view of the comments on this issue, we believe that certain steps are needed to improve consistency in the counting of surgical procedures. We appreciate the commenter's recommended definition of surgical procedures, and will consider whether such instructions would reduce inconsistency in counting of procedures, while still being consistent with the legislative and regulatory intent of this provision. We also will review all aspects of the counting of procedures to consider what further actions may be necessary to improve consistency. Our goal is to facilitate greater consistency in the manner and criteria used by all intermediaries.

Comment: Several commenters expressed concern that the existing regulations only allow hospitals in existence as of 1987 to qualify for reasonable cost pass-through and requested us to review this issue. The commenters indicated that this threatens new rural hospitals' ability to continue to provide surgical and anesthesia services to patients.

Response: To enable rural hospitals to secure anesthesia services for their patients, these regulations include a rural hospital's option for reasonable cost pass-through for the services of one full-time equivalent CRNA, as long as the hospital qualifies for ''pass-through'' treatment. The statute specifies the criteria and the regulation tracks the statutory language. Therefore, we believe we do not have the authority to extend this provision to hospitals that do not otherwise meet the criteria as described by the statute.

Comment: Some commenters sought clarification as to whether this provision is available to SCHs.

Response: SCHs that otherwise meet the statutory criteria are eligible to receive this pass-through payment. We are not aware that there has been any confusion in the past on this issue, but we are clarifying the point here in response to the comment.

Comment: Several commenters recommended that we eliminate the threshold altogether, or raise it even higher. One commenter stated that the need for the pass-through demonstrates that fee schedule payments for nonphysician anesthetists are inadequate to defray the costs associated with this service.

Another commenter suggested that CAHs should be exempt from the qualifying criteria to receive these pass-through payments. The commenter suggested that removing this requirement for CAHs would eliminate the unnecessary paperwork required for these hospitals to demonstrate they continue to meet the minimum thresholds.

A third commenter argued that the cost pass-through provision should permit rural hospitals to qualify on the basis of employing anesthesiologists as well. This commenter referred to survey data that purported to show a serious shortage of anesthesia providers in support of this argument.

Response: As described above, we believe the statute is specific as to the threshold requirements to qualify for the CRNA pass-through payments. Accordingly, a hospital or CAH that wishes to qualify for CRNA pass-through payments must meet the statutory criteria, including the threshold requirement. We also believe the statute does not provide authority to expand this policy to pay pass-through costs to hospitals for anesthesiologists' services. We believe the change we are making, increase the threshold from 500 to 800 procedures per year, is appropriate and note that it is generally supported by the commenters.

Comment: The AANA requested a technical correction to the reference in the proposed rule that, according to data from AANA, the average total annual compensation for CRNA in 2001 is approximately $155,000. According to the AANA, the most recent data for calendar year 2000 reflect an average salary in rural areas of $111,000, with a total annual compensation of $141,000.

Response: In the preamble of this final rule, we have revised the prior reference accordingly to avoid any potential confusion.

Comment: One commenter questioned whether anesthesiologists assistants are recognized as qualified providers under this provision.

Response: As we noted in the proposed rule and in the discussion above, our understanding of Congressional intent was that this pass-through payment applied to the services of all qualified hospital-employed nonphysician anesthetists (67 FR 31464). Therefore, a hospital otherwise meeting the criteria for this pass-through payment by employing an anesthesiologists assistant would be eligible for pass-though payments.

Comment: One commenter requested clarification of whether the requirement at § 412.113(c)(2)(i)(D) that ''each qualified nonphysician anesthetist employed by or under contract with the hospital or CAH has agreed in writing not to bill on a reasonable charge basis for his or her patient care in that hospital or CAH'' applies only to Medicare beneficiaries or to all patients.

Response: This requirement is to ensure that the nonphysician anesthetist is not also billing Medicare for Part B services under the fee schedule. Therefore, the requirement only pertains to services provided to Medicare beneficiaries. In this final rule, we are adding a revision to § 412.113(c)(2)(i)(D) to reflect the limited applicability of this requirement.

Accordingly, we are adopting as final the proposed changes to § 412.113(c)(2)(ii) and (c)(2)(iii), with one change. We are revising § 412.113(c)(2)(i)(D) to specify that each qualified nonphysician anesthetist employed by or under contract with the hospital or CAH has agreed in writing not to bill on a reasonable charge basis for his or her patient care to Medicare beneficiaries in that hospital or CAH.

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, Terminations, and Cancellations

Under § 412.273(a) of our regulations, a hospital or hospital group 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 after 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, the May 9, 2002 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. The procedure for canceling a withdrawal or termination is discussed in detail below.

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 after 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 August 1, 2001 (FY 2002) 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 covered in the August 1, 2001 final rule, which we are addressing in this final 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 after 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 to avoid a lapse in reclassification status the following year. Therefore, in the May 9, 2002 proposed rule, we proposed to clarify, in new paragraph (iii) of § 412.273(b)(2), 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 reclassification options 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, in the May 9, 2002 proposed rule, we proposed 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 means 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. 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, in the May 9, 2002 proposed rule, we proposed 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 also proposed 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, in the May 9, 2002 proposed rule, we proposed 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)).

We did not receive any comments on these proposed changes. Therefore, in this final rule we are adopting the proposed changes as final.

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 weighted 3-year average of its average hourly wages using 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 in the August 1, 2001 final rule (66 FR 39890), we have now determined that there is a need to clarify further 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 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 the new hospital does not 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 when the parties agree to accept assignment of the provider agreement. 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, as we proposed in the May 9, 2002 proposed rule, in this final rule we are revising § 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 will 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 will 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. Thus, we are revising § 412.230 to clarify, under 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.

Comment: One commenter indicated that our efforts to clarify our policy regarding change of ownership create a financial incentive for new owners to go through the ''onerous and costly'' process of obtaining new provider numbers in order to obtain geographic reclassification. The commenter believed that any valid change in ownership under § 489.19 should allow a hospital the opportunity to request reclassification and that we should clarify that all payment areas impacted by the assignment of a new provider number should be consistently applied.

Response: This clarification establishes clear, predictable guidelines as to how hospitals' data will be treated for reclassification purposes. The rule was not adopted to govern provider behavior, since we cannot predict hospitals' behavior in situations where they may perceive it to be to their financial advantage to change their ownership arrangements. Rather, given the guidelines established by CMS, hospitals are free to act in their best interests.

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 (Pub. L. 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 be 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. There must be at least three existing teaching hospitals with PRAs in the MSA for this calculation.

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. 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 final 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, in the May 9, 2002 proposed rule, we proposed 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 proposed to continue to calculate a weighted average PRA. However, rather than using 1984 base year data, we proposed 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 proposed 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, line 3.08, and line 3.11 of the Medicare cost report, CMS–2552–96,Worksheet E–3, Part IV.)

(We note that, under step 2, we have added ''line 3.11'' of the cost report to capture dental and podiatry FTE counts as part of the nonprimary care FTE counts. We made this addition in response to a comment received, as discussed below under the comment and response section for this area.)

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 years 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 this revised 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 x 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) $54,320,000/485FTEs = $112,000, the weighted average PRA for MSA 1234 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.

In the May 9, 2002 proposed rule, we proposed that the 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. We proposed a revision under a proposed new § 413.86(e)(5)(i)(C).

Comment: One commenter expressed concern about our proposed changes to the calculation of weighted average PRAs for new teaching hospitals. The

commenter believed that our proposed methodology is as administratively burdensome as the existing methodology, because the servicing intermediary would be required to solicit most recently settled cost report data from all other intermediaries servicing providers in the defined territory every time a new PRA needs to be calculated. As an alternative to using most recently settled cost report data, the commenter suggested that we specify a cost reporting period from which all future data can be updated (that is, cost reporting periods ending between October 1, 1998 and September 30, 1999). The commenter indicated that it would be helpful if we would provide all intermediaries with a nationwide listing of all teaching hospitals (extracted from the HCRIS and compiled in a database/spreadsheet format), including provider number, MSA number, county, PRAs, and primary and nonprimary care FTE counts from the specified cost reporting period.

Response: We understand the commenter's concerns, but we believe that using data from most recently settled cost reports results in a weighted average PRA that more appropriately reflects the pertinent dynamics of residency training in a specific geographical area. We note that the requirement to use data from all hospitals in an MSA, regardless of whether they are serviced by different intermediaries, exists even under current regulations. In addition, generally, hospitals in the same MSA either use the same fiscal intermediary or one of two fiscal intermediaries and, therefore, we do not believe that it is unreasonably difficult to obtain information from another intermediary. Furthermore, as we have done in the past, we will continue to provide assistance to the intermediaries involved in the process of calculating the weighted average PRAs. Finally, we will consider the commenter's suggestion concerning the compilation of a nationwide database.

Comment: One commenter asked whether, considering that dental and podiatry residents are also nonprimary care, the FTE count of dental and podiatry residents from line 3.11 of worksheet E–3 Part IV should be included in determining the FTE counts in step 2 of the calculation in the proposed rule (67 FR 31467).

Response: Step 2 of the proposed calculation states, ''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).'' We agree with the commenter that the dental and podiatry FTE counts should also be included, and, therefore, we are revising step 2 in the example in this final rule to state that intermediaries should use the FTE counts from line 3.07, line 3.08, and line 3.11 of the Medicare cost report.

Accordingly, in this final rule, we are adopting as final the proposed revised § 413.86(e)(5)(i)(B) and the proposed new § 413.86(e)(5)(i)(C) without modification.

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 members 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. Consistent with the broad authority conferred by the statute, we established criteria for defining an ''affiliated group'' and an ''affiliation agreement'' in both the August 29, 1997 final rule (62 FR 45965) and the May 12, 1998 final rule (63 FR 26317). Because we had received many inquiries from the hospital industry on this policy, we proposed in the May 9, 2002 proposed rule to clarify in regulations the requirements for participating in an affiliated group. Most of these requirements are explicitly derived from the policy explained in the August 29, 1997 and May 12, 1998 final rules.

Specifically, we proposed to add under § 413.86(b) a new definition of ''Affiliation agreement.'' Under this new definition, we proposed to specify 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 proposed 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) were proposed to be redesignated as § 413.86(g)(5)(v) through (vii), respectively; and existing §§ 413.86(g)(7) through (g)(12) were proposed to be redesignated as §§ 413.86(g)(8) through (g)(13), respectively, to accommodate these additions.) Specifically, we proposed 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 the 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) was explicitly derived from policy stated in the May 12, 1998 final rule (63 FR 26336). We proposed

to incorporate in regulations policy that was previously established under the formal rulemaking process.

We proposed 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, in virtually every agreement, 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 abusive practices that do 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. As we explained in the preamble to the May 9, 2002 proposed rule, 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 hospital-specific FTE cap on the number of residents. In addition, we have separately addressed issues that arise when residents are displaced because of a hospital closure. We have in place a policy at existing § 413.86(g)(8) (which was proposed to be redesignated as § 413.86(g)(9) in the May 9, 2002 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, in the May 9, 2002 proposed rule, we proposed 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 the 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 proposed to make a conforming clarification at § 412.105(f)(1)(vi) for purposes of IME payments.

Definition of ''Affiliation Agreement'' and the Requirements at Revised § 413.86(g)(7)

Comment: Several commenters were concerned about our requirement at proposed § 413.86(b) in the definition of ''affiliation agreement'' that the agreement specify FTE cap adjustments based on a 12-month period that begins July 1 and ends June 30. Many commenters believed that the requirement should be changed so that hospitals may execute affiliation agreements at any time during the year. One commenter believed that since, regardless of the date it is executed, the resident count set forth in the agreement must be reconciled with the hospital's cost reporting period, permitting hospitals to execute agreements throughout the year would reduce the hospital's administrative burdens without imposing much, if any, additional hardship on Medicare program administration. Another commenter suggested that CMS could delay the filing date for affiliations from July 1 until either the first day of a hospital's next cost reporting period beginning after commencement of the July 1 residency period, or October 1, whichever time period is longer.

Response: We set a July 1 deadline for submission of affiliation agreements (proposed § 413.86(g)(7)(i)), as well as specifications of FTE cap adjustments in the affiliation agreements, based on the July 1 residency training year because we believed that choosing one date was administratively less burdensome to our fiscal intermediaries for purposes of audit of the participating hospitals' Medicare cost reports. In addition, we chose July 1 because we believe that date is the start date of virtually all residency training programs across all specialties. We would be more sympathetic to the commenters' request for changes in the execution date if we had heard of residency training programs that begin on dates other than July 1. Until we hear of specific programs that begin on other than July 1, we continue to believe that it is appropriate and consistent with efficient administration of the Medicare program to maintain the existing policy based on the July 1 residency training program year. We believe that it is not only less burdensome for our fiscal intermediaries (as well as CMS) to receive affiliation agreements at one point in the year alone, but we also believe it is less burdensome to participating hospitals. We believe that the vast majority of participating hospitals will know prior to July 1 how many residents will be training at the hospital in any given residency program year and how many residents would be rotating in from other hospitals.

Comment: One hospital commenter described a situation in which its existing affiliation agreement with another hospital, which was submitted to the fiscal intermediary with a copy to CMS (at that time HCFA) Central Office on July 1, 1998, states that the affiliation agreement ''shall continue in effect on an indefinite basis until terminated by the agreement of all Hospitals * * * of the affiliated group.'' The commenter asked us whether this term language meets the requirements in the proposed rule.

The same commenter mentioned that its affiliation agreement from 1998 does not specify each participating hospital's direct and indirect FTE cap, ''as this was not required in the August 29, 1997,

and May 12, 1998 final rules.'' In addition, the commenter asked whether changes in a hospital's FTE caps can be accounted for under the proposed rule. Finally, the commenter asked whether documents other than the affiliation agreement, such as attachments to the affiliation agreement, can be used to identify a hospital's direct and indirect FTE caps.

Response: As we proposed at § 413.86(b), each affiliation agreement should specify the term of the agreement ''which at a minimum is one year,'' beginning on July 1 of a year. We stated similarly in the May 12, 1998 final rule on affiliation agreements (63 FR 26341) that ''each agreement must be for a minimum of one year.'' However, there is nothing to prohibit affiliation agreements from being automatically renewable each year or from being for terms greater than one year in length. Therefore, the language that the commenter apparently used in its affiliation agreement would meet existing Medicare policy on affiliation agreements and their effectiveness. As long as the affiliation agreements cover a period of time of at least one year beginning July 1 of a year, the affiliation agreements meet the term requirement at § 413.86(b).

To address the commenter's statement that it did not report the direct and indirect GME FTE caps for the participating hospitals in its affiliation agreement because it was not previously required to do so, we stated clearly in the May 12, 1998 interim final rule that hospitals must specify the ''planned changes to individual hospital counts under an aggregate FTE cap'' (63 FR 26341). Although, under existing policy, hospitals might have reported ''planned changes'' to FTE caps in a number of ways, there is no question that they were required to do so. The revised requirements at § 413.86(b) specify that the hospital must include in the affiliation agreement each participating hospital's direct and indirect GME FTE caps in effect prior to the affiliation. The reason for requiring that affiliation agreements specify the direct and indirect FTE caps for participating hospitals is so that all hospitals will report the ''planned changes'' in the same way, allowing for ease of administration for CMS and fiscal intermediaries.

We also understand that some hospitals qualify for other FTE cap adjustments, such as those for new programs under § 413.86(g)(6)(ii). Hospitals would report their most current FTE caps in effect in the period immediately prior to the effective date of the affiliation for both direct GME and indirect medical education, so that the caps are reflective of the other FTE cap adjustments.

To respond to the commenter's question about whether attached documents to the affiliation agreement will suffice to identify direct and indirect GME FTE caps, we believe attached documents would be adequate, so long as they are considered part of the overall package of the affiliation agreement. We have stated repeatedly to the provider community that affiliation agreements need *not* be lengthy documents. In the past, we have received affiliation agreements that range in length from 2 pages to 30 pages. Each type of agreement (short or long) would be adequate as long as the affiliation agreement meets the provisions under proposed § 413.86(b).

Comment: One commenter asked how the proposed rule contemplates handling changes in the hospital's FTE adjustments if actual rotations in a given residency year turn out differently than what was stated in the affiliation agreement at the start of the residency year on July 1.

Response: We stated in the May 12, 1998 final rule (63 FR 26339) that the hospitals in the affiliated group may submit modifications to the initially reported distribution of the aggregate FTE count by June 30 of the current residency training year, if actual FTE counts for the program year are different than projected in the original agreement. While modifications to the original distribution of the aggregate FTE cap are permitted in order to allow for some fluctuations based on the actual placement of those residents within the affiliated hospitals, the overall affiliation agreement cannot be modified (for example, by adding other hospitals to increase the original aggregate cap). In most cases, we expect that the modifications to the affiliation agreements, which should be signed by all participating hospitals and submitted to the fiscal intermediary, will reflect the realities of what actually occurred as far as the number of residents that rotated in and out of each hospital during the program year. Accordingly, we would be skeptical of modifications that deviate significantly from the original affiliation agreement.

Comment: One commenter that suggested a technical change in the terminology for affiliation agreements to ''resident limit aggregation agreements'' or ''aggregation agreements.'' The commenter believed that ''affiliation agreement'' historically is a term of art in the academic community and generally relates to agreements made between hospitals and medical schools or among sponsors of medical residency education programs.

Response: We are aware that there has been some confusion at times among members of the provider community when using the term ''affiliation agreement,'' and we recognize that the term is utilized in contexts other than in the Medicare usage of the term for GME payment. However, we believe the Medicare use of the term is an appropriate one, rather than ''aggregation agreement'' or ''resident limit aggregation agreement.'' We note that section 1886(h)(4)(H)(ii) of the Act uses the term ''affiliated group'' and contemplates that the Secretary will define that term. Further, as we stated above, the point of the policy is that there are ''affiliations'' among the participating hospitals; that is, rotations of residents among the hospitals for purposes of applying the Medicare FTE caps. Therefore, we are not adopting the commenter's suggested technical change.

Cross-Training Requirement

Comment: Numerous commenters inquired about or addressed our proposal at § 413.86(g)(7)(ii) to clarify in regulations the requirement of a rotation of residents among the hospitals participating in every affiliated group. One commenter agreed that this requirement is appropriate in regard to nonrelated hospitals that join together in an affiliation agreement, since the cross-training is the only basis for the affiliation. However, the commenter believed it should not be applied to affiliation agreements involving only commonly owned or related hospitals because commonly owned hospitals in an affiliated group are already held to the aggregate resident cap. The commenter believed it is unnecessary and burdensome to add a further requirement that each hospital participate in a rotation to other hospitals in order to be included as part of the affiliated group.

Another commenter disagreed that this provision on cross-training between all hospitals in an affiliated group joined by common ownership is a clarification instead of a new rule. Consequently, this commenter believed the implementation of the cross-training provision should be prospective and deferred to become effective with affiliations beginning July 1, 2003. The commenter stated that if its proposal is not accepted, hospitals not in compliance should be given an opportunity to file a new affiliation agreement rather than forfeit the ability to affiliate altogether for the 2002–2003 period.

Response: We disagree with the commenter's statement that commonly owned hospitals in an affiliated group are ''already'' held to the aggregate resident cap. Hospitals are only held to an aggregate resident cap through the act of entering into a Medicare affiliation agreement, and a Medicare affiliation is not valid without the existence of a cross-training relationship. Our proposal to add an explicit cross-training requirement at § 413.86(g)(7)(ii) resulted from our belief that all hospitals that affiliate, regardless of the criteria under which they qualify to affiliate, should meet the cross-training requirement. The intent of affiliated groups is to provide flexibility within the FTE caps to hospitals that have a rotational relationship; affiliated groups are not meant to serve as a mechanism for circumventing the FTE caps. However, we acknowledge that the existing definition of ''affiliated group'' at § 413.86(b) is silent with respect to whether the cross-training requirement applies to hospitals that affiliated based on the common ownership criterion.

Nevertheless, we emphasize that the proposed cross-training requirement is derived from a broad-based cross-training policy expressed in previous final rules applying to all affiliated groups, including hospitals affiliated under common ownership. Specifically, in the May 12, 1998 final rule (63 FR 26336) we state, ''The criteria we established to determine whether two or more hospitals qualify to be an affiliated group were designed to identify hospitals that have relationships for training residents and to allow those hospitals to continue to have the flexibility to rotate residents under an aggregate FTE cap.'' Further, we initially amended the definition of an affiliated group at § 413.86(b) (63 FR 26337) to include hospitals under common ownership in response to a commenter's statement that hospitals under a single health care system ''* * * functionally operate coordinated and centrally controlled GME programs and often *rotate their residents among their various facilities* depending on training needs and other considerations'' (emphasis added). Finally, we state, ''A hospital will be permitted to engage in multiple agreements with different hospitals, as illustrated below. For example, hospital A can have an agreement with hospital B for an internal medicine program and another agreement with hospital C for emergency medicine. Although hospitals B and C do not have an agreement for any program, the affiliated group is A, B, and C; that is, the FTE resident counts at hospitals A, B, and C cannot exceed the sum of the combined caps for the three hospitals'' (63 FR 26338–26339).

Therefore, to be consistent with the cross-training requirement we proposed at § 413.86(g)(7)(ii), we are adding a reference to the cross-training requirement in paragraph (3) of the definition of ''affiliated group'' under § 413.86(b). However, because our existing definition of affiliated group did not explicitly state the cross-training requirement for hospitals that affiliate based on common ownership, we recognize that our policy may have been subject to misinterpretation. Therefore, we are making this cross-training requirement for hospitals under common ownership effective for affiliation agreements beginning July 1, 2003, the date of the first training year beginning after publication of the final regulation. Accordingly, hospitals that have affiliated under the common ownership criterion but have not met, or currently are not meeting, the rotational requirement are not required to meet the cross-training requirement until July 1, 2003.

We also address the application of the cross-training requirement at § 413.86(g)(7)(ii) to the other bases for affiliation listed in the definition of ''affiliated group'' at existing regulations at § 413.86(b). Concerning hospitals located in the same urban or rural area or in contiguous areas, we believe that application of the cross-training requirement is explicit in existing policy and not a change. We believe that the existing regulations clearly express the cross-training requirement that residents must rotate among hospitals within the affiliated group during the course of the program. Paragraph (1) of the existing definition states that hospitals may qualify as an affiliated group if the hospitals are in the same urban or rural area or in contiguous areas, and ''if individual residents work at each of the hospitals during the course of the program.'' However, to maintain consistency, we are revising the language under paragraph (1) of the definition of an ''affiliated group'' to reference the new cross-training language at § 413.86(g)(7)(ii).

The language in paragraph (2) of the existing definition of ''affiliated group'' comes from the May 12, 1998 final rule (63 FR 26358). When we issued this language at existing paragraph (2) regarding affiliations of hospitals that are jointly listed as the sponsor of a program, we did not explicitly restate the cross-training requirement because it was assumed that these hospitals, by virtue of joint sponsorship, already meet the cross-training requirement. However, to be consistent, and to further emphasize that the cross-training requirement applies to *all* affiliating hospitals, we are also adding an explicit cross-training requirement at paragraph (2) in the definition of ''affiliated group'' under § 413.86(b) by referencing § 413.86(g)(7)(ii).

Comment: One commenter stated that our requirement concerning the cross-training of residents within an affiliated group is unwarranted due to the establishment of a single FTE cap for each hospital, rather than program-specific FTE caps for each hospital. The commenter contended that hospitals that agree to affiliate should be allowed to manage training of residents in a manner that ensures the most appropriate training is received, even if this means that there is no cross-training of residents. The commenter included the following example:

AB Health system operates a pediatrics program and a geriatrics program in two hospitals, A and B. Individual hospital 1996 FTE caps were established at 10 FTEs for Hospital A and 10 FTEs for Hospital B. Historically, residents in both programs rotated between both hospitals. In 2002, the programs were reorganized so that Hospital A now specializes in pediatrics and Hospital B now specializes in geriatrics, and as a result, the hospitals no longer cross-train residents. Hospital A currently trains 12 pediatric FTEs and Hospital B currently trains 8 geriatric FTEs.

The commenter explained that the cross-training requirement would effectively reduce the number of residents Medicare will recognize AB Health System in 2002 by 2 FTEs less than the number in 1996. The commenter asserted that, accordingly, the cross-training requirement is inconsistent with our establishment of one overall FTE cap per hospital.

Response: As we stated above, the provision for affiliated groups was included by Congress to accommodate hospitals that have an existing rotational relationship. It was understood that because of the movement of residents between hospitals, the number of residents at each hospital could vary each year. Therefore, because of these existing rotational arrangements, Congress intended to allow hospitals to aggregate and modify the FTE caps on a temporary basis. We do not believe it is appropriate to allow hospitals that do not have a rotational relationship to aggregate their FTE caps simply as a means of maximizing their Medicare reimbursement. However, we note, as we have stated above, hospitals that

affiliate under the common ownership criteria do not have to meet the cross-training requirement until July 1, 2003.

We emphasize again that the cross-training requirement for affiliations is not a new concept in policy regarding Medicare affiliated groups. Indeed, the May 12, 1998 final rule repeatedly stated the idea that the policy was established in order to ''allow those hospitals to continue to have the flexibility to rotate residents under an aggregate FTE cap'' (63 FR 26336). However, because much confusion or concern has been expressed in numerous inquiries and among several commenters about the proposed clarification of the cross-training requirement, particularly when it relates to the common ownership scenario, we are amending our regulations to further specify how the cross-training requirement will be applied in each of the scenarios for affiliated groups, including common ownership. Specifically, we are revising § 413.86(g)(7)(ii) to read as follows:

> Each hospital in the affiliated group must have a shared rotational arrangement, as defined in § 413.86(b), with at least one other hospital within the affiliated group, and all the hospitals within the affiliated group must be connected by a series of such shared rotational arrangements.

We are specifying here and also at § 413.86(b) that ''shared rotational arrangement'' means a residency training program under which a resident(s) participates in training at two or more hospitals in that program. If residents rotate from one hospital to another at some point during the period of years required to complete training in a particular program, those hospitals have a ''shared rotational arrangement.'' In addition, all the hospitals within the affiliated group must be connected by a series of shared rotational arrangements. In other words, in order for the cross-training requirement to be met, there must be, at a minimum, a ''chain'' of rotations occurring from one hospital to the next within the affiliated group. For example, assume Hospitals A, B, C, and D form an affiliated group. Hospital A and Hospital B both train residents in an internal medicine program. In addition, Hospital B trains surgery residents, who also spend time training at Hospital C. Hospital C and Hospital D both operate an anesthesiology program and anesthesiology residents train in both Hospital C and Hospital D. Thus, Hospitals A and B, Hospitals B and C, and Hospitals C and D are connected by a series of shared rotational arrangements. This arrangement meets the cross-training requirement. All hospitals do not have to cross-train residents; this means that Hospital A does not have to send residents to Hospital B, Hospital C, and Hospital D, nor does Hospital B have to send residents to Hospital A, Hospital C, and Hospital D, nor does Hospital C have to send residents to Hospital A, Hospital B, and Hospital D, etc. A continuous linear chain is sufficient.

In another example of a ''shared rotational arrangement,'' Hospital A and Hospital B affiliate and they both offer training in family practice. If, at some point during the 3 years required to complete the family practice program, residents rotate from either Hospital A to Hospital B, Hospital B to Hospital A, or back and forth between Hospital A and Hospital B, then Hospital A and Hospital B have a ''shared rotational arrangement.'' Hospitals A and B may meet the definition of a ''shared rotational arrangement'' by rotating residents for a portion of a particular program year (PGY), or by rotating residents for an entire program year, so long as the family practice residents spend time at both hospitals to complete their training in family practice. For example, family practice residents may spend 3 months of their PGY1 at Hospital A and 9 months at Hospital B, or, the residents may spend their entire PGY1 training at Hospital A, and spend their entire PGY2 and PGY3 training at Hospital B. In either case, Hospital A and Hospital B have a shared rotational arrangement because they rotate residents over the course of a common training program.

Following are some examples of arrangements that do not meet the cross-training requirement:

- Hospitals A and B train residents at their respective hospitals but do not rotate residents between the 2 hospitals.
- Hospitals A, B, and C attest that they are aggregating their FTE caps, but only Hospitals A and B actually rotate residents between them, while Hospital C does not rotate residents to either Hospital A or Hospital B. In this scenario, Hospitals A and B may qualify as an affiliated group, but Hospital C may not be included for purposes of aggregating its FTE cap with Hospitals A and B, because Hospital C does not rotate residents with either Hospital A or Hospital B. Thus, Hospital C breaks the ''chain''; Hospital C is not connected to the other hospitals by a series of shared rotational arrangements.
- Hospitals A, B, C, and D attempt to aggregate their FTE caps. Hospitals A and B rotate residents between them, and Hospitals C and D rotate residents between them. In this scenario, Hospitals A and B may qualify as an affiliated group, and Hospitals C and D may qualify as a second affiliated group, but Hospitals A, B, C, and D may not qualify as a single affiliated group because the ''chain'' is broken by the lack of a series of shared rotational arrangements between Hospitals A or B and Hospitals C or D.

Finally, we believe that our regulations would be more consistent if we also amended the proposed definition of ''affiliation agreement'' at § 413.86(b) to require participating hospitals to specify the adjustment to each hospital's FTE counts resulting from the FTE resident's (or residents') participation in the shared rotational arrangement(s) at each hospital participating in the affiliated group for each year the affiliation agreement is in effect. We are also stating under this section that this adjustment to each participating hospital's FTE count is reflected in the total adjustments to each hospital's FTE caps under paragraph (3) of the definition for ''affiliation agreement'' at § 413.86(b). We believe this additional information will assist the fiscal intermediaries in tracking the FTE residents and ensuring that cross-training occurs in at least one program at each of the hospitals participating in the affiliated group, in accordance with the rotation requirement under revised proposed § 413.86(g)(7)(ii).

Example: Assume Hospital A has a direct GME FTE cap of 30 FTEs and an IME FTE cap of 29 FTEs. In the 2003–2004 residency year, Hospital A has an internal medicine residency program with 6 FTE residents training at Hospital A in each program year (a total of 18 FTEs). Hospital A also has a surgery residency program with 3 FTE residents training at Hospital A in each program year (a total of 9 FTEs). Note that Hospital A is not at its FTE cap for direct GME (there are 3 empty FTE slots) or IME (there are 2 empty FTE slots) in this fiscal year. Hospital A decides to rotate some of its residents over to Hospital B, which has an FTE cap of 5 FTEs for both direct GME and IME. Hospital B also rotates residents in a pediatric program to Hospital C. Hospital C has a direct GME cap of 9.5, and an IME cap of 10. The three hospitals affiliate to form an aggregate cap of 44.5 FTEs for direct GME and an aggregate cap of 44 FTEs for IME. Hospital A rotates 3 internal medicine FTEs and 1.5 surgery FTEs to Hospital B, for both direct GME and IME (for Hospitals A and B, this would be ''the adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in the shared rotational arrangement(s) at each hospital

participating in the affiliated group''). In addition, Hospital A also moves more of its FTE cap to Hospital B: an additional 3 FTEs for direct GME and 2 FTEs for IME (as noted above, these FTEs were available in Hospital A's caps), because Hospital B would like to train more residents in other specialties than can be accommodated under its own cap of 5 FTEs. Hospital B sends 0.5 FTE for GME and 1 FTE for IME to Hospital C. These produce a net decrease to Hospital A's direct GME cap of 7.5 FTEs (to equal an adjusted cap of 22.5 for direct GME) and a net decrease to its IME cap of 6.5 FTEs (to equal an adjusted cap of 22.5 for IME). The net increase to Hospital B's direct GME cap is 7.0 (to equal an adjusted cap of 12.0 FTEs for direct GME) and a net increase to its IME cap of 5.5 FTEs (to equal an adjusted cap of 10.5 FTEs for IME). The net increase to Hospital C's direct GME cap is 0.5 (to equal an adjusted cap of 10 FTEs for direct GME and the net increase to its IME cap is 1.0 FTEs (to equal an adjusted cap of 11 FTEs for IME).

Accordingly, the requirements as specified under paragraphs (2), (3), and (4) of the definition of ''affiliation agreement'' at § 413.86(b) may be met if affiliation agreements give the following information (although it may be stated in narrative form, as above), using the information for Hospitals A and B and C above:

DIRECT GRADUATE MEDICAL EDUCATION

[FTE caps]

	FTE cap	Total cap adjustment	Revised caps
Hospital A	30	-7.5	22.5
Hospital B	5	7	12
Hospital C	9.5	0.5	10
Aggregate Cap	44.5		44.5

SHARED ROTATIONAL ARRANGEMENT

	Minus	Plus
Hospital A	-4.5	
Hospital B	-0.5	4.5
Hospital C		0.5

INDIRECT MEDICAL EDUCATION

[FTE caps]

	FTE cap	Total cap adjustment	Revised caps
Hospital A	29	-6.5	22.5
Hospital B	5	5.5	10.5
Hospital C	10	1	11
Aggregate Cap	44		44

SHARED ROTATIONAL ARRANGEMENT

	Minus	Plus
Hospital A	-4.5	
Hospital B	-1	4.5
Hospital C		1

Thus, while the respective hospitals aggregate their FTE caps as a whole, and list the upward and downward adjustments to the participating hospitals' direct and indirect FTE caps, under revised paragraph (3) of the definition of ''affiliation agreement'' under § 413.86(b), the affiliation agreement must now separately list the positive and negative adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in the shared rotational arrangement(s) at each hospital participating in the affiliated group for each year the affiliation agreement is in effect (this may be different than the total effect of the affiliation on the hospital's cap).

In this final rule, we also are modifying § 413.86(g)(7) to add a new paragraph (iii) to state that, in accordance with proposed § 413.86(g)(7)(ii), during the shared rotational arrangements in the affiliation, more than one of the hospitals in the affiliated group must count the proportionate amount of the time spent by the resident(s) in their FTE resident counts, and that no resident may be counted in the aggregate as more than one FTE.

The Termination Clause

We received numerous comments concerning our proposed policy change on the effect of an affiliation termination on each participating hospital's FTE cap. We proposed that, upon termination of an affiliation, each affiliated hospital will revert back to its original FTE caps for both direct GME and IME prior to the affiliation. Many commenters urged us to reconsider the proposal and to keep the existing policy allowing for FTE cap redistribution upon affiliation termination.

Comment: Several commenters noted the Conference Report accompanying the Balanced Budget Act of 1997 (BBA) which stated that while CMS was given flexibility in implementing the resident limits, the flexibility is ''limited by the conference agreement that the aggregate number of FTE residents should not increase over current levels.'' (H.R. Conference Report, Rept. No. 105–217, 105th Cong., 1st Sess., 1997, pp. 821–822). One commenter stated that they believe the Conference Report makes clear that the conferees understood that ''a sizeable number of hospitals elect to initiate 'as well as terminate' medical education programs over a period of time,'' and that the Conferees were ''concerned that within the principles of the cap * * * there is proper flexibility to respond to such changing needs * * *.'' These commenters believe that our policy change would therefore be contrary to Congress' wishes.

Response: As we explain above, and also in the proposed rule, existing policy allows affiliated hospitals to redistribute their FTE caps (within the limits of the aggregate FTE caps) upon the termination of the affiliation agreement in order to enable hospitals by agreement to more closely reflect the realities of the residency rotational arrangement. However, we proposed to change this policy because we believed it was susceptible to abusive practices such as the formation of affiliation agreements solely for the purpose of obtaining permanent adjustments to FTE caps. In fact, the commenters who advocated retaining the existing policy argued that this provision is needed to allow hospitals to increase their caps, when another hospital closes.

To address the commenters' belief that our proposed change is contrary to Congressional wishes, we note that the language quoted above from the Conference Agreement accompanying the BBA that the commenters use to support that assertion was actually intended to address Congress' newly enacted policy in the BBA on new residency program adjustments (see section 1886(h)(4)(H) of the Act for the statutory provision on this adjustment), rather than affiliated groups. In fact, the cited paragraph in the Conference Report starts out by stating: ''Among the specific issues that concerned the Conferees was application of a limit to new facilities, that is, hospitals or other entities which established programs after January 1, 1995.'' (Conference Report at 821). A separate provision on affiliations appears later in the Conference Report. The Report states: ''Another issue was the treatment of institutions which are members of an affiliated group. In some circumstances, the Conferees believe that the intent of this provision would best be met by providing an aggregate limit for such affiliates.'' Therefore, we believe that the language cited by the commenters was not meant to be applied to affiliated groups.

In addition, section 1886(h)(4)(H)(ii) of the Act specifies that ''The Secretary may prescribe rules which allow institutions which are members of the same affiliated group (as defined by the Secretary)'' to elect to apply the FTE cap on an aggregate basis (emphasis added). Thus, the statute granted the Secretary the discretion to promulgate regulations that specify what defines an affiliated group and when the FTE caps can be aggregated. Based on our analysis of the Conference Report language, as well as the statutory language, we believe the purpose of the affiliations provision is to provide temporary flexibility in the rotation of residents within the confines of the hospital-specific cap on the number of FTE residents. We do not believe the provision was meant to provide a vehicle for a hospital to circumvent the statutory FTE cap on the number of residents through permanent cap adjustments due to hospital closures.

Comment: Several commenters believed that the existing termination clause policy allowing for permanent cap adjustment ''is currently the only option available to retain'' resident slots due to hospitals or program closure. One commenter stated that the permanent transfer of residents through the use of affiliation agreement termination provisions allows the programs to continue to benefit the community indefinitely. Several of the commenters suggested that our existing policies specified at § 413.86(g)(8) that allow for temporary FTE cap adjustments to address hospital and residency program closure are ''short-lived'' and inadequate to address community needs.

Response: We understand that medical needs within a particular community may go unfulfilled whenever a hospital closes its doors, or even, in some communities, when a residency program closes. Our temporary FTE cap adjustments at § 413.86(g)(8) for hospital closures and also program closures are meant to address the situation of the residents who become ''displaced'' in either of the scenarios; they are not intended to address community medical needs (although, we know that in many cases, the temporary adjustments produce an incidental beneficial result to the community).

If Congress intended to provide permanent cap adjustments to address community needs because of hospital or program closures, we believe there would be such a provision in the Act. Until the law is amended to provide for such an explicit permanent adjustment to a hospital's FTE caps, we believe that our proposal for reverting back to pre-affiliation FTE caps upon affiliation termination is the proper policy.

Comment: Several commenters stated that the fact that a few hospitals abused the policy should not be a reason to make this policy change that affects all hospitals. One commenter believed that other appropriate safeguards can and should be put in place to avoid abuse. This commenter believed that abuse could be limited by requiring a hospital to have been part of the affiliated group for at least a full year prior to the termination of the agreement and not be part of temporary adjustment provided for at § 413.86(g)(8).

Response: In proposing the policy change requiring that when a Medicare affiliation agreement terminates, the hospitals' FTE caps revert to their original levels, we did not intend to target all hospitals due to the actions of, what the commenter has labeled, a few ''abusive hospitals.'' Rather, our intent was to clarify that we believe that any attempt to use affiliations to provide for a permanent increase in the FTE caps is not consistent with either the statute or Congressional intent.

As we noted in the preamble to the proposed regulations, in reviewing affiliation agreements that hospitals have submitted, we found that very few hospitals have altered their FTE caps following the termination of their affiliation agreements. Instead, they opt to revert to their 1996 base year caps. In fact, it is typically only where a hospital is about to close and there is the possibility that the hospital's FTE cap will be ''lost,'' that a termination clause is created to be used to transfer those slots to another hospital.

As stated above, section 1886(h)(4)(H)(ii) of the Act specifies that ''The Secretary may prescribe rules which allow institutions which are members of the same affiliated group (as defined by the Secretary)'' to elect to apply the FTE cap on an aggregate basis. We believe the basis of the policy on affiliations is to provide flexibility in the rotation of residents within the confines of the aggregate cap on the number of FTE residents. We do not believe this statutory provision was meant to provide a vehicle for a hospital to circumvent the statutory FTE cap on the number of residents through permanent cap adjustments due to

hospital closures. If Congress intended to provide for permanent cap adjustments to address situations where a hospital closes, we believe there would be a specific provision in the law to provide for such an adjustment.

Comment: We stated in the proposed rule (67 FR 31469), and also above, that the policy was proposed to be effective October 1, 2002, for hospitals with affiliation agreements that would terminate (for any reason) on or after that date. One commenter believed that the change should become effective with affiliations beginning, not terminating after October 1, 2002. Several other commenters agreed; they suggested that ''under no circumstances should a change be made that would retroactively affect an existing lawful agreement.'' Finally, one commenter suggested the change should apply only to agreements that were executed after the publication of the proposed rule so that, ''at least, it applies only to agreements in which the parties had notice of the anticipated change in policy.''

Response: We disagree with the commenters' suggestions. As we have stated above, we believe that the permanent FTE cap adjustment policy allows for the circumvention of the statutory caps. As such, we believe that the policy change should be applicable as soon as possible; that is, beginning with any terminations of affiliations that occur beginning with the effective date of this final rule.

We also disagree with the commenters that our policy change is ''retroactive''. If a hospital that is part of an already existing affiliated group decides for whatever reason to terminate the affiliation agreement, that termination would not retroactively affect the movement of the FTE caps back to their hospitals of origin. Rather, the reversion back to the pre-affiliation FTE caps occurs on a prospective basis after the termination has taken place.

Finally, to address the comment suggesting that the change in termination policy be effective with affiliation agreements executed after the publication of the proposed rule (which was on May 9, 2002), since the policy depends upon the action of a hospital terminating the affiliation agreement rather than executing the agreement, we believe it is more appropriate to maintain our proposed effective date. And, as we stated above, we believe the provider community is receiving adequate notice of this change in policy on terminations of affiliations through the notice and comment rulemaking process. Thus, we are adopting our proposal to require that the FTE caps for each hospital in the affiliated group will revert back to each hospital's FTE cap prior to entering into the affiliation upon termination of the affiliation.

Comment: Two commenters noted that the proposed rule stated that the FTE caps of hospitals in the affiliated group would revert back to their pre-affiliation levels upon termination. The commenters requested that, in cases where multiple hospitals enter into an affiliation agreement, but for whatever reason, one or more of the original affiliating hospitals wished to withdraw from the agreement, the remaining hospitals should be able to continue the affiliation agreement. One commenter stated that allowing affiliated groups to shrink from their original size to include only those hospitals that are interested in continuing their participation will ensure success of the affiliated group, while allowing CMS to reimburse hospitals subject to the limit of an aggregate cap. The commenter provided the following example: Hospitals A, B, and C enter into an affiliation agreement for the academic year beginning July 1, 2003. Each hospital has 1996 FTE caps of 8, respectively, which combine to equal an aggregate cap of 24. During this academic year, Hospital C decides to terminate its participation in the affiliated group. Hospital C takes back its 8 FTEs, its original FTE cap. Hospital A and Hospital B wish to continue affiliating, and Hospital A's FTE cap increases by 4 to equal 12, and Hospital B's FTE cap decreases by 4 to equal 4, for an aggregate cap of 16 FTEs.

Response: We believe the commenters may be confusing our proposal to require FTE caps of hospitals in the affiliated group to revert back to their pre-affiliation levels upon termination, with our policy with respect to hospitals that continue to affiliate. Our proposal would only preclude hospitals from using termination agreements as a means of permanently adjusting FTE caps. However, our proposal does not preclude hospitals from terminating their participation in an affiliation agreement, as long as each formerly participating hospital's respective original FTE caps are not changed as a result of the termination. Therefore, no modification to our regulations is necessary to adopt the commenters' request to allow affiliated groups to be reduced from their original size. The scenario described by the commenters is permissible under existing regulations. When a hospital withdraws from the affiliation, the equivalent amount of its pre-affiliation FTE cap is subtracted from the original aggregate cap, and reverts back to that hospital. The hospitals that wish to continue participating in the affiliation must submit a modified agreement to their respective intermediaries by June 30 of that academic year indicating the revised aggregate FTE cap, and adjustments to each hospital's caps, based only on the FTE caps of the hospitals that continue to affiliate.

Other Issues on Affiliated Groups

Comment: Two commenters requested that we remove our geographical restriction for hospitals to participate in an affiliated group; one commenter specifically requested that participants in an Osteopathic Postdoctoral Training Institution (OPTI) be permitted to participate in affiliated group without regard to geography. Two commenters requested that we change our policy at § 413.86(g)(6)(i)(D) concerning the prohibition of new teaching hospitals from participating in affiliated groups once the new residency program has been established. Another commenter asked that we define ''displaced residents'' for purposes of our policies at § 413.86(g)(8) on closed hospital and closed programs.

Response: Since these comments do not address issues that were specifically proposed in the May 9, 2002 notice of proposed rulemaking, we are not responding to these comments in this regulation.

Technical Corrections

We are making a technical change to the language under the definition of ''affiliated group'' under § 413.86(b) under paragraph (2). Paragraph (2) refers to hospitals that are jointly listed as the sponsor, primary clinical site, or major participating institution for one or more of the programs as these terms are used in the ''*Graduate Medical Education Directory, 1997–1998.*'' We note that the usage of the referenced terms has not changed in more recent publications of the Directory and is not expected to change in the future. Therefore, in this final rule, as part of our revision to the definition of ''affiliated group'' to incorporate the cross-training requirement for hospitals in an affiliation agreement, we are changing the reference to reflect use of the most current publication of that Directory.

When we issued the May 9, 2002 proposed rule, due to a typographical error, we inadvertently indicated that we proposed to make changes to § 413.86(g)(5)(iv) instead of § 413.86(g)(4)(iv) to incorporate revised provisions relating to determining the weighted number of FTE residents for hospitals that are part of the same affiliated group. As a result, we erroneously stated that we proposed to add a new paragraph under

§ 413.86(g)(5)(iv) and to redesignate paragraphs (g)(5)(iv), (g)(5)(v), and (g)(5)(vi) as paragraphs (g)(5)(v), (g)(5)(vi), and (g)(5)(vii) respectively to accommodate the new paragraph. We are correcting these errors in this final rule, We are changing the reference from § 413.86(g)(5)(iv) to § 413.86(g)(4)(iv). In addition, since we are revising § 413.86(g)(4)(iv) rather than inserting a new paragraph, there is no need to redesignate any paragraphs under § 413.86(g)(4).

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.

In the May 9, 2002 notice, we proposed clarifying 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).

Comment: One commenter agreed that our clarification on the prohibition against a hospital counting residents training at other hospitals is one that is ''longstanding Medicare policy, based on language in both the regulations and the statute.'' As such, this commenter recommended that we amend our regulations to include this clarification as part of § 413.86(f)(2), ''rather than remain as a footnote to longstanding Medicare policy.''

Response: As we clarified in the proposed rule and also above, existing § 413.86(f) states, in part, that a hospital may count residents 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. Thus, we believe our existing regulations are already very clear that hospitals cannot count resident rotations at other hospitals; indeed, the hospital can only count residents working ''at the hospital''. However, because we continue to receive many questions on this policy, even though it is a longstanding one, in this final rule we are revising §§ 413.86(f) and 412.105(f) to explicitly prohibit the counting of residents at other hospitals.

As we stated above, and also in the proposed rule, we are aware of some scenarios where one hospital incurs the residency training costs of residents training at other hospitals. However, even in this scenario, the hospital incurring the costs of the residents at the other hospitals is precluded from claiming any FTEs for the proportion of time spent in training at the other hospitals.

Comment: One commenter stated that CMS should consider allowing hospitals to enter into agreements that would permit one hospital to claim the resident FTE time worked at another hospital as long as the hospital claiming the resident time is incurring ''all or substantially all'' of the training costs at the other hospitals, similar to the regulations specified at existing § 413.86(f)(4) for nonhospital sites.

Another commenter stated that it disagrees with our clarification concerning the situation where a teaching hospital cannot count resident rotations to nonteaching hospitals, even when the teaching hospital incurs ''all or substantially all'' of the costs and the rotation is part of the accredited program. One commenter requested that it be allowed to count the ''round time'' at another hospital. One commenter requested clarification on whether our policy that prohibits a hospital from counting residents rotating to other hospitals applies to the situation where residents rotate to hospitals not participating in Medicare, such as State-operated psychiatric facilities and hospitals located in foreign countries.

Response: We do not believe that it is consistent with the requirements at sections 1886(d)(5)(B)(iv) and 1886(h)(4)(E) of the Act to expand the policy at § 413.86(f)(4) concerning counting residents in nonhospital settings to allow hospitals to count residents training at other hospitals even if the hospitals seeking to count the residents incur ''all or substantially all'' of the costs. In fact, it is only because the statute has specifically provided for counting residents training at nonhospital sites that it is appropriate to include any resident not training at the hospital in the hospital's FTE count.

In addition, section 1886(h)(4)(A) of the Act requires the Secretary to establish rules for the computation of FTE residents in an approved medical residency training program. Furthermore, at paragraph (B) of that section, the statute requires that the regulations take into account individuals who serve as residents simultaneously with more than one

hospital. Therefore, we believe that the Secretary has the authority to allow a hospital to count only those residents actually training in that hospital. Even where the residents are training at other hospitals or foreign hospitals, it is not appropriate for the hospital to include those residents in its FTE count. Further, although the commenter refers to rotations occurring at ''nonteaching'' hospitals, we note that by virtue of the fact that residents are rotating and training at a hospital, the hospital is, by definition, a teaching hospital. In fact, each Medicare-participating hospital at which the residents are rotating over the course of the program year should be completing the direct GME and IME (if applicable) worksheets of the Medicare cost report in order to claim and receive Medicare payment for their respective portions of the FTE training time, regardless of whether the hospital incurs any costs for training those residents. Accordingly, we are not adopting the policy change suggested in these comments.

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

In the May 9, 2002 proposed rule, we presented certain proposed policies to clarify areas of the regulations under § 489.24 that implemented sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Act and solicited comments from hospitals, physicians, patients, and beneficiary groups. These sections of the Act impose specific obligations on Medicare-participating hospitals that have an emergency department. 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 individuals, regardless of whether or not they are beneficiaries of any program under the Act. These provisions of the Act, taken together, are frequently referred to as the Emergency Medical Treatment and Labor Act (EMTALA), also known as the antidumping statute.

In response to our proposals, we received approximately 600 pieces of correspondence, most of which contained multiple comments. A large number of the comments were received on the last day of the comment period for the proposed rule (July 8, 2002). Because of the number and nature of the public comments we received on our proposed clarifications and our limited timeframe for developing the final acute care hospital inpatient prospective payment system regulations for publication by the statutory deadline of August 1, we have decided, with one exception, to address the public comments and finalize the proposals in a separate document. The one proposal being finalized in this document is our proposed revision to the second sentence of § 413.65(g)(1) to clarify the application of EMTALA to provider-based entities. That proposal, and the action we are taking with respect to it, are described more fully in section V.L.2.g. (Clarification of Obligations of Hospital Outpatient Departments and Hospital-Based Entities) of this preamble.

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. Except where superseded by new legislation, § 413.65 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.L.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 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 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. However, as we discussed in the May 9, 2002 proposed rule, we are providing for a further delay, as discussed below.

(3) Criteria for Temporary Treatment as Provider-Based

Section 404(c) of BIPA 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. 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.

The provision concerning temporary treatment as provider-based in section 404(c) of BIPA is effective only for requests filed before October 1, 2002. As explained further below, the procedures in new § 413.65(b)(3) will be followed in making any determinations of provider-based status in response to attestations submitted on or after October 1, 2002.

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 May 9, 2002 Proposed Rule

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, in the May 9, 2002

proposed rule, we proposed 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 proposed 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 is not necessary to resolve payment issues 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 also proposed 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 the May 9, 2002 proposed document, we proposed 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 proposed 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 proposed 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 proposed this change because we believed it 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 clarified 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.''

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 could exceed 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,

even if they are not provider-based, 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 proposed 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 proposed 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 proposed to 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. (As explained below, existing § 413.65(m) is being redesignated as § 413.65(n) in this final rule.)

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 did not propose to apply the criteria at § 413.65 to ambulance services.

We note that, in the May 9, 2002 proposed rule, we inadvertently did not make a conforming change to the regulations at § 413.65(a) to state that the provider-based rules do not apply to ambulances. Therefore, we are making this conforming change in this final rule.

Comment: One commenter recommended that all inpatient departments be exempt from the provider-based rules, regardless of whether they are on campus or off campus, since, due to their ''very status as inpatient departments, they are necessarily integrated into the operations of the main provider. * * *'' Several other commenters recommended that ancillary or other departments located within a hospital (that is, on campus) be deemed to be provider-based and thus not be required to show actual compliance with provider-based criteria.

Response: We do not agree that facilities that treat a patient population made up primarily or entirely of inpatients should necessarily be considered, on that basis alone, to be a fully subordinate and integral component of the main provider. There are instances where a Medicare payment differential exists between a hospital-based inpatient service and a freestanding service. For example, if an institution that primarily provides inpatient care is able to participate in Medicare as a part of a hospital, Medicare payment to the hospital will be made for the full range of inpatient hospital services defined in section 1861(b) of the Act. If the facility is not considered a part of a Medicare-participating hospital, Medicare payment would be made only for a much narrower range of services, such as physical and other therapies, which can be paid in ambulatory care settings. Compliance with the provider-based criteria is also needed to ensure that Medicare payment is made appropriately in merger situations, where the crucial issue is whether a facility is integral and subordinate to another that participates as a hospital. For example, under the TEFRA payment system applicable to psychiatric, children's and cancer hospitals, Medicare payment to the hospital for inpatient services usually is directly affected by the hospital-specific TEFRA target rate. If a particular hospital chooses to reorganize to include a new site that otherwise could participate in Medicare only as a separate hospital or as a remote location or satellite of still another hospital, the amount of payment would be affected. Similarly, for the reasons explained in detail in the May 9, 2002 proposed rule (67 FR 31482), a merger of two hospitals can significantly affect the payments made to them for their GME programs, even when each hospital is paid under the acute inpatient hospital prospective payment system. Under these circumstances, compliance with the provider-based criteria is also needed to warrant the higher payment level that would result.

We also do not agree that location on the main campus of a hospital should be the sole determinant of provider-based status, since hospitals can and frequently do lease space on their campuses to physicians and other providers or suppliers of health services, and these providers or suppliers may have no more connection to or integration into the hospital's operations than the lease agreement and physical proximity. For example, a hospital may lease some of its space to an independent diagnostic testing facility (IDTF) that furnishes radiology services, which are frequently considered by hospitals to be among their ancillary services. Such a facility could be paid significantly more as a provider-based department than as a freestanding facility. Because of this payment difference, we believe it is important that the facility meet standards that establish that it is an integral and subordinate part of the main provider hospital, and thus that the higher payment level associated with provider-based status is warranted. Therefore, we are not revising this final rule to permit on-campus facilities to qualify as provider-based solely because of location.

Comment: One commenter suggested that consolidations of facilities on separate campuses should not be subject to the provider-based requirements, but should be regulated only by the requirements on State licensure, Medicare certification, and Medicare enrollment.

Response: For the reasons explained in the response to the preceding comment, consolidation of facilities under a single provider number frequently has significant implications for Medicare payment levels. In many cases, the amount paid for services of a consolidated facility can be significantly more than the sum of what would be paid to two or more separate facilities for the provision of identical services. Current State licensure and Medicare certification requirements are focused on the protection of patient health and safety, and the determination of whether a facility is part of the main provider is not central to that concern. On the contrary, licensure and certification requirements may be easily manipulated by providers seeking to maximize payment under Medicare or Medicaid

without improving either the quantity or the quality of care furnished. Thus, it is crucial that we establish criteria to ensure that consolidated facilities are truly integral and subordinate to a single main provider.

Comment: Some commenters wrote on behalf of multicampus hospitals that operate under a single provider number and agreement, but include several campuses that are separately licensed by the State. The commenters stated that they have been structured in this way since before the inception of the Medicare program and thus did not adopt their current structures in an effort to maximize GME or DSH payments. The commenters explained that if multicampus hospitals are not exempted from the provider-based requirements, the hospitals would have to either designate one campus as the main campus and rearrange the clinical, financial, and other arrangements between the hospitals in order to comply with the provider-based requirements, or obtain a separate Medicare provider agreement and number for each campus. If the second course were chosen, total Medicare payment to the separate hospitals would be considerably less than what is currently being paid to them as multicampus organizations. Because the hospitals are unwilling to pursue either of the options outlined above, the commenter requested that either all multicampus hospitals be exempted from the provider-based requirements, or that an exemption be created for any such hospitals that have been structured as multicampus hospitals since the beginning of the Medicare program.

Response: We understand the commenter's concern, but for the reasons cited earlier in this preamble believe that it is important to apply the provider-based criteria to multicampus hospitals in which each campus is separately licensed, as well as to those in which all components operate under a single State license. In particular, such an exemption could lead to increased levels of Medicare GME and DSH payments, relative to the amounts payable if the provider-based criteria were applied. In fact, the commenter admitted that Medicare payment to the separate hospitals would be considerably less than what is paid to them as a single but multicampus hospital. We continue to believe it is important to pay for services of hospital facilities as part of a single hospital only when they meet the provider-based criteria we have established. Therefore, we are not adopting this comment.

Comment: One commenter requested more clarification of how the provider-based criteria apply to multicampus hospitals, and to multihospital systems (that is, chain organizations that include two or more hospitals, each of which participates separately in Medicare). The commenter was particularly interested in learning what would be the main campus of a multihospital system, and whether a facility or organization at one location of a multihospital system could be provider-based with respect to another hospital in that system.

Response: If a hospital comprises several sites at which both inpatient and outpatient care are furnished, it will normally be necessary for the hospital to designate one site as its ''main'' campus for purposes of the provider-based rules. Each of the other sites (referred to in our regulations as ''remote locations'') would then be expected to meet the provider-based requirements with respect to that main campus. Thus, any facility not located on a hospital's main campus would be considered to be an ''off-campus'' facility. Hospitals would normally be given considerable discretion in selecting which site is to be the ''main'' campus for provider-based purposes. In such a case, any outpatient facility also providing services at a ''remote location'' that are to be billed as services of the hospital would be considered as a potential hospital department for purposes of provider-based status and would be expected to meet the provider-based criteria with respect to the location designated by the hospital as its main campus. However, it is important to note that the provider-based criteria apply to individual hospitals, not to multihospital systems (for example, systems owned and operated by chain organizations). Where such a system exists, its hospitals will participate separately in Medicare, and the provider-based criteria will apply separately to each hospital in the chain. If a facility or organization located on the campus of one hospital in the chain wishes to be treated as part of another, separately participating hospital in the chain, the facility or organization would have to meet the provider-based criteria with respect to that hospital, on the same basis as if the two hospitals were not part of the same chain organization.

Comment: Several commenters stated that, in some areas, it is common for children's hospitals to set up and staff neonatal intensive care units (NICUs) in community hospitals, in order to extend these services into rural areas where they might not otherwise be available. The commenter noted that these units frequently cannot meet the location requirement for provider-based status in § 413.65(e)(3) of the proposed regulations, and asked that the final rule be revised to create a special exception to this requirement, to allow these units to continue to be treated as provider-based once the grandfathering period ends and to permit the creation of new units of the same type.

Response: We understand these commenters' concerns, but note that these units raise serious questions about the appropriate treatment of facilities located at long distances from the main children's hospital that nevertheless claim to be a part of that hospital. While these facilities may have very limited Medicare utilization, they frequently receive substantial amounts of payment under Medicaid, thus making it important to ensure that they are classified and paid appropriately. After considering these issues, we have concluded that it would not be appropriate to waive the location requirement for provider-based status, or make some other ad hoc exception to the provider-based criteria, for these facilities. However, we have explained in the FAQs the inability of units in certain locations to qualify for provider-based status does not preclude States from adopting revisions to their Medicaid plans to provide more generous payment to such units. While we are not making a special exception for NICUs, we recognize the importance of further emphasizing that when a payment difference exists, compliance with the provider-based rules is needed to justify payment for services in a facility as provider-based. Therefore, in this final rule, we are clarifying the regulations at § 413.65(a) to state that the determinations of provider-based status are made for payment purposes.

Comment: Some commenters requested clarification of how the provider-based criteria apply to multicampus hospitals that participate in Medicare under a single provider number but comprise two or more campuses that are physically separate from one another. The commenters were particularly concerned about which campus is to be identified as the main campus and about whether clinics or other facilities located on one campus of a hospital may be considered provider-based with respect to another campus.

Response: We agree that multicampus hospitals present special implementation issues. However, the following general principles will be applied. First, when hospital facilities are dispersed among two or more geographically separate campuses, it will be necessary for one of the campuses to be designated by the hospital as the main campus. Facilities at the other campus(es) would be

considered provider-based only if they meet the provider-based criteria in relation to the main campus. We would normally accept the provider's own selection of a main campus, unless the regional office concludes, in a particular case situation, that the campus selected by the provider clearly does not actually function as the main campus. The location requirements for a facility at a campus other than the main campus would be applied based on the distance between the facility and the main campus. Hospital chain organizations, which include a number of separately certified hospitals, would not be considered multicampus hospitals.

Comment: One commenter stated that the provider-based criteria are being applied under Medicaid only because the same certification standards apply under Medicaid as under Medicare. The commenter also pointed out that States are not required to follow Medicare payment system rules in making payment under their Medicaid programs. The commenter then argued that this State flexibility to determine Medicaid payment means that CMS should prohibit States from applying the provider-based criteria in determining payment under Medicaid.

Response: The commenter is correct in noting that the Medicaid regulations at 42 CFR 440.10 and 440.12 define inpatient and outpatient hospital services, for Medicaid purposes, as services furnished in or by an institution that meets the requirements for participation in Medicare as a hospital. Medicare participation by an institution as a hospital is contingent on the institution's compliance with many participation requirements, not merely the health and safety rules set forth in 42 CFR Part 482. The institution is also required under section 1866 of the Act and regulations at 42 CFR Part 489 to comply with various other statutory and regulatory provisions relating to (among other areas) charges to beneficiaries, maintenance of billing and other records, and the screening and stabilization, or appropriate transfer, of emergency cases. To the extent the hospital is required to comply with the provider-based criteria in Medicare regulations as part of its Medicare hospital participation obligations, the definitions of services in § 440.10 and 440.12 also require that it comply with these requirements for Medicaid purposes.

Regarding the commenter's remarks on State flexibility, we recognize that States are authorized to adopt, through their State plans, payment definitions and methods that differ from those used under Medicare. Thus, the commenter is correct in noting that a State may adopt payment methods that do not differentiate between facilities that meet the provider-based requirement and those that do not. To the extent that States amend their State plans to contain such payment methods, we do not object to these actions. However, we do not believe it would be consistent with State flexibility to prohibit States that wish to apply provider-based criteria in making their payment decisions from doing so. Such a prohibition would not benefit either States or their Medicaid recipients and, on the contrary, could increase State and Federal Medicaid spending unnecessarily. Therefore, we are not making any change in this final rule based on this comment.

Comment: Several commenters noted that Indian Health Service (IHS) and tribal clinics and other facilities meeting the criteria in § 413.65(l) (redesignated as § 413.65(m) in this final rule) are in effect excluded from the scope of the provider-based criteria by the grandfathering provision included in that section. The commenters further noted that under Public Law 93–638, the Indian Self-Determination Act, as amended, tribes have the right to contract for the management of all or a portion of the IHS programs that provide services in their communities. The commenters pointed out that tribal and IHS facilities remain the primary source of health care in many remote rural communities. However, because of the unique IHS and tribal administrative systems, many clinics and other facilities that might lose their grandfathered status under § 413.65(l) (redesignated as § 413.65(m) in this final rule) are not able to meet provider-based criteria. To avoid disrupting the operation of these vital sources of care in remote rural areas, and consistent with the objectives of the Indian Self-Determination Act, the commenters recommended that all clinics and other facilities operated by IHS or tribes should be exempted from the provider-based regulations.

Response: We understand the concern about the need to preserve access to health care by patients using IHS facilities in rural communities. However, we note that existing § 413.65(l) provides grandfathering protection for the facilities in operation when the existing provider-based rules were published, and that section 432 of BIPA amended the Medicare statute to permit payment for physician services in IHS clinics, thus providing an alternate funding source for facilities that become freestanding. Therefore, we do not believe a further change of the kind recommended by the commenter is needed.

Comment: One commenter noted that excluding facilities providing only physical, occupational, or speech therapy to ambulatory patients from the provider-based requirements does not meet CMS' own stated criteria for such exclusions, in cases where those facilities are operated by CAHs. A payment difference based on provider-based or freestanding status would exist in such cases. If such facilities were operated as freestanding they would be paid on a fee schedule basis. However, if they were operated as integral and subordinate parts of CAHs, they would be paid on the same reasonable cost basis as other components of the CAH. The commenter recommended that the exclusion language in § 413.65(a)(1)(ii)(H) be revised to state that the exclusion applies to such facilities other than those which are operated as part of a CAH.

Response: We agree and are revising this final rule to reflect this comment.

Accordingly, we are adopting as final the proposed revision to § 413.65(a)(1)(ii)(G), the addition of § 413.65(a)(1)(ii)(J), and the revisions of the definitions of ''Department of a provider,'' ''Provider-based entity'' and ''Remote location of a hospital under § 413.65(a)(2). In addition, in response to public comments, we are revising existing § 413.65(a)(1)(ii)(H) to clarify that the exclusion of facilities providing only physical, occupational, or speech therapy to ambulatory patients applies to these facilities only if they are not operated as part of a CAH.

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.

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 believed an additional delay in the effective date of the provider-based criteria is needed. Therefore, in the May 9, 2002 proposed rule we proposed 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 proposed 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 proposed to make the new requirements effective on October 1, 2002, with respect to provider-based status for facilities not qualifying for the grandfathering provision.

Comment: One commenter requested clarification of how the proposed delay in effective date for the facilities grandfathered under section 404(a) of BIPA will be applied. Specifically, the commenter asked whether facilities benefiting from the grandfathering would be able to take advantage of any additional flexibility provided under the final rules before the hospital's first cost reporting period beginning on or after July 1, 2003.

Response: As explained in the preamble to the proposed rule, the purpose of the delayed effective date for grandfathered facilities is to allow more time for any necessary contractual or organizational changes that hospitals or their grandfathered facilities might need to undertake to achieve actual compliance with the provider-based criteria. Under our proposal, this would be accomplished by simply extending the BIPA mandated grandfathering provision until the hospital's first cost reporting period beginning on or after July 1, 2003. To clarify the effect of the delay, we are revising the final rule to specify that the grandfathering provision applies to the requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), (h), and (i) of § 413.65 of this final rule. To the extent a particular grandfathered hospital might benefit from any other changes in paragraphs of § 413.65 other than those listed in the immediately preceding sentence, it would be able to receive that benefit as of October 1, 2002, which is the effective date of any revisions to the other paragraphs.

Comment: Several commenters requested that the grandfathering of facilities treated as provider-based on October 1, 2000 should continue indefinitely, not just until the start of the first cost reporting period on or after July 1, 2003, as we had proposed.

Response: We are providing an extension in the effective date of the provider-based rules for grandfathered facilities until cost reporting periods beginning on or after July 1, 2003, to allow these facilities sufficient time to make any contractual and organizational changes needed to comply with the new rules. However, we do not believe it is appropriate to allow the facilities that were treated as provider-based in the past to continue to be treated that way permanently, without ever having to meet the same requirements as newer facilities. To do so would create a permanent double standard under which some older facilities would continue indefinitely to be rewarded for their previous inappropriate billing. We note that even the statutory provision under section 404(a) of BIPA was set for a limited 2-year time period.

Comment: One commenter suggested that grandfathering be provided for all hospital facilities for which affirmative determinations of provider-based status had been made by CMS (previously, HCFA) before October 1, 2000, or that such facilities be presumed to meet the provider-based criteria in the revised regulations without having to attest to compliance with those criteria, so that any future determination that a facility is not provider-based would be applied on a prospective basis only.

Response: For the reasons noted above, we do not believe a general grandfathering of facilities is appropriate. In addition, the criteria in the program memorandum and instructions in effect before October 1, 2000, differ from the new proposed rules to be effective on October 1, 2002. Therefore, we do not believe it is appropriate to assume that facilities that received a provider-based determination under a prior set of criteria meet the new set of provider-based criteria in this final rule. Regarding the recommendation that any revised determination be made effective on a prospective-only basis, we note that, under § 413.65(c)(2), providers that have received affirmative determinations of provider-based status with respect to facilities or organizations are required to report material changes in the relationships between themselves and any provider-based facility or organization. A provider having a determination of provider-based status will need to comply with this rule and, in particular, as stated in revised § 413.65(l)(1), will need to report any aspect of its ownership or operation of the facility that it reasonably believes might not meet applicable provider-based requirements, to ensure that any redeterminations are made effective only prospectively.

Accordingly, we are adopting as final the proposed revision to § 413.65(b)(2), with a further clarification in response to a comment that the grandfathering provision applies to the requirements, limitations, and exclusions of § 413.65 (d), (e), (f), (h), and (i) only.

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, in the May 9, 2002 proposed rule, we proposed to revise the application requirements as follows:

First, we proposed to delete the existing application requirement under § 413.65(b)(3). We proposed 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). We also proposed to require the provider to maintain documentation of the basis for its attestations and to make that documentation available to CMS upon request. We noted that, under this 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. It

could benefit the provider to obtain a determination because, under the proposed § 413.65(l)(1) treatment of a facility as provider-based would cease only with the date that CMS determines that the facility no longer qualifies for provider-based status, 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. By contrast, a provider which did not seek such a determination or obtained a determination but failed to report a material change in its relationship with the facility, could face a partial recovery of past payments. Also, under proposed § 413.65(j) (Inappropriate treatment of a facility or organization as provider-based) a provider that does not seek a provider-based determination and incorrectly bills as such could be subject to the partial recovery of payments for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889. We further proposed 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 an 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 noted that, under the 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 indicated that, alternatively, we would consider 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. In the May 9, 2002 proposed rule, we specifically solicited comments on the appropriateness of this or other alternative application procedures.

Comment: Some commenters stated that although it appears that the mandatory application requirement under the existing regulations has been replaced with the voluntary attestation process, the preamble of the May 9, 2002 proposed rule made several references to procedures for applying for provider-based status. The commenters stated that if such references to an application in the final rule must be maintained in order to deal with applications submitted prior to the creation of the attestation process, such references should be clarified accordingly.

Response: While we have proposed to replace the mandatory requirement for provider-based determinations under existing § 413.65(b) with a voluntary attestation process, we note that providers still have the option of obtaining a determination of provider-based status for their facilities, which we encourage. The proposed method for doing so is through the attestation process. Under § 413.65(b)(3), the provider may obtain a determination of provider-based status by submitting an attestation stating that the facility meets the relevant provider-based requirements (depending on whether the facility is located on campus or off campus).

As we stated in the May 9, 2002 proposed rule (67 FR 31481), ''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.'' For purposes of this final rule, we are clarifying that, effective October 1, 2002, an attestation of provider-based status has the same effect as a request for provider-based status, in that approval of an attestation would result in a determination that a facility or organization is provider-based. Prior to October 1, 2002, the effective date of the final rule (or, in the case of grandfathered facilities, prior to the start of the provider's first cost reporting period beginning on or after July 1, 2003), the provider would submit a request for provider-based determination (as opposed to an attestation). (Until the effective date of these regulations on October 1, 2002, providers should contact their CMS Regional Offices for information regarding application procedures). For providers wishing to obtain a provider-based determination after October 1, 2002, the providers would submit an attestation to CMS. Accordingly, until a uniform request or attestation form is available, at a minimum, the provider 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 request or attestation is submitted. The provider must also enumerate each facility and state its exact location (that is, its street address and whether it is on campus or off campus) and the date on which the facility became provider-based to the main provider. Documentation in support of the attestation of provider-based status must be submitted with the attestation for facilities located off campus. Main providers that submitted a request for a provider-based determination after October 1, 2000, but prior to the publication of this final rule, would be protected under section 404(c) of BIPA from recovery of overpayments in periods prior to the date on which CMS determines a facility is not provider-based.

We note that even though we proposed to remove the current general requirement that a determination of provider-based status be obtained, we did not propose to revise paragraph (n) of § 413.65 (redesignated in this final rule as paragraph (o)). That paragraph states that provider-based status cannot be effective before the earliest date on which a request for provider-based status has been made and all requirements of 42 CFR Part 413 have been met. To avoid creating confusion for providers and contractors and to allow the regulations to be implemented properly, we are making a conforming change to paragraph (o) to eliminate any reference to a mandatory application or determination, with one exception. As explained later in this preamble, we also state in § 413.65(o) that if a facility or organization is found by CMS to have been inappropriately treated as provider-based under paragraph (j) for certain time periods, or previously was

determined by CMS to be provider-based but no longer qualifies as provider-based because of a material change occurring during those periods that was not reported to CMS, CMS will not treat the facility or organization as provider-based for payment until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under Part 413.

Comment: One commenter stated that the proposed rules do not appear to provide hospitals that submit an attestation with any benefit with respect to recoupment of overpayments. For example, the commenter stated that, under the proposed rule, a provider could submit an attestation and begin providing and billing for provider-based services for years before receiving a determination from CMS that it is not provider-based and consequently be subject to the recovery of payments if CMS later determines that the facility is not provider-based. The commenter requested that a provider that submits a complete attestation not be liable for recovery of overpayments, but rather it should only be improper to bill as provider-based subsequent to a determination by CMS that a facility is not provider-based. Another commenter expressed concerns about possible long delays by CMS in reaching decisions on attestations and recommended that CMS require its regional offices to approve or disapprove provider-based status for each facility within 60 days after having received the attestation regarding that facility. Another commenter stated that it would like a written response to the attestations and accompanying documentation from CMS for the providers to keep on file.

Response: We do not agree that it would be appropriate to allow a provider that has attested inaccurately to being provider-based to retain payments made to the provider as if the facility were in full compliance with provider-based criteria. However, CMS would not recover all past payments for periods subject to reopening, but instead would recover only the difference between the amount of payment 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. At the time that CMS determines that a facility that submitted a complete attestation is actually not provider-based, payment would continue for up to 6 months but only at a reduced rate as described at § 413.65(j)(5).

Regarding the timeliness of action on attestations, we agree that providers should not be subject to long delays before action is taken. In response to this and other comments requesting further information on the procedures CMS will follow when an attestation is received, we are revising § 413.65(b)(3) by adding new paragraphs (iii) and (iv). In new paragraph (b)(3)(iii), we are clarifying that whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, CMS will send the provider written acknowledgement of receipt of the attestation, review the attestation for completeness, consistency with the criteria in § 413.65, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility is provider-based. In new paragraph (b)(3)(iv), we are clarifying that whenever a provider submits an attestation of provider-based status for an off-campus facility or organization, CMS will send the provider written acknowledgement of receipt of the attestation, review the attestation for completeness, consistency with the criteria in § 413.65, consistency with the documentation submitted with the attestation, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility is provider-based.

We also will work with our regional offices and intermediaries as necessary to ensure that providers that submit attestations receive a prompt response. However, because of workload considerations and uncertainty about the volume of attestations that may be received, we have not yet specified a timeframe for completion of action on an attestation.

Comment: One commenter recommended that if CMS finds an attestation to be incomplete, the provider be given an additional 30 days to submit supplementary information in support of the attestation.

Response: We agree that providers who inadvertently omit needed information from an attestation should be given a reasonable opportunity to supplement that information. However, at the same time, we agree with the commenters who pointed out the importance to the provider of receiving a timely decision on whether a particular facility qualifies for provider-based status. If CMS were to delay a decision for a provider that repeatedly submitted incomplete attestations, this would prevent a timely response and could defeat the purpose of the attestation procedure. We intend to develop further implementing instructions and procedures that will strike a reasonable balance between the need for additional information and the need for a timely decision.

Comment: One commenter requested that we reiterate that, since providers are no longer required under the proposed revised regulations to submit an attestation or an application for provider-based status as a precondition to billing for provider-based services, CMS would only consider a provider to be billing inappropriately if the provider was wrong in its conclusion that it meets the provider-based requirements. The commenter also asked that we clarify that facilities grandfathered under BIPA also need not submit an attestation, even at the expiration of the grandfathering period. Facilities grandfathered by BIPA will be treated the same as all other facilities on the date that their grandfathering period expires, which is the start of the cost reporting periods that begin on or after July 1, 2003.

Response: The commenter is correct in the view that providers, regardless of whether they are grandfathered under BIPA, are not obligated to submit attestations or applications for provider-based status before they begin billing as provider-based, and that a provider would only be considered to be billing inappropriately if the facility actually did not meet the relevant provider-based rules. However, we note that if a provider does not submit a complete attestation of provider-based status, and CMS subsequently determines that the provider is billing inappropriately, the provider would be subject to recovery of overpayments under § 413.65(j)(ii) for services at that facility(ies) for all prior cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889.

Comment: One commenter noted that all hospitals, even those previously subject to grandfathering, will be subject to the new regulations as of their first cost reporting periods starting on or after July 1, 2003. In view of this obligation, the commenter believed that it is unnecessary for attestations to be submitted for any facilities that are located on the campus of the hospital that claims them as provider-based. The commenter also recommended that if CMS later determines that the facility does not meet the provider-based criteria, CMS should not recover any past payments attributable to improper billing, but apply its determination only prospectively.

Response: As explained more fully earlier in this preamble, under these final rules, while the provider-based criteria must be met, no provider is required to submit an attestation for any facility as a precondition to billing for its services as a provider-based facility. This is the case even where the facility is located on the main campus of a hospital. However, we believe an attestation has value, in that a provider that makes such an attestation presumably does so after having reviewed the provider-based criteria and assessed a particular facility's structure and operations in relation to them. Moreover, the attestation relates to compliance with only a minimal level of integration, and does not require any supporting documentation. Therefore, we do not believe that providing an attestation will require an unreasonable level of effort from the provider.

Comment: One commenter recommended that off-campus facilities be required to submit attestations of compliance with the provider-based criteria before the date on which the revised regulations become effective for them. (For grandfathered facilities, §§ 413.65(d), (e), (f), (h), and (i) of the revised regulations would become effective for the hospital's first cost reporting period starting on or after July 1, 2003.) The commenter also recommended that if these facilities are later found not to have met the provider-based requirements, any determination that they are not provider-based should be applied only prospectively.

Response: As explained in response to a previous comment, we cannot agree that a provider should be allowed to retain payments made as if a facility were provider-based after a determination has been made that the provider-based criteria were not met. Therefore, this final rule provides for recovery of past payments to the extent necessary to make those payments relate more closely to what would have been paid if the facility's services had been billed on a freestanding basis.

Comment: One commenter expressed approval of our proposal under which supporting documentation would not have to be submitted with the attestation for on-campus facilities. The commenter suggested that the paperwork burden for providers could be further reduced if the regulations were revised to eliminate the need for supporting documentation for attestations regarding off-campus facilities or organizations as well. Another commenter stated that hospital-licensed community health centers frequently are located within a few miles of the main provider-campus and are closely integrated with it. The commenter believed these facilities should not be required to submit supporting documentation.

Response: We understand and share the commenters' interest in reducing the paperwork burden on providers. However, this important objective must be balanced against the equally important need to ensure proper accountability by providers for the status of the facilities or organizations for which they are claiming provider-based status. Determining whether an off-campus facility is truly integrated with a main provider is more difficult than for a facility located on the main campus of a provider, and this is why there are additional requirements for off-campus facilities to demonstrate provider-based status. In view of this, we believe it is reasonable to require that an attestation regarding an off-campus facility, including hospital-licensed community health centers, be accompanied by supporting documentation that clearly shows the basis for the attestation.

Comment: One commenter noted that proposed § 413.65(b)(3)(i) requires a provider that makes a provider-based attestation with regard to an on-campus facility to make documentation supporting that attestation available to CMS upon request. The commenter recommended that the regulation be revised to require that the supporting documentation also be made available to CMS contractors (fiscal intermediaries and carriers) upon request. *Response:* We agree, and are revising the final rule accordingly.

Comment: One commenter asked CMS to provide guidance as to the type of documentation that is required to be submitted with an attestation for an off-campus facility. Another commenter suggested that before a uniform application is available, providers should be required to submit information regarding physical location, a contact person, and the date the facility became provider-based to the main provider.

Response: As stated above, until a uniform attestation form is available, at a minimum, the attestation should include the identity of the main provider and the facility(ies) or organization(s) 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. The provider must also enumerate each facility and state its exact location (that is, its street address and whether it is on campus or off campus) and the date on which the facility became provider-based to the provider. We plan on issuing further guidance in program instructions after publication of this final rule.

Comment: One commenter noted CMS' authority to terminate payment prospectively if a provider fails to provide all necessary information as part of the continuation of payment provisions under § 413.65(j)(5). Given this authority, and because the commenter believed it will be difficult for providers to know what constitutes a complete attestation, the commenter recommended that CMS provide the opportunity for providers to supplement their original submissions with additional information within 30 days of receipt of notice from CMS that the submission is incomplete.

Response: Under § 413.65(b)(3), a complete request (or attestation) is one that includes all information needed to permit CMS to make a determination. We have stated above that we plan to issue further guidance as to what information should be included in an attestation. However, we note that, under § 413.65(j)(5), a provider must notify CMS in writing within 30 days of the date that CMS issues its denial of provider-based status, of whether the provider intends to seek a determination of provider-based status for the facility or whether the practitioners will be seeking to enroll to bill Medicare or Medicaid for services at that location as a freestanding facility. If the provider notifies CMS of its intentions within 30 days, the provider has up to 6 months to take whatever steps are necessary to comply with the relevant rules, whether that means providing CMS with supplemental documentation or making changes to meet the regulatory requirements (for example, a provider is renegotiating its management contracts). Therefore, we believe it is unnecessary to add an additional 30 days to the interim period in which payment continues at a reduced rate.

Comment: One commenter asserted that if CMS has concerns about the status of on-campus facilities, it should be incumbent on CMS to initiate an investigation and to provide notice to the provider and opportunity for the facilities to fix any discrepancies prior to losing provider-based status. The commenters added that it is still unclear whether every service on the hospital's campus would need to submit an attestation, or if one attestation is sufficient to cover all on-campus facilities. Some commenters also asked whether, and in what timeframe, these sites will receive a written response from CMS.

Response: We do not agree with this commenter's suggestion that providers that have been inappropriately treating certain facilities as provider-based and have not attempted to obtain a provider-based determination should be protected from recovery of past overpayments. However, we note that § 413.65(j)(5) of this final rule would allow such a provider up to 6 months of continued payment, at an adjusted rate, to meet applicable billing requirements.

In regard to the commenter's request for clarification concerning whether every service on the hospital's campus would need to submit an attestation, or if one attestation is sufficient to cover all on-campus facilities, we emphasize that the provider-based rules do not apply to specific services; rather, these rules apply to facilities as a whole. That is, the facility in its entirety must be a subordinate and integrated part of the main provider. For example, a provider may have several outpatient facilities, some located on campus and some located off campus, yet each facility as a whole must meet the applicable rules for provider-based status. However, a main provider would not need to submit a separate application for each one of its facilities for which a provider-based determination is sought. A provider may attest in a single application package that each one of its facilities in which it intends to bill for services as if the facility is provider-based meets the applicable provider-based rules under § 413.65. For those facilities that are located on campus, no documentation is required to be submitted with the attestation. Documentation must be submitted for those facilities located off campus. However, we are requiring that as part of its attestation, the main provider enumerate each facility and state its exact location (that is, its street address and whether it is on campus or off campus).

As noted earlier, the commenters also asked whether, and in what timeframe, a provider that submits an attestation will receive a written response from CMS. While we are making revisions in these final rules to provide more information about the actions CMS will take in response to such an attestation, at this time, due to the uncertainty of the volume of requests that will be submitted by providers, we cannot state an exact timeframe in which the provider-based determinations will be made for on-campus or off-campus facilities. Each attestation will be received and processed by the appropriate CMS Regional Office (or fiscal intermediary) and will be reviewed as soon as possible.

Comment: One commenter asked if a ''re-attestation'' is required after a certain period of time.

Response: Just as providers are no longer explicitly required to submit an initial attestation, there is also no explicit requirement for hospitals to re-attest that their facilities continue to meet the provider-based requirements. However, we note that, under proposed § 413.65(k) (revised as § 413.65(l) in this final rule), if CMS determines that a facility that had previously been determined to be provider-based no longer qualifies for provider-based status, and the failure to qualify for provider-based status results from a material change in the relationship between the main provider and the facility that the main provider *did* report to CMS, treatment of the facility as provider-based would cease with the date that CMS determines that facility no longer qualifies for provider-based status. Conversely, if a main provider *did not* report a material change to CMS, the main provider will be subject to recovery of overpayments as described under § 413.65(j)(1)(ii).

Comment: One commenter stated that the use of the term ''advance determination'' is confusing because the rule does not provide for an advance determination of provider-based status.

Response: We agree with the commenter and are removing all references to ''advance'' used in connection to provider-based determinations from this final rule. We note that, under proposed § 413.65(k) (revised as § 413.65(l) in this final rule), a provider that submits a complete attestation of compliance with the provider-based status requirements for a facility that has not previously been found by CMS to have been inappropriately treated as provider-based, may bill and be paid for services of the facility as provider-based from the date of its attestation of provider-based status until the date that CMS determines that the facility is not provider-based.

Accordingly, we are adopting as final the proposed changes to § 413.65(b)(3) with the following modifications: We are revising § 413.65 by adding new paragraphs (b)(3)(iii) and (iv) to include further information on procedures for submitting and processing attestations; removing references to the term ''advance'' in connection with determinations in paragraphs (b)(3)(i) and (ii); and adding language under paragraph (b)(3)(i) regarding the availability of documentation to contractors.

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, in the May 9, 2002 proposed rule, we proposed 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 were proposed to 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, in the May 9, 2002 proposed rule, we proposed 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 was proposed to 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 proposed 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 proposed 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 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 proposed to relocate the requirement to paragraph (e) as described below.

We also proposed 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 proposed other changes to paragraph (g).

We did not receive any comments on these proposed changes. Therefore, in this final rule, we are adopting the proposed changes as final.

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 than for on-campus facilities or organizations, 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, in the May 9, 2002 proposed rule, we proposed to retain certain requirements to demonstrate integration that we proposed to remove for on-campus facilities or organizations. These requirements were set forth in proposed new § 413.65(e). The requirements set forth in proposed paragraphs (e)(1), (e)(2), and (e)(3) included 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 did not receive any comments on these proposed changes. Therefore, in this final rule, we are adopting the proposed changes as final.

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, in the May 9, 2002 proposed rule, we proposed 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 proposed to 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 proposed to make minor changes to the second sentence of the redesignated paragraph (f) to clarify its meaning.

Comment: One commenter noted that proposed § 413.65(f) states that facilities or organizations operated by two or more providers engaged in a joint venture cannot be considered provider-based if they are not located on the campus of the potential main provider. The commenter believed that the rule would be more easily understood if paragraph (f) were revised to state that a facility or organization owned by two or more providers engaged in a joint venture cannot be considered provider-based unless it is located on the campus of at least one of the providers engaged in the joint venture.

Response: We agree that clarification of the joint venture requirements is needed. Therefore, in this final rule we are revising § 413.65(f) to clearly state that, in order for a facility or organization operated as a joint venture to be considered provider-based, it must (1) be partially owned by at least one provider; (2) be located on the campus of a provider who is a partial owner; (3) be provider-based to that one provider whose campus on which the facility or organization is located; and (4) meet all of the requirements applicable to all provider-based facilities and organizations in § 413.65(d). Therefore, to be treated as provider-based, the facility operated as a joint venture must be provider-based to the provider whose campus on which the facility is located, regardless of whether that provider is the majority owner.

For example, if Hospital A owns 60 percent of Facility C and Hospital B owns 40 percent of Facility C, but Facility C is located on the campus of Hospital B, Facility C may only be provider-based to Hospital B.

Comment: One commenter asked if the provider where the service is located has to be the billing provider of the joint venture. The commenter also had questions about the rules concerning public awareness and other criteria as they relate to a joint venture service. The commenter asked whether the facility had to advertise as a joint venture, as a service of the provider where the site is located, or as a service of the billing provider.

Response: As we explained in the response to the previous comment, the facility owned by a joint venture must be provider-based to the provider whose campus on which the facility is located, regardless of whether that provider is the majority owner. The main provider does not have to advertise as a joint venture, but as a facility that is provider-based to the main provider. Accordingly, the services in the facility would be billed using the provider number of the provider whose campus on which the facility is located. (The facility cannot, of course, be provider-based with respect to both hospitals.) In addition, the facility owned by a joint venture must also meet all the requirements applicable to all provider-based facilities in § 413.65(d).

Comment: Some commenters requested that CMS allow facilities owned by a joint venture but not located on a hospital's campus to be considered provider-based. The commenters stated that joint ventures among and between hospitals in rural areas greatly help to improve access to care.

Response: While it is not our intent to limit access to care, we continue to believe that facilities owned by joint ventures that are not located on a main provider's campus do not qualify as provider-based. Thus, we are not adopting the commenter's request.

Accordingly, we are adopting as final the proposed § 413.65(f), with clarifying changes to the criteria for being determined a joint venture as discussed under the responses to comments.

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, in the May 9, 2002 proposed rule, we proposed 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 proposed to make three changes in existing § 413.65(g). First, we proposed to revise paragraph (g)(1) by deleting the second sentence of that paragraph. In paragraph (g)(2), we proposed 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 proposed 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. We believed that this clarification was 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. Further, we proposed to 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.

We did not receive any comments on these proposed changes to § 413.65(g)(2) and (g)(7). Therefore, in this final rule, we are adopting the proposed changes as final

With regard to the proposed changes to § 413.65(g)(1), although we stated above that we are planning to finalize EMTALA policy proposed on May 9, 2002 in a separate document to be published shortly, we are adopting as final the proposed change concerning the applicability of EMTALA to provider-based entities located on the hospital main campus. Currently, under § 413.65(g)(1), if any individual comes to any hospital-based entity (including an RHC) located on the hospital main 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. We stated in the proposed rule (67 FR 31477) that, 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 of the Act, which restricts EMTALA applicability to hospitals. To avoid confusion on this point and the extension of EMTALA requirements to other nonhospital providers, we are clarifying at § 413.65(g)(1) that EMTALA applies in this scenario to only those departments on the hospital's main campus that are provider-based. Accordingly, EMTALA does not apply to provider-based entities (such as RHCs) that are either on or off the hospital campus.

Because we received no public comments on this proposed clarification on the applicability of EMTALA to provider-based entitles, we are adopting as final this one change at § 413.65(g)(1) by deleting the second sentence at existing § 413.65(g)(1) that addresses this policy. However, we note again that in this final rule we are not adopting other clarifications in the proposed rule concerning application of EMTALA to provider-based departments, on or off the campus, or any other proposals concerning EMTALA. We received over 600 pieces of correspondence on these subjects. In order to give proper consideration to these comments, we plan to issue a final policy on the EMTALA proposals in a separate document.

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 in the May 2002 proposed rule 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 proposed to restrict the applicability of proposed redesignated paragraph (h) to off-campus facilities or organizations. In addition, we proposed two additional changes that we believe are needed to respond to questions that are raised frequently about the regulation. First, we proposed to 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 did not propose to specify who may employ other support staff, such as maintenance or security personnel, and who are not directly involved in providing patient care, nor did we propose to require licensed professional caregivers such as physicians, physician assistants, or certified registered nurse anesthetists to become provider employees. We also proposed 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.

Comment: One commenter supported the proposal eliminating restrictions on management contracts and joint ventures for on-campus facilities. The commenter also supported the modification to the management contract rules applicable to off-campus facilities that requires the main provider to employ only those staff who are directly involved in the delivery of patient care, other than staff who may be paid under the Medicare fee schedule, management staff, and other support staff. Another commenter recommended that CMS limit the management contract restrictions for off campus facilities by allowing the management company to employ at least some of the patient care staff at the facility, as long as the facility remains integrated with, and under the control of, the main provider.

Response: We agree with the commenter who stated that it is appropriate to require the main provider to employ only those staff who are directly involved in the delivery of patient care, other than staff who may be paid under the Medicare fee schedule, management staff, and other support staff. We considered the comment suggesting that the regulations be further changed to allow at least some of these staff to be provided under a management contract. However, we are not adopting this change. We note that the revisions in the proposed rule would have significantly relaxed the requirements relating to management contracts by restricting the scope of those provisions to off-campus facilities and by expanding the range of services that may be furnished under management contracts in those facilities. Under our proposal, even if only the services described in this comment would have to be furnished by the provider, the provider would be permitted to bill as if it delivered the services itself. If we were to further weaken the management contract requirements, this would remove any effective control on such contracts, thereby allowing the provider to claim provider-based payment for a facility with which it has only a contractual relationship. We believe such a tenuous connection between the provider and the facility does not warrant payment for the facility's services as services of an ''integral and subordinate'' part of the provider. Therefore, we are not adopting this comment.

Comment: One commenter recommended that inpatient facilities be exempted from the management contract requirements in proposed § 413.65(h).

Response: We note that our proposed rule accomplished much of what the commenter recommended, in that it would exempt on-campus facilities, including those facilities that treat a patient population made up largely or entirely of inpatients, from the management contract requirements in § 413.65(h). We are adopting this proposal without change in the final rule. However, for the reasons discussed earlier in responding to comments on the scope of the provider-based requirements, we do not believe it would be appropriate to exclude off-campus facilities and organizations from the management contract requirements.

Comment: One commenter recommended that CMS regional offices be authorized to exempt facilities or organizations from the management contract requirements on a case-by-case basis, depending on the circumstance in each case.

Response: We agree that regional offices need to exercise judgment in application of the criteria, but do not agree that the exercise of that judgment should include discretion to entirely waive applicability of a requirement. This could lead to wide variations in the applicability of the provider-based criteria in different areas of the country. Therefore, we are not making any change in the final rule based on this suggestion.

Comment: Some commenters requested clarification of the relationship between provision of services under management contracts and under arrangements of the kind described in section 1861(w)(1) of the Act. The commenters further recommended that proposed § 413.65(i), which states that a facility or organization cannot qualify for provider-based status if all services at the facility are furnished under arrangements, be revised so that it does not apply to on-campus facilities. The commenters expressed concern that if that change is not made, management contracts for on-campus facilities or organizations that are permitted under proposed §§ 413.65(d) and (h) would nevertheless be prohibited by § 413.65(i).

Response: Generally, we believe there is a substantial difference between the use of management contracts to obtain some or all input services needed to operate a health care facility, including not only management but professional and other staffing, security, maintenance, other support services, and the use of section 1861(w)(1) arrangements by a provider to obtain specialized health care services that it does not itself offer, and that are needed to supplement the range of services that the provider does offer its patients. In the first situation, it is possible that all or virtually all services needed to operate a facility could be obtained under contract, resulting in nothing more than a nominal connection between the facility and the provider that claims it as an integral and subordinate part. To prevent a facility operated in this way from inappropriately claiming to be part of a provider, reasonable controls on management contracts are needed. In the latter case, a provider may

legitimately obtain limited specific services under arrangements without sacrificing its ability to function independently as a provider and directly furnish care to its patients.

In this context, we would agree with the commenter that a provider that operates a facility that qualifies legitimately as provider-based may choose to obtain some specialized services for its patients under arrangements without needing to meet the management contract requirements of § 413.65(h) with respect to each individual service. As noted above, these requirements apply to facilities, not to individual services. However, we continue to believe it would be inappropriate for a facility, whether located on or off campus, to evade the provider-based requirements by claiming to provide all of its services under arrangements. Therefore, we are not making further changes to § 413.65(i).

Comment: One commenter stated that CMS' intentions were unclear in the proposed regulations at § 413.65(h)(1) that state, ''Leased employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) are not considered to be employees of the provider for purposes of this paragraph.'' The commenter added that it is unclear if this provision prohibits arrangements under which a management company employs clinical staff paid under a fee schedule that are subsequently leased to the main provider to provide services in the provider-based facility. The commenter suggested that we clarify this language and, in the final rule, state that the exception to the main provider employment requirement for patient care staff that furnish services paid for under a fee schedule also applies to leased employees from a management company.

Response: In the proposed rule, we stated that the main provider is required to employ only those staff who are directly involved in the delivery of patient care other than staff who may be paid under the Medicare fee schedule, management staff, and other support staff. Therefore, the main provider may not use ''leased'' employees if those employees are directly involved in delivering patient care and cannot be paid under the Medicare fee schedule. However, this provision would *not* prohibit arrangements under which a management company employs clinical staff who may be paid under a fee schedule that are leased to the main provider to provide services in the provider-based facility. The management company may otherwise employ and provide the staff who furnishes patient care services that may be paid for by Medicare under a fee schedule. Accordingly, as the commenter recommended, we are clarifying the regulations text to state that, other than staff that may be paid under a Medicare fee schedule, the main provider may not utilize the services of leased employees who are directly involved in patient care in off-campus facilities.

Comment: One commenter stated that the proposed regulation that would require the main provider to employ all staff who ''are directly involved in the delivery of patient care, except for management staff * * *'' is confusing, because in many instances, managers are involved both in management activities and in furnishing direct patient care.

Response: If these managers are also medical professionals who may receive payment for their patient care services under a Medicare fee schedule, they do not need to be employed directly by the main provider.

Comment: Some commenters stated that the prohibition of off-campus management contracts will have harmful consequences, particularly in areas where private hospitals have partnerships with local government to operate off-campus psychiatric facilities in remote, underserved areas. The commenter explained that the county government manages an off-campus psychiatric facility as an inpatient psychiatric unit of a private hospital, and that county employees provide all patient care services in the unit. Although the facility is currently grandfathered under section 404(a) of BIPA, the facility will be unable to qualify for provider-based status when the grandfathering period expires, resulting in a loss of essential mental health services to the surrounding communities. The commenters requested that counties that have partnerships with private entities in order to ensure access to care and meet all other provider-based criteria be exempted from the management contract prohibition.

Response: While we are sympathetic to the needs of the medically underserved, we do not believe the management contract requirements to be overly restrictive. Rather, we believe the employment of the staff of an off-campus facility is a significant factor in determining the degree to which a facility or department is integrated (that is, provider-based) with its parent hospital. This is particularly important in a facility operated under a management contract. Because such a facility already receives management (and typically, many other services and supplies) from the management company, employment of the caregivers by the provider provides a strong link to the provider's other operations and demonstrates that the facility continues, despite the purchase of management services under contract, to be an integral and subordinate part of the provider. As such, we do not believe that it is appropriate to exempt any off-campus facilities from the management contract requirement.

Accordingly, we are adopting as final the proposed § 413.65(h) with one change to paragraph (h)(1) to clarify use of leased employees by a provider as discussed in the response to comments.

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 having submitted a complete attestation regarding provider-based status as described earlier, 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 estimate 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.

In the May 9, 2002 proposed rule, we proposed 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 proposed 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, we proposed (proposed § 413.65(j)(1)(ii)) that 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 proposed to make recovery for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889. Also, we proposed to adjust future payments to estimate 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 proposed 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.

Comment: One commenter stated that, under current policies, teaching hospitals may claim the time residents spend training at freestanding facilities (known as ''nonhospital sites'') only when there is a written agreement between the hospital and the nonhospital site. No written agreement is needed if the site is provider-based. The commenter asked that if CMS determines that a facility does not meet the provider-based rules, the indirect medical education (IME) payments that were received by the teaching hospital should not be affected.

Response: If CMS determines that a provider, whether teaching or nonteaching, is inappropriately receiving payment in a facility since the facility is determined not to be provider-based, CMS would take several actions, including, as described under § 413.65(j)(3), reviewing payments for past cost reporting periods in order to recover the difference between the amount of payment that was made to the provider and an estimate of payments that CMS would have made had the facility not been provider-based. It is conceivable that overpayments may have been made, not only for IME but also for direct GME, to a teaching hospital that incorrectly treated a facility as provider-based, and, as such, we would recover an amount of payment for both IME and direct GME that would otherwise not have been received by the hospital had the facility been freestanding.

(2) Good Faith Effort

We proposed to retain the existing exception for good faith effort (proposed redesignated § 413.65(j)(2)). Under this exception, we specified that 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 § 413.65(g)(2).

Under § 413.65(j)(5), we proposed that 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.

As clarified in § 413.65(o) of this final rule, we would not resume provider-based payment to such a facility or organization based on an attestation of compliance. On the contrary, if a facility or organization is found by CMS to have been inappropriately treated as provider-based under paragraph (j) for any period on or after October 1, 2002 (or, in the case of facilities or organizations described in § 413.65(b)(2), for cost reporting periods starting on or after July 1, 2003), CMS will not treat the facility or organization as provider-based for payment until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under Part 413.

Comment: One commenter suggested that, given the complexities surrounding the provider-based rules and the delays in implementing the regulations and establishing a uniform process, the final rule should provide that any provider that complies with the good faith exception under § 413.65(j)(2) should also not be subject to any retroactive recoupment of payments under proposed paragraphs (j) and (k).

Response: The regulations at § 413.65(j)(2) state that recovery of overpayments will not be made for any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001, if the provider made a good faith effort to treat its facilities as provider-based during all that period. This good faith exception was originally included in the April 7, 2000 regulations (originally applicable to periods before October 10, 2000, the original effective date of the provider-based regulations, but subsequently delayed to January 10, 2001).

We believe a good faith exception is appropriate for cost reporting periods beginning before January 10, 2001, when the provider-based regulations first became effective, since it would protect providers that were unaware of the new regulations, yet operated facilities that met a minimal threshold for integration. However, CMS has now published two proposed rules and one final rule on provider-based status, has published ''Qs and As'' on its website, and has consulted extensively with the hospital industry through teleconferences and meetings. Given the publicity that the provider-based regulations have received and the latest delayed effective date of these rules, we do not believe it is appropriate to extend the scope of the good faith exception.

Accordingly, we are adopting the proposals discussed above as final. In addition, we are revising section 413.65(j)(2)(ii) to refer to ''billed with the correct site-of-service'' rather than ''site-of-service indicator'', for consistency with the revision to § 413.65(g)(2) described above.

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

Under proposed revised § 413.65(k), we proposed to 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 proposed 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 indicated that 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 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 proposed 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 proposed not to recover payments for any period before the provider's first cost reporting period beginning on or after July 1, 2003.

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

Comment: One commenter requested that provider-based payment for services of a facility be allowed to continue while the facility is challenging any determination that it is not provider-based.

Response: As we explain in the proposed revised regulations at § 413.65(k), provider-based payment for services at a facility will continue until the date that CMS determines that the facility does not meet the provider-based rules. Once a determination concluding that a facility does not meet the provider-based rules is made, we believe it is inappropriate to continue paying for services at that facility as provider-based. Then, depending upon a number of factors, including whether the facility had previously been determined by CMS to be provider-based and whether the loss of provider-based status resulted from a material change that was or was not reported to CMS, CMS will take actions with respect to recovery of overpayments and continuation of payments at the appropriate nonprovider-based reduced rate, as described in the proposed revised § 413.65(j).

Comment: One commenter noted that proposed paragraph (k) contains some rules applicable to facilities for which there has not been a previous

determination of provider-based status (paragraph (k)(1)) and others that apply to facilities for which such a determination has been made (paragraphs (k)(2) and (k)(3)). The commenter believed these rules would be more clearly understood if the rules for each situation were stated in separate paragraphs.

Response: We agree with the commenter. In this final rule, we are placing the text of proposed paragraph (k)(1) concerning facilities for which there has been no previous determination in new paragraph (k), and the text of proposed paragraphs (k)(2) and (k)(3) concerning facilities for which previous determinations have been made in paragraph (l). Proposed sections (l) through (n) are being redesignated as paragraphs (m) through (o).

In addition, as noted earlier in this preamble, we state in § 413.85(o) of this final rule that, effective for any period on or after October 1, 2002 (or, in the case of facilities or organizations described in § 413.85(b)(2), for cost reporting periods starting on or after July l, 2003), if a facility or organization previously was determined by CMS to be provider-based but no longer qualifies as provider-based because of a material change occurring during those periods that was not reported to CMS, CMS will not treat the facility or organization as provider-based for payment until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under Part 413.

Comment: Regarding the references in paragraphs (k)(1) and (k)(2) of proposed § 413.65 (to be redesignated as (l)(2) and (l)(3), as explained above) to reporting of material changes in the relationship between a provider and a facility or organization that had been found to be provider based, one commenter recommended that the term ''material change'' be defined more specifically, to give providers more direction as to what events to report. The commenter believed a material change should be defined as including only ''a change of ownership, adoption of a new management contract for an off-campus department of a provider or a provider-based entity, change to an off-campus location, or a change in licensure status.''

Response: We share the commenter's belief that the events listed would be considered material changes. However, we do not agree that the term ''material change'' should include only these events. On the contrary, other types of occurrences, such as formation of a separate medical staff for the facility or organization or discontinuation of a service on the main provider's campus that would prevent referral of patients from the facility organization to the main provider would also represent material changes. Because we believe limiting the definition of the term ''material change'' as suggested by the commenter would inappropriately restrict the range of events to be reported, we are not adopting this comment.

Comment: One commenter recommended that reporting of material changes not be required for on-campus facilities. The commenter believed this reporting is unnecessary because adequate safeguards are already built into the provider enrollment requirements.

Response: Several of the kinds of changes noted in response to the preceding comment, relating to the integration of clinical services of the facility or organization with those of the main provider, are not subject to any mandatory reporting under the provider enrollment process but could affect provider-based status. Therefore, we are not making any change in the final rule based on this comment.

Comment: One commenter noted that, in the preamble to the proposed rule, CMS states that there would be '' * * * 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 following notification of the redetermination, but not less than 6 months after the date of notification'' (67 FR 31483). The commenter pointed out that this minimum 6-month compliance period is not included in the proposed § 413.65(k)(2). Rather, this regulation states that under these circumstances, provider-based status ''ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.'' The commenter requested that CMS revise § 413.65(k)(2) to reflect the minimum 6-month compliance period.

Response: We agree that the language quoted by the commenter from page 31483 of the preamble to the proposed rule is inconsistent with the language in the proposed regulations text. While this language is consistent with the current policy as stated in existing § 413.65(k), the inclusion of the language on page 31483 of the proposed rule was inadvertent on our part. We note that the correct proposed policy, which correctly *mirrors* the proposed regulation text at § 413.65(k)(2), is stated on page 31487 of the proposed rule. Specifically, we state that ''if we determine that a facility of 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 reported to CMS 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.'' We did not intend to propose to allow a 6-month grace period before a facility's status as provider-based would be revoked.

While we regret the confusion caused, we are not adopting the commenter's request regarding a 6-month grace period prior to removal of a provider-based status designation, since we do not believe it would be appropriate to provide for payment to the provider as provider-based for a period for which the provider was clearly not provider-based. While we do not plan to recover overpayments from a facility or organization that no longer qualifies as provider-based if the provider reported a material change in the relationship between the provider and the facility or organization, CMS retains the authority to recoup overpayments and apply civil monetary penalties if a provider is in violation of section 1128A or 1128B of the Act.

Accordingly, we are adopting our proposals as final with the following changes: We are reorganizing the text of proposed § 413.65(k) into new paragraphs (k) and (1), without substantive change, to distinguish the rules applicable to facilities for which there has been no previous determination from those that apply to facilities for which a previous determination has been made. Proposed sections (l) through (n) are being redesignated as paragraphs (m) through (o).

k. Technical Amendments

We proposed to correct a typographical error in the heading of paragraph (m) of § 413.65 (redesignated as paragraph (n) in this final rule) so that it reads ''FQHCs and ''look alikes' ''.

In paragraph (n) of § 413.65 (redesignated as paragraph (o) in this final rule), we proposed 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.

We did not receive any public comments on these technical amendments and are adopting them as final without change except for the redesignation of paragraph codes indicated above.

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 we may issue. 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, we have 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 CMS directive. Also, given that the intermediaries are our (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 ''must 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 our 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 us 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 understood 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 understood 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 CMS Administrator (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 CMS Administrator (in the context of reviewing PRRB decisions), to limit our authority to direct the actions of our agents with respect to reopening matters. (*See Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. 449, 452–53 (1999)(§ 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 our authority to direct the intermediary to reopen or not reopen a specific matter; instead, we have 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 CMS directives that may be issued 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, in the May 9, 2002 proposed rule, we proposed to revise § 405.1885(b) to make clear that,

in order to trigger the intermediary's obligation to reopen, our notice 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 also proposed to clarify § 405.1885 to reflect our longstanding interpretation (discussed above) that a change of legal interpretation or policy through 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 our inherent authority to direct the activities of our contractor-agents, the fiscal intermediaries, with respect to particular reopening matters, just as with any other aspect of program administration. Therefore, we proposed, in a new paragraph (e) of § 405.1885 (the existing paragraph was 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, we 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.

We received a number of comments regarding the proposed revisions to the reopening rules. The commenters largely opposed the our proposed revisions to § 405.1885. Their comments and our responses are as follows.

Comment: A fiscal intermediary asked if CMS was implicitly proposing to make all reopening decisions. According to another commenter, the proposed rule would enhance CMS' control over the reopening process by displacing the intermediary's role as the evaluator of the merits of reopening matters.

Response: The revisions to the reopening regulations are not intended to change the usual allocation of responsibilities between CMS and the fiscal intermediaries, which leaves most reopening decisions to the intermediaries. We are simply clarifying the regulations to reflect our longstanding interpretations, not revamping settled reopening policies and procedures.

As the courts have recognized, the reopening regulations are based on the Secretary's general rulemaking authority. (See *HCA Health Servs. of Oklahoma, Inc.* v. *Shalala,* 27 F.3d 614, 618 (D.C. Cir. 1994).) In the past, our main role has been to provide general guidance regarding the reopening regulations, such as the instructions included in Chapter 29 of the Medicare Provider Reimbursement Manual, Part 1 (''PRM''). The intermediaries have typically decided, without consulting with us, whether to reopen specific intermediary determinations or hearing decisions in accordance with §§ 405.1885(a) and (c) and the PRM. Of course, our authority to require intermediary reopening has been recognized specifically in § 405.1885(b). In certain instances, we have directed the intermediaries' reopening actions on a recurring reimbursement issue, such as the ''disproportionate share'' issue addressed in HCFA Ruling 97–2 (February 27, 1997). On occasion, we have instructed an intermediary to reopen a specific matter, such as in implementing the settlement of an administrative appeal or a lawsuit.

The foregoing allocation of responsibilities is not altered by the revisions to the reopening regulations. Rather, we are clarifying the regulations to comport with our longstanding interpretation that the intermediary's duty to reopen a determination or decision under § 405.1885(b) arises only if we specifically direct it to reopen in order to ensure consistency with a legal provision, as we understood such provision when the determination or decision was issued. Moreover, revised § 405.1885(e) simply clarifies our interpretation that the intermediary's discretion whether to reopen under §§ 405.1885(a) and (c) is subject to CMS' authority to direct the ''original jurisdiction'' of its own contractor over reopening matters, as with any other area of program administration. Thus, while the intermediaries will continue to decide most reopening matters without consulting with CMS, § 405.1885(e) reflects our authority to direct the intermediaries as we deem necessary and appropriate.

Comment: Two commenters stated that the reopening process has been the province of the intermediary. According to the commenters, the proposed changes to § 405.1885(e) would give CMS the sole authority to decide reopening matters that were formerly the intermediary's responsibility, which would eliminate the discretionary character of intermediary reopening decisions. Thus, the commenters concluded, intermediary reopening denials would be subject to PRRB and judicial review despite the Supreme Court's decision in *Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. 449 (1999).

Response: We disagree with the commenters' assertion that the proposed revisions to the reopening regulations would affect the reviewability of intermediary reopening denials. As discussed above, although the intermediaries have typically decided, without consulting with CMS, whether to reopen specific intermediary determinations or hearing decisions, the contractors' reopening actions have always been subject to the general guidance and any particular directives issued by CMS. Again, the respective roles of CMS and the intermediaries are simply not changed by the revisions to the reopening regulations. Since the intermediaries will continue to decide most reopening matters without consulting with CMS, reopening decisions will typically reflect the usual exercise of the intermediary's unreviewable discretion.

Although the revisions to the reopening regulations pertain to different issues than those resolved by the Supreme Court's *Your Home Visiting Nurse* decision, we believe that the revised regulations are consistent with the Court's decision and related precedent. The Supreme Court held that an intermediary's rejection of a provider's reopening request is not reviewable by the PRRB or the Federal courts. *Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. at 452–58. The revisions to the reopening regulations do not address or affect the reviewability of intermediary reopening denials. Rather, the revisions clarify our settled policies regarding the intermediary's original jurisdiction over the reopening question. *Id.* at 453. Specifically, the revisions to

§ 405.1885(b) clarify our longstanding view that intermediary reopening is required only if we specifically mandate reopening in order to ensure consistency with a legal provision, as we understood such provision when the intermediary determination or decision was issued. Furthermore, as proposed, revised § 405.1885(e) clarifies our understanding that the intermediary's discretion whether to reopen under §§ 405.1885(a) and (c) is subject to our authority to direct the original jurisdiction of our contractor over reopening matters, as with any other area of program administration.

We recognize that the Supreme Court, in rejecting mandamus relief in *Your Home Visiting Nurse* for lack of a ''clear nondiscretionary duty,'' reasoned that § 405.1885(a) and PRM section 2931.2 permit but do not require reopening. *Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. at 456–57. (However, we note that intermediary discretion did not figure in the Court's rejection of PRRB and Federal question jurisdiction over intermediary reopening denials. *Id.* at 452–56.) Given that the intermediaries will decide most reopening matters without consulting us, as in the past, such decisions will still be based on the discretionary provisions of § 405.1885(a) and PRM section 2931.2 and thus *Your Home Visiting Nurse* will be squarely on point.

We believe that a reopening denial is no less discretionary—and unreviewable under Your *Home Visiting Nurse* and related precedent—when we mandate the intermediary's action. Notably, in both *Monmouth Medical Center* and *Bartlett Memorial Medical Center,* the courts rejected PRRB and federal question jurisdiction over the prohibition of intermediary reopening included in HCFA Ruling 97–2. *Monmouth Medical Center* v. *Thompson,* 257 F.3d at 810–13; *Bartlett Memorial Medical Center.* v. *Thompson,* 171 F. Supp. 2d at 1220–22. Mandamus relief was ordered in both cases, based on the courts' finding that the Ruling engendered a clear nondiscretionary duty to reopen under § 405.1885(b). However, the Supreme Court has consistently held that reopening denials are ''committed to agency discretion by law' within the meaning of the Administrative Procedure Act, and hence unreviewable.'' *Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. at 457 (following *ICC* v. *Locomotive Engineers,* 482 U.S. 270, 282 (1987)). We believe that, under basic principles of agency law, it would be incongruous to suppose that reopening denials required by the principal, CMS, are somehow less discretionary than denials based on the judgment of our agents, the fiscal intermediaries. (See *ICC* v. *Locomotive Engineers,* 482 U.S. at 277B84 (despite statutory authorization of reopening for material error, Interstate Commerce Commission's refusal to reopen is committed to the agency's unreviewable discretion by law).)

Comment: A commenter stated that CMS should not restrict intermediaries' ability to reopen cost reports when they find it fair and appropriate to do so. The commenter explained that, in dealing with thousands of providers throughout the country, the intermediaries encounter numerous factual scenarios that different contractors might treat through varying means. The commenter concluded that, if a statute or regulation is ambiguous and CMS has not issued a policy statement on an issue, the intermediaries should be free to decide whether to reopen the matter and make revisions deemed suitable.

Response: In the absence of a CMS directive, intermediary reopening decisions have been guided by the criteria of ''new and material evidence,'' ''clear and obvious error,'' and consistency with a legal provision. (See PRM section 2931.2.) The revisions to the reopening regulations do not change the PRM guidelines. Instead, revised § 405.1885(e) clarifies our settled view that we have full authority to direct an intermediary to reopen, or not to reopen, under §§ 405.1885(a) and (c) based on the PRM reopening criteria.

However, as explained above, the intermediaries will continue to decide most reopening matters without consulting with CMS. In cases where we have not interpreted a statute or regulation or issued a policy statement on a reimbursement issue, the intermediaries will typically be free to decide whether to reopen the matter. Although the different intermediaries will be guided by the reopening guidelines in the PRM, different contractors may reach varying decisions on whether to reopen, or how to revise, a determination or decision. The traditional flexibility and variability of intermediary reopening decisions will not change as a result of the revisions to the reopening regulations.

Comment: A commenter stated that if CMS publishes a policy statement clarifying a particular Medicare issue, the intermediaries should have the ability to reopen cost reports to ensure that all providers are treated uniformly. Another commenter stated that it is not reasonable to expect intermediaries to apply rulings retroactively in some instances.

Response: We believe that an important component of a new reimbursement policy is the policy's scope of applicability. Given that Medicare is a uniform nationwide program, we typically do not leave to the discretion of the intermediaries questions about the scope of applicability of our reimbursement policy or policy clarification. Instead, a CMS regulation or policy guideline on a reimbursement issue usually includes an effective date. New reimbursement policies normally apply on a prospective-only basis. (See *Bowen* v. *Georgetown University Hospital,* 488 U.S. 204, 208–16 (1988) (Medicare statute does not permit retroactive rulemaking).) The alternative suggested by the commenter, of letting the intermediaries determine through reopening the scope of applicability of a new CMS reimbursement policy, would undermine the interests of nationally uniform program administration. Also, if the intermediaries were to reopen and apply a reimbursement policy that was not in place when payment was determined originally, such reopenings might involve impermissible retroactive rulemaking.

Comment: A commenter asserted that the proposed revisions to § 405.1885(b) would inappropriately expand CMS' authority by permitting the agency to order an intermediary to disregard a judicial decision holding a policy void *ab initio,* on the theory that CMS understood the disputed legal provision differently when the intermediary determination was rendered. Thus, the commenter concluded, the proposal violates fundamental principles of separation of powers.

Response: The revisions to § 405.1885(b) do not expand our reopening authority. Rather, revised paragraph (b)(1) clarifies our settled interpretation that an intermediary's duty to reopen a determination or decision under § 405.1885(b) arises only if we specifically direct it to reopen in order to ensure consistency with a legal provision, as we understood such provision when the determination or decision was issued.

We did not propose paragraph (b)(1) as a means of sidestepping a judicial decision holding a reimbursement policy void *ab initio,* on the theory that we understood the disputed legal provision differently when the intermediary determination at issue in the lawsuit was rendered. If a provider secures a final, nonappealable judgment rejecting a reimbursement policy, we would certainly comply with such a court judgment for the provider's fiscal

period at issue in the lawsuit— even if we had a different understanding of the law when the intermediary determination at issue in the case was rendered. Given our compliance with the final, nonappealable judicial decision, there clearly would be no separation of powers problem.

The commenter may be assuming that reopening is necessary for the implementation of a final, nonappealable judgment. That would be a debatable assumption for a number of reasons. For example, we would be required to redetermine reimbursement in accordance with a final, nonappealable court judgment for the fiscal period at issue in the lawsuit, even if the 3-year period for reopening the intermediary determination at issue in the case had expired long ago. Also, we often implement final adverse judgments and lawsuit settlement agreements outside the reopening process. Instead of reopening the reimbursement matter and issuing a revised notice of program reimbursement (see §§ 405.1801(a), 405.1803, and 405.1889), we may simply recalculate reimbursement in accordance with the final court decision or settlement agreement, and issue an implementation notice detailing the reimbursement effect of the court judgment or settlement agreement.

However, the comment does indicate that the proposed rule was susceptible to the interpretation that CMS would be precluded from requiring the reopening of a particular intermediary determination or decision in order to implement a specific final agency decision (see §§ 405.1833, 405.1871(b), 405.1875, and 405.1877(a)); a particular final, nonappealable court judgment; or a specific agreement to settle an administrative appeal or a lawsuit. In order to allay the commenter's concern and make explicit our authority to use reopening procedures in such circumstances, as we deem appropriate, we have added a new paragraph (b)(3) to proposed § 405.1885(b). Paragraph (b)(3) states that notwithstanding paragraph (b)(1)(i) of this section, CMS may direct the intermediary to reopen a particular intermediary determination or intermediary hearing decision in order to implement, for the same intermediary determination or intermediary decision— (1) a final agency decision under §§ 405.1833, 405.1871(b), 405.1875, or 405.1877(a); (2) a final nonappealable court judgment; or (3) an agreement to settle an administrative appeal or a lawsuit.

Comment: According to one commenter, the inclusion of the condition ''as CMS understood those legal provisions, at the time the [intermediary] determination or decision was rendered,'' in the provisions of § 405.1885(b) for mandatory intermediary reopening would give CMS unlimited and standardless discretion whether or not to reopen.

Response: Paragraph (b)(1)(i) does include a guideline for CMS' decision whether to require intermediary reopening under § 405.1885(b). If an intermediary determination or decision is inconsistent with the applicable law, regulations, CMS Ruling, or CMS general instructions in effect, as CMS understood such legal provisions when the intermediary rendered the determination or decision, then CMS may decide to direct the intermediary to reopen and revise the determination or decision. However, we are not required to mandate intermediary reopening in such cases. Thus, given the Supreme Court's decisions in *Your Home Visiting Nurse* and *ICC* v. *Locomotive Engineers,* if CMS directs the intermediary to not reopen, our instruction and the intermediary reopening denial are committed to the agency s unreviewable discretion under the Administrative Procedure Act, 5 U.S.C. 701(a)(2).

Moreover, we believe that our longstanding practice of looking to the law in effect, as we understood the law, when the intermediary determination or decision was rendered, is supported by analogous principles followed by the courts. For example, it is settled that '' 'the legal effect of conduct should ordinarily be assessed under the law that existed when the conduct took place.' '' *Landgraf* v. *USI Film Products,* 511 U.S. 244, 265 (1994) (citation omitted). Also, the courts consistently hold that past judicial decisions, even if subsequently deemed erroneous, are *res judicata* and should not be resurrected and redecided. (See, *Federated Department Stores, Inc.* v. *Moitie,* 452 U.S. 394, 398 (1981).) Of course, this principle works both ways: if a disposition benefiting a claimant becomes final before a contrary decision on the same issue in another case, the claimant is not required to surrender the benefit despite the intervening change in decisional law. (See, *Aaron* v. *Kansas,* 115 F.3d 813, 814 n.1 (10th Cir. 1997).)

Comment: One commenter asserted that when the courts find a CMS policy unlawful, and the agency revises its policy to comport with the courts' decisions, providers should be entitled to reopening and application of the new policy within applicable time limits. According to a hospital system, foreclosing reopening of a matter that was settled inconsistently with decisional law would lead to inconsistent decisions regarding different providers, and have the agency persist in conduct held unlawful by the courts.

Response: We disagree. As proposed, paragraph (b)(2) clarifies our longstanding view that a change of legal interpretation or policy by CMS, whether made in response to judicial precedent or otherwise, is not a basis for reopening an intermediary determination or decision under § 405.1885.

The prospect of widespread reopening for application of a new legal interpretation or policy, whether in response to judicial precedent or otherwise, might involve impermissible retroactive rulemaking. (See *Bowen* v. *Georgetown University Hospital,* 488 U.S. at 208–16.) If we were to allow systemic reopening for application of a legal interpretation or policy adopted in response to judicial precedent, our fiduciary responsibilities for the Medicare trust funds would arguably call for similarly widespread reopening when a new legal interpretation or policy is not favored by providers. The result might be a spate of litigation involving alleged retroactive rulemaking and other complex legal issues.

Furthermore, we have not viewed the reopening process as a ready alternative to the mechanism for administrative appeals and judicial review established by the Medicare statute and regulations. Under the statute (section 1878(a) of the Act) and the regulations (§§ 405.1801(a), 405.1803, and 405.1807), an ''intermediary determination'' is, by definition, a ''final determination'' of program reimbursement. We believe that, if a provider does not file a timely appeal of a final determination on a reimbursement issue, there is no right to reopening of that issue in light of judicial decisions in other cases on the same issue. Put simply, reopening is not designed for the revival of stale claims, *Albert Einstein Medical Center.* v. *Sullivan,* 830 F. Supp. 846, 850 (E.D. Pa. 1992), aff'd, 6 F.3d 778 (3d Cir. 1993), or the addition of new claims. *Saint Mary of Nazareth Hospital Center.* v. *Schweiker,* 741 F.2d 1447, 1449 (D.C. Cir. 1984).

In addition, we believe that our longstanding policy of not reopening for application of a new legal interpretation or policy, whether in response to judicial precedent or otherwise, comports with analogous judicial practice. When the Supreme Court decides a legal issue, the Court's ''controlling interpretation of federal law'' applies to ''all cases still open on

direct review,'' *Harper* v. *Virginia Department of Taxation,* 509 U.S. 86, 97 (1993), but ''[n]ew legal principles * * * do not apply to cases already closed.'' *Reynoldsville Casket Co.* v. *Hyde,* 514 U.S. 749, 758 (1995). Thus, while a provider that files a timely appeal may, if it ultimately prevails, be reimbursed differently for an item than providers that do not appeal timely, we do not believe that the decision in the prevailing provider's case should apply to other providers' cost reports that were closed and not appealed timely.

Our settled reopening policy, clarified in § 405.1885(b)(2), also furthers the interests of administrative finality in a program of extraordinary magnitude. For example, there were only 37 fiscal intermediaries in 1997 as compared to approximately 38,000 participating providers. Of course, each provider submits an annual cost report containing thousands of cost items, any one of which may give rise to a reimbursement issue. (See *Athens City Hospital, Inc.* v. *Schweiker,* 743 F.2d 1, 3 (D.C. Cir. 1984) (detailing cost report contents).) We believe it would be unworkable to reopen thousands of final, unappealed cost reports each time a judicial decision calls into question one of our many reimbursement policies. Indeed, the Supreme Court concluded that, ''given the administrative realities we would not be shocked by a system in which underpayments could never be the basis for reopening'' since the ''few dozen fiscal intermediaries often need three years * * * to discover overpayments in the tens of thousands of NPRs that they issue, while each * * * sophisticated Medicare-provider * * * is generally capable of identifying an underpayment in its own NPR within the 180-day time period specified in 42 U.S.C. 139500(a)(3)'' for an appeal to the PRRB. *Your Home Visiting Nurse Services, Inc.* v. *Shalala,* 525 U.S. at 455–56. Thus, instead of the ''persistent'' unlawful conduct suggested by the commenter, we believe that our policy of not reopening closed cost reports in response to decisions in other cases is essential for maintaining administrative finality in a program of extraordinary magnitude that is administered with limited resources.

Comment: A group of health law attorneys recommended that CMS propose more elaborate revisions to the reopening regulations. The commenter saw the need for an orderly process for the correction of factual errors and erroneous interpretations of Medicare law. Also, the commenter recommended that § 405.1885(b) be amended so that CMS must require intermediary reopening for all providers located in the jurisdiction of a court that declares a Medicare policy unlawful. The commenter stated that, in light of the Supreme Court's *Your Home Visiting Nurse* decision, § 405.1885(a) should be revised to require intermediaries to grant provider requests for reopening to correct factual errors and improper application of policy rather than leaving the reopening decision to the intermediaries' discretion. According to the same commenter, the regulations should also detail the circumstances, if any, in which the intermediary may reopen in light of a judicial decision or other change in law. In the same vein, a different commenter stated that some level of materiality should be established so that providers are not confronted with several sets of adjustments for various cost reporting years.

Response: We proposed revisions to the reopening regulations in response to the *Monmouth Medical Center* and *Bartlett Memorial Medical Center* decisions. Our limited purpose was to clarify longstanding interpretations of the reopening regulations, which we believe were misapprehended by the courts.

More elaborate revisions to the reopening regulations are beyond the scope of the proposed rule. In any event, we believe the reopening regulations and related provisions of the PRM provide an orderly process for the correction of factual errors and erroneous interpretations of the law in effect, as we understood the law, when the intermediary determination or decision was rendered. We also believe that the reopening criteria prescribed in PRM section 2931.2 provide the intermediaries with sufficient guidance regarding the materiality of a potential reopening and revision to program reimbursement.

In lieu of the commenter's suggestion that we allow reopening for application of a judicial decision in another case or for some other change in law, we have revised § 405.1885(b) to reflect our longstanding practice of not reopening for application of a new legal interpretation or policy, whether in response to judicial precedent or otherwise. As explained above, we believe this reopening policy avoids retroactive rulemaking problems; comports with analogous judicial practice and the limited nature of the reopening process; and furthers the goals of administrative finality in a program of extraordinary magnitude that is administered with limited resources.

We also do not believe that the Supreme Court's *Your Home Visiting Nurse* decision requires any revision to § 405.1885(a) or any other reopening provision. As discussed above, the Court's rejection of PRRB and Federal court review of intermediary reopening denials continues the ''tradition of nonreviewability * * * [of] refusals to reconsider * * * by agencies as by lower courts; * * * another tradition that [the Administrative Procedure Act,] 5 U.S.C. 701(a)(2) was meant to preserve.'' *ICC* v. *Locomotive Engineers,* 482 U.S. at 282. Thus, we believe *Your Home Visiting Nurse* and related precedent apply equally to intermediary reopening denials directed by CMS and to denials by the intermediary acting alone.

For the reasons discussed above and although the commenters largely opposed our proposed revisions to the reopening provisions, we are finalizing these provisions as proposed with a technical change to § 405.1885(b)(3).

VI. 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 hospital 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 inpatient capital-related costs. Beginning in FY 2002, 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, if applicable)

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 the 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 were 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, in the May 9, 2002 proposed rule (67 FR 31488), we proposed, 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 proposed to 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 stated that we believe this amendment will 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 policy will 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, the new hospital exemption will 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 exemption from the capital prospective payment system for the first 2 years of operation will 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) will 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 will 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.

Comment: Three commenters addressed our proposed policy for new hospitals after the 10-year transition period for cost reporting periods beginning on or after October 1, 2002. One commenter asked whether new providers would have the option of electing payment at 100 percent of the Federal rate for their first 2 years of operation rather than the special payment provision of 85 percent of their reasonable costs. Another commenter expressed concern about the negative impact the proposed policy would have on its facility if the policy were applied retroactively, while still another commenter requested that the policy be effective for new hospitals with cost reporting periods beginning on or after October 1, 2001 rather than October 1, 2002.

Response: We agree with the commenter's suggestion that new hospitals (as defined in § 412.300(b)) should have the option of electing payment for their first 2 years of operation through either the special payment provision for new hospitals at 85 percent of their reasonable costs, or beginning immediately to receive payments based on 100 percent of the Federal rate. However, the payment method that the new hospital selects would remain in effect through the hospital's first 2 years of operation; the hospital would not be allowed to revert to the alternate payment method. If 100 percent of the Federal rate is the payment method selected, the new hospital must make the request to the fiscal intermediary in writing by the later of December 1, 2002, or within 60 days of the start of the provider's cost reporting period. We are revising the regulations at § 412.304(c)(2) to reflect this change.

While we are making this change effective for cost reporting periods beginning on or after October 1, 2002, we are not making this change effective for any periods prior to that date because doing so would constitute retroactive rulemaking.

Accordingly, in this final rule, we are adopting as final the proposed regulation change at § 412.304(c), with modifications. In § 412.304(c)(2)(i), we are specifying that a new hospital is paid (1) 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; or (2) if the new hospital elects, 100 percent of the Federal rate under the capital prospective payment system. If the new hospital elects to be paid 100 percent of the Federal rate, it must make the request to the fiscal intermediary in writing by the later of December 1, 2002, or within 60 days of the start of the provider's cost reporting period. We are specifying that once a new hospital elects to be paid based on 100 percent of the Federal capital prospective payment rate, it may not revert to payment at 85 percent of its allowable Medicare inpatient hospital capital-related costs.

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, in the May 9, 2002 proposed rule (67 FR 31489), we proposed 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, beginning on or after October 1, 2001.

We did not receive any comments on this proposal. Accordingly, we are adopting as final the proposed new § 412.312(e).

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, in the May 9, 2002 proposed rule (67 FR 31489), we proposed 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 proposed to restore the 2.1 percent reduction for discharges occurring on or after October 1, 2002, under proposed § 412.308(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.

We did not receive any comments on this proposal and are, therefore, adopting as final the proposed new § 412.308(b)(6).

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) are 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 the current policy at § 412.348(g). Therefore, in the May 9, 2002 proposed rule (67 FR 31490), we did not propose any changes to the special exceptions policy. However, we did provide 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 will 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.

We did not receive any comments on this clarification.

VII. 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), where applicable, 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 will 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 and then multiplying this figure by the number of Medicare discharges. Effective for cost reporting periods beginning on or after October 1, 2002, rehabilitation hospitals and units are no longer paid on a reasonable cost basis but will be paid under the inpatient rehabilitation facility prospective payment system. Moreover, we have proposed the establishment of a DRG-based prospective payment system for long-term care hospitals (LTCHs) (67 FR 13415). As part of this process, we proposed a 5-year transition period from reasonable cost-based reimbursement to a fully Federal prospective payment system. However, a LTCH, subject to the blend methodology, may elect to be paid based on a 100 percent of the Federal prospective rate. (See sections VII.A.3. and 4. for a more detailed discussion.)

Comment: One commenter requested clarification as to whether payment to excluded hospitals and units are subject to the TEFRA bonus and penalty provisions and continuous improvement bonuses.

Response: Certain providers that are excluded from the acute care hospital inpatient prospective payment system will continue to receive bonus/relief payments as well as continuous improvement bonus payments, when appropriate, as provided for in § 413.40(d).

Comment: With regard to the expiration of the caps on target amounts for excluded hospitals and units, a commenter requested clarification as to how the FY 2003 target rate is to be determined.

Response: Our regulations at § 413.40(c)(4)(ii) state that ''the target amount equals the hospital's target amount for the previous cost reporting period, increased by the update factor for the subject cost reporting period * * *.'' Thus, for cost reporting periods beginning in FY 2003, the hospital or

unit should use its previous year's target amount, updated by the appropriate rate-of-increase percentage.

2. Updated Caps for New Excluded Hospitals and Units

Section 1886(b)(7) of the Act establishes a payment limitation 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 statute, 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 will 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)(iii)(B)(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 amounts included in the following table reflect the updated 110 percent of the national median target amounts for each class of new excluded hospitals and hospital units for cost reporting periods beginning during FY 2003. These figures are updated with the most recent data available to reflect the market basket increase percentage of 3.5 percent. This 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 CMS's 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 labor-related share	FY 2003 nonlabor-related share
Psychiatric	$ 7,054	$ 2,804
Long-Term Care	17,286	6,872

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, subject to the blend methodology, 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 proposed (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 proposed a 5-year transition period from reasonable cost-based reimbursement to the fully Federal prospective rate. We also proposed that certain long-term care hospitals 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. We are in the process of developing a final rule for the long-term care prospective payment system.

5. Changes in the Types of Patients Served or Inpatient Care Services That Distort the Comparability of the Cost Reporting Period to the Base Year are Grounds for Requesting an Adjustment Payment in Accordance with Section 1886(b)(4) of the Act

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment (exception) payments made to excluded hospitals and units, by reason of section 1886(b)(4) of the Act, during the previous fiscal year.

However, the data on adjustment payments made during the previous fiscal year are not available in time to publish a report describing the total amount of adjustment payments made to all excluded hospitals and units.

The process of requesting, adjudicating, and awarding an adjustment payment for a given cost reporting period is likely to occur over a 2-year period or longer. First, an excluded hospital or unit must file its cost report for a fiscal year with its intermediary within 5 months after the close of the fiscal year. The fiscal intermediary then reviews the cost report and issues a Notice of Program Reimbursement (NPR) in approximately 2 months after the filing of the cost report. If the hospital's operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment within 6 months from the date of the NPR. The intermediary, or CMS, depending on the type of adjustment requested, then reviews the request and determines if an adjustment payment is warranted. This determination is often not made until more than 6 months after the date the request is filed. Therefore, it is not possible to provide data in this final rule on adjustments granted for cost reports ending in the previous Federal fiscal year (that is, FY 2002), since those adjustments may not have been requested by the publication date of this final rule. However, in an attempt to provide interested parties with data on the most recent adjustments for which we do have data, we are publishing data on adjustments that were processed by the fiscal intermediaries or CMS during FY 2001.

The table below includes the most recent data available from the fiscal intermediaries and CMS on adjustment payments that were adjudicated during FY 2001. As indicated above, the adjustments made during FY 2001 only pertain to cost reporting periods ending in years prior to FY 2000. Total adjustment payments awarded to excluded hospitals and units during FY 2001 are $23,148,456. The table depicts for each class of hospital, in the aggregate, the number of adjustment requests adjudicated, the excess operating cost over the ceiling, and the amount of the adjustment payment.

Class of Hospital	Number	Excess cost over ceiling	Adjustment payment
Psychiatric	38	$23,211,026	$11,724,665
Rehabilitation	16	8,761,312	3,860,336
Long-Term Care	3	5,665,211	4,868,889
Children	3	2,696,518	1,043,565
Cancer	2	2,846,386	1,651,001

6. Technical Correction

On June 13, 2001, we published in the **Federal Register** an interim final rule (66 FR 32172) implementing section 307(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106–554). Section 307(a) provided for a 25-percent increase in TEFRA target amounts for long-term care hospitals ''For cost reporting periods beginning during FY 2001 * * *.'' When we addressed this provision in the interim final rule, we stated the effective date correctly in the preamble language. However, in the regulation text, we inadvertently used an incorrect effective date. We are making the conforming change to reflect the correct date in this final rule.

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 acute care hospitals in which they are located, but are, in fact, organizationally and functionally separate from those hospitals. Therefore, in the May 9, 2002 proposed rule, we proposed 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: (1) Not under the authority or control of the governing body or chief executive officer of the hospital in which it is located; and (2) 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 proposed 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 the 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.

Comment: One commenter stated that the use of the word ''authority'' in the criteria under § 412.25(e) of the proposed rule is ambiguous and unnecessary. The commenter expressed concern that the term could be construed in a manner that would undercut the ability of hospitals to provide necessary services. Therefore, the commenter believed that the word ''authority'' should be omitted from the final regulations. In addition, the commenter recommended that the most practical way to apply hospitalswithinhospitals criteria effectively to satellite facilities would be to amend § 412.22(e) to make it apply to both types of facilities or to incorporate those criteria by reference in proposed § 412.22(h)(2). The commenter believed that these revisions would be in keeping with CMS' intent and would result in a proper policy of treating hospitals-within-hospitals and satellite facilities equitably.

Response: After a review of the pertinent regulations, we agree with the commenter that the word ''authority'' should not be referenced in the regulations. We believe that deleting the reference allows for consistency between those criteria set forth for satellite facilities and those for hospitals-within-hospitals. Accordingly, in this final rule, we are revising §§ 412.22(h)(2)(iii)(A) and 412.25(e)(2)(iii)(A) to delete the word ''authority'' from the criteria.

However, we do not believe that revising § 412.22(e) to apply to both satellite facilities and hospitals-within-hospitals would be appropriate. A number of the criteria that apply to hospitals-within-hospitals would not be applicable to satellite facilities. One example is the requirement that the cost of services that the hospital-within-a-hospital receives from the ''host'' hospital is not more than 15 percent of the hospital's inpatient operating costs would not be an appropriate criterion. This criterion would not be appropriate for satellite facilities because the test would not only look at the costs incurred by the satellite facility but also at the costs incurred by the entire hospital, including both the satellite facility and the main hospital. For example, a main hospital has 100 beds and its satellite facility has 5 beds located in an acute care hospital. Since costs of the entire excluded hospital (at both the main hospital and the satellite facility) are reported on one cost report, by only looking at the costs that are shared between the satellite facility and the acute care hospital, the costs of services that the satellite facility receives from its ''host'' hospital will invariably be less than 15 percent of the costs of the entire hospital, even if all the costs of the satellite facility were incurred by the ''host'' hospital.

Comment: One commenter stated that given that long-term care hospitals and rehabilitation hospitals and units are now, or will be shortly, paid on prospective basis, the rule limiting the number of beds in a satellite facility may no longer be necessary. The commenter believed that the rules on hospitals-within-hospitals should be adequate to address CMS' concerns about payment advantage. Hence, the commenter recommended that the satellite facility rules be eliminated because they are no longer necessary and are burdensome.

Response: We have solicited comments regarding the bed limit for satellite facilities in the March 22, 2002 proposed rule to implement the long-term care hospital prospective payment system (67 FR 13464–13465). We will address the commenter's concerns along with any other comments received when we issue the final rule for the long-term care hospital prospective payment system.

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, in the May 9 proposed rule, we proposed 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.

Comment: Several commenters recommended that the advanced notice period for CAHs to elect the all-inclusive billing option be set firmly at 30 days rather than allowing the fiscal intermediaries to choose a timeframe ranging from 15 days to 60 days. One commenter recommended retaining the 60-day notice to fiscal intermediaries. Another commenter stated that the implementation of such flexibility could pose problems and requested that intermediaries be required to communicate due dates effectively to CAHs. The commenters expressed concern that, by allowing each intermediary to set the period for advance notice confusion could arise, as well as result in different policies could be created across the country.

Response: We have reviewed the commenters' concerns with regard to our proposal to allow the fiscal intermediaries to set the timeframe for election of the optional payment method for CAHs. We agree that, by allowing this type of flexibility, there exists the possibility of confusion between the fiscal intermediaries and the CAHs. In addition, we recognize that various policies might be established across the country, instead of one national policy. Therefore, we believe that to help provide some stability and uniformity to this policy, it would be in the best interest of all concerned if a definite period of time is set for the CAHs to notify their intermediaries of their decision to elect the optional payment method. Accordingly, in light of the commenters concerns and input from the intermediaries, we believe that a sufficient amount of time for CAHs to notify their fiscal intermediaries of an election of the optional payment method is 30 days before the beginning of the affected cost reporting period. We believe this will give the fiscal intermediaries enough time so that payments can be made accurately, avoiding possible delays in, or duplication of, payment.

Accordingly, in this final rule, we are revising § 413.70(b)(3)(i) to state that the CAH's election of the optional payment method must be made to the fiscal intermediary 30 days prior to the start of the 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 the May 9, 2002 proposed rule, we proposed 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. In addition, 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 can identify 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 proposed in the May 9, 2002 proposed rule to eliminate the requirement for CAHs to complete an RAI believing it to be appropriate and would not jeopardize 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 additional 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 proposed to revise § 485.645 to specify that CAHs are required to complete a comprehensive assessment, comprehensive care plan, and discharge plan 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).

Comment: Fifteen commenters fully supported the elimination of the requirement that CAHs complete a lengthy patient assessment form for swing-bed patients, stating that the completion of the 400 plus question comprehensive assessment was an onerous and administrative burden, considering the RAI is not used for payment or quality purposes.

Response: We appreciate the commenters' support. As we stated in the proposed rule, we believe there are sufficient safeguards in the CAH regulations to ensure the health and safety of each swing-bed patient in a CAH. The facility would still be required to develop a comprehensive care plan for each swing-bed patient that includes measurable objectives and a timetable to meet a patient's medical, nursing, and psychosocial needs that are identified in an assessment.

Comment: One commenter disagreed with the elimination of the requirement. The commenter stated that CMS' failure to provide the basis for its decision to eliminate the RAI for CAHs violates the Administrative Procedure Act (APA). Further, the commenter stated that removing the RAI requirement would jeopardize quality of care for swing-bed patients in CAHs.

Response: In order to promulgate a substantive rule, the APA requires the agency to observe notice-and-comment rulemaking procedures, which we have

done. We believe that in the May 9, 2002 proposed rule, we clearly stated the issue and provided rationale for proposing the change.

Currently, all long-term care facilities are required to collect and submit assessment data to the State from the RAI for quality and payment purposes. There are no such collection and submission requirements for CAHs in the existing Medicare conditions of participation. On average, patients stay 10 days in a CAH swing bed. However, patients in SNFs have an average length of stay of approximately 25 days and patients in a nursing facility stay, on average, 230 days in a calendar year. The Medicare RAI assessment schedule for SNFs requires that the initial assessment be performed during days 1 through 5 of a patient's stay, but may be performed as late as days 6 through 8, termed ''grace days'', which gives staff additional flexibility in conducting the assessments. The initial assessment is used to assign patients to a resource utilization group (RUG), the case-mix group classification grouping that is used in establishing payments for the first 14 days of care. Subsequently, periodic assessments through the patient's stay at a SNF are performed to determine the RUG assignment and payment rate.

We believe that the commenter's concern that the removal of the RAI requirement for CAH's would jeopardize quality of care is unfounded. At this time, we believe that the quality of care interest in a CAH is better served by eliminating a requirement in which a very limited staff resource is required to complete a document with 400 plus questions for each swing-bed patient and from which data are not submitted to CMS, or compared with other facilities. Also, the existing requirement for a post-discharge plan of care would address post-hospital care needs of the patient.

We emphasize that the focus of the proposed rule was not to make major revisions to swing-bed requirements for CAHs. The proposal was to only eliminate the use of a specific form, the RAI tool. CAHs would still be required to complete comprehensive assessments on their swing-bed patients.

Comment: One commenter stated that quality of care measurements for swing-beds should be consistent and compatible to the measurement system used by nursing homes. The commenter suggested that a quality indicators program should be implemented in all facilities with swing beds.

Response: Quality measures currently are not calculated for CAHs because there are no data submitted to CMS to calculate. Further, even if data were available, the calculation of quality measures requires assessments to be conducted on days 5 and 14. The average length of stay in a CAH, which is 10 days, is inconsistent with this process.

CMS plans to develop an assessment tool in the future that will have a ''modular format'' whereby a provider with shorter patient stays would be able to collect a smaller set of data. In the future, we may consider whether or not it is appropriate and feasible to require CAHs to use and submit data from this specific format.

Comment: One commenter stated that there is no monitoring of compliance with conditions of participation in any swing beds. The commenter stated that surveys are infrequently conducted and when they are conducted, they are announced. The commenter also suggested that CMS apply the current long-term care transfer rule to all swing beds.

Response: We acknowledge that the monitoring and survey issues addressed by the commenters are important issues. However, the issues are outside the purview of this rule. The commenter's concerns will be shared with our survey and certification group.

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 policies 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 decision 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 final 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 B to this final 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.* In our May 9, 2002 proposed rule, we published a list of data files that are available for purchase (67 FR 31493 through 31495).

B. Information Collection Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-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 evaluate fairly 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.

The majority of the information collection requirements contained in this final rule are currently approved. Section IX.B.1. below lists the OMB approval numbers and the current expiration dates for the information collection requirements, referenced by specific Parts under Title 42 of the Code of Federal Regulations, in this final rule that are currently approved.

In the May 9, 2002 proposed rule, we solicited public comments on each of the information collection requirements referenced in the proposed rule that are described in section IX.B.2. of this final rule, as required under the PRA of 1995.

1. Currently Approved Requirements

Regulation references in 42 CFR	OMB approval number	Current expiration date
Part 412	0938–0691	September 30, 2002.
	0938–0050	May 31, 2004.
	0938–0573	September 30, 2002.
		October 31, 2003.
		September 30, 2002.
Part 413	0938–0050	May 31, 2004.
	0938–0667	October 31, 2002.
	0938–0477	July 31, 2005.

2. Requirements for Which Public Comment Were Sought in the May 9, 2002 Proposed Rule

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

Appropriate Wage Data

As specified in § 412.230, 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 that due to the fact that hospital's maintain this data for other business purposes or state reporting requirement, or both the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3) or both.

In addition, while this regulatory requirement is being added, the wage data collection requirement associated with this proposed regulatory requirement is currently approved under OMB collection 0938–0573 (Medicare Geographic Reclassification Review Criteria), with a current expiration date of September 30, 2002.

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

Responsibility for Obtaining Provider-Based Determinations

Under § 413.65, 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 will 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 will be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS upon request.

We estimate that the burden associated with these requirements is an average of 1.5 hours per provider, for approximately 3,000 providers per year, for an annual burden of 4,500 hours. This estimate is based on the fact that 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 will 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 that due to the fact that hospitals maintain this data for other business purposes or state reporting requirements or both, the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3) or both.

We did not receive any public comments on the proposed information collection and recordkeeping requirements. The total burden associated with the new and revised requirements referenced in this section are 4,500 annual hours.

3. New Requirement in This Final Rule

Section 412.304(c)(2)(i)(A) Implementation of the Capital Prospective Payment System: Election by New Hospitals To Be Paid Based on 100 Percent of the Federal Rate

This section specifies that if a new hospital elects to be paid under the capital prospective payment system based on 100 percent of the Federal rate, instead of 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, the new hospital must submit a written request to the fiscal intermediary. This request must be submitted by the later of December 1, 2002, or 60 days before the beginning of its cost reporting period.

We estimate that the burden associated with these requirements is an average of 1 hour per provider, for approximately 100 providers per year, for an annual burden of 100 hours.

The new information collection and recordkeeping requirements in this final rule will be submitted to the Office of Management and Budget (OMB) for review under the authority of the PRA. These requirements will not be effective until they have been approved by OMB.

If you have any comments on the information collection and recordkeeping requirements under § 412.304(c)(2)(i)(A), please mail the 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–F, 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.: Brenda Aguilar, CMS Desk Officer, Attn.: CMS–1203–F.

X. Waiver of Proposed Rulemaking

The Administrative Procedure Act generally requires that agency rules be published in the **Federal Register** as a notice of proposed rulemaking with a period for public comment (5 U.S.C. 533(b)). This notice-and-comment procedure can be waived, however, if an agency finds good cause that the procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

A. Technical Correction to Regulations Relating to DSH Adjustment Factor

On June 13, 2001, we Issued in the **Federal Register** an interim final with comment period (66 FR 32172) to

update the regulations to incorporate the changes made by section 211(b) of Public Law 106–554. Section 211(b) of Public Law 106–554 amended section 1886(d)(5)(F)(iv)(III) of the Act to revise the calculation of the DSH payment adjustment for hospitals affected by the revised thresholds as specified in section 211(a) of Public Law 106–554. These changes were effective for discharges on or after April 1, 2001, and no changes were made by section 211(b) for discharges prior to April 1, 2001. In the June 13, 2001 interim final rule with comment period, we inadvertently changed the adjustment factor for rural hospitals with fewer than 100 beds from 4 percent to 5 percent under § 412.106(d)(2)(iv)(A) for discharges occurring before April l, 2001. As indicated in section V.E.3 of this final rule, we are correcting this error

Since this change is being made to correct a technical error, we find that the notice-and-comment procedure is unnecessary, and, therefore, find good cause to waive the notice of proposed rulemaking and issue the correction as final.

B. Technical Correction to Regulations Relating to TEFRA Target Amount for Long-Term Care Hospitals

Also, in the June 13, 2001 interim final rule with comment period (66 FR 32172), we implemented section 307(a) of Public Law 106–554. Section 307(a) provided for a 25-percent increase in TEFRA target amounts for long-term care hospitals ''For cost reporting periods beginning during FY 2001 * * * .'' As indicated in section VII.A.6. of this preamble, in the June 2001 interim final rule with comment period, we stated the effective date correctly in the preamble language, but in the regulation text, we inadvertently used an incorrect effective date. We are making the conforming change to reflect the correct date in this final rule.

We find it unnecessary to undertake notice-and-comment rulemaking with regard to this change because our change merely conforms the regulation text to existing policy and provides technical correction to the regulations. It does not make any substantive changes to policy. Therefore, for good cause, we are waiving the notice-and-comment procedure with regard to this change.

C. Technical Corrections Relating to Affiliated Groups

As discussed in section V.I.3. of this preamble, we are making a technical change to the language under the definition of ''affiliated group'' under § 413.86(b) under paragraph (2) to reference the use of the more recent publications of the Graduate Medical Education Directory. Since this change updates a technical reference to an annual publication, we find the notice-and comment procedure is unnecessary, and therefore find good cause to waive the notice of proposed rulemaking and issue the correction as final.

When we issued the May 9, 2002 proposed rule, due to a typographical error, we inadvertently indicated that we proposed to make changes to § 413.86(g)(5)(iv) instead of § 413.86(g)(4)(iv) to incorporate revised provisions relating to determining the weighted number of FTE residents for hospitals that are part of the same affiliated group. As a result, we erroneously stated that we proposed to add a new paragraph under § 413.86(g)(5)(iv) and to redesignate paragraphs (g)(5)(iv), (g)(5)(v), and (g)(5)(vi) and paragraphs (g)(5)(v), (g)(5)(vi), and (g)(5)(vii), respectively, to accommodate the new paragraph. As discussed in section V.I.3. of this preamble, we are correcting these errors in this final rule. Since we are making these changes to correct a technical error, we find that the notice-and-comment procedure is unnecessary and therefore find good cause to waive the notice of proposed rulemaking and issue the correction in this final 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 485

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

For the reasons stated in the preamble of this final rule, 42 CFR Chapter IV is 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 must be reopened and revised by the intermediary if, within the 3-year period specified in paragraph (a) of this section, 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.

(3) Notwithstanding paragraph (b)(1)(i) of this section, CMS may direct the intermediary to reopen a particular intermediary determination or intermediary hearing decision in order to implement, for the same intermediary determination or intermediary decision—

(i) A final agency decision under §§ 405.1833, 405.1871(b), 405.1875, or 405.1877(a) of this part;

(ii) A final nonappealable court judgment; or

(iii) An agreement to settle an administrative appeal or a lawsuit.

* * * * *

(e) Notwithstanding 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).

The revision, republication, and addition read as follows:

§ 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 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 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).

The revision, republication, and addition read as follows:

§ 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 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 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 412.88 is amended by republishing the introductory text of paragraph (a) and revising paragraph (a)(1) to read as follows:

§ 412.88 Additional payment for new medical service or technology.

(a) For discharges involving new medical services or technologies that meet the criteria specified in § 412.87, Medicare payment will be:

(1) One of the following:

(i) The full DRG payment (including adjustments for indirect medical education and disproportionate share but excluding outlier payments);

(ii) The payment determined under § 412.4(f) for transfer cases;

(iii) The payment determined under § 412.92(d) for sole community hospitals; or

(iv) The payment determined under § 412.108(c) for Medicare-dependent hospitals; plus

* * * * *

8. 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, for purposes of a hospital seeking sole community hospital designation, CMS will not consider the nearby hospital to be a like hospital if the total inpatient days attributable to units of the nearby hospital that provides a level of care characteristic of the level of care payable under the acute care hospital inpatient prospective payment system are less than or equal to 8 percent of the similarly calculated total inpatient days of the hospital seeking sole community hospital designation.

* * * * *

9. Section 412.105 is amended by—

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

B. Revising paragraph (a)(1).

C. Revising paragraph (f)(1)(iii)(A).

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

E. Amending the following cross-references 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 the subchapter'' is removed and ''§ 413.86(g)(9)(i) and (g)(9)(ii) of the 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 the subchapter'' is removed and ''§ 413.86(g)(9)(i) and (g)(9)(iii)(A)'' 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 through the end of the first 12-month 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.

* * * * *

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

(iii)(A) Full-time equivalent status is based on the total time necessary to fill a residency slot. No individual may be counted as more than one full-time equivalent. If a resident is assigned to more than one hospital, the resident counts as a partial full-time equivalent based on the proportion of time worked in any areas of the hospital listed in paragraph (f)(1)(ii) of this section to the total time worked by the resident. A hospital cannot claim the time spent by residents training at another hospital. A part-time resident or one working in an area of the hospital other than those listed under paragraph (f)(1)(ii) of this section (such as a freestanding family practice center or an excluded hospital unit) would be counted as a partial full-time equivalent based on the proportion of time assigned to an area of the hospital listed in paragraph (f)(1)(ii) of this section, compared to the total time necessary to fill a full-time residency slot.

* * * * *

(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.

* * * * *

§ 412.106 [Amended]

10. In § 412.106(d)(2)(iv)(A), the phrase ''5 percent'' is removed and the phase ''4 percent'' is added in its place.

* * * * *

11. 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.

* * * * *

12. Section 412.113 is amended by revising paragraphs (c)(2)(i)(D), (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)(i) * * *

(D) Each qualified nonphysician anesthetist employed by or under contract with the hospital or CAH has agreed in writing not to bill on a reasonable charge basis for his or her patient care to Medicare beneficiaries in that hospital or CAH.

(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.

* * * * *

13. 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 hospital's provider number 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.

* * * * *

14. Section 412.273 is amended by—

A. Revising the section heading.

B. Revising paragraphs (b)(2)(i) and (b)(2)(ii).

C. Adding a new paragraph (b)(2)(iii).

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

E. Adding a new paragraph (d).

The revisions and additions read as follows:

§ 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).

* * * * *

15. 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, unless the new hospital elects to be paid under the capital prospective payment system based on 100 percent of the Federal rate.

(A) If the new hospital elects to be paid based on 100 percent of the Federal rate, the new hospital must submit a written request to the fiscal intermediary by the later of December 1, 2002 or 60 days before the beginning of its cost reporting period.

(B) Once a new hospital elects to be paid based on 100 percent of the Federal rate, it may not revert to payment at 85 percent of its allowable Medicare inpatient hospital capital-related costs.

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

* * * * *

16. 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.

* * * * *

17. 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 413.40 is amended by revising paragraph (c)(4)(iii)(A)(*2*) to read as follows:

§ 413.40 Ceiling on the rate of increase in hospital inpatient costs.

* * * * *

(c) * * *

(4) * * *

(iii) * * *

(A) * * *

(*2*) In the case of long-term care hospitals, for cost reporting periods beginning on or after October 1, 2000, the hospital-specific target amount is the net allowable costs in a base period increased by the applicable update factors multiplied by 1.25.

* * * * *

3. Section 413.65 is amended by—

A. Revising paragraphs (a)(1)(ii), (a)(1)(ii)(G), and (a)(1)(ii)(H).

B. Adding new paragraphs (a)(1)(ii)(J) and (a)(1)(ii)(K).

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

D. Revising paragraphs (b)(2), (b)(3), (c) and (d).

E. Removing paragraph (j).

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

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

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

I. Adding a new paragraph (e).

J. Revising redesignated paragraph (f).

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

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

M. Revising paragraph (k).

N. Redesignating paragraphs (l), (m), and (n) as paragraphs (m), (n), and (o), respectively.

O. Adding a new paragraph (l).

P. Revising the heading of redesignated paragraph (n).

Q. Revising redesignated paragraph (o).

The revisions and addition read as follows:

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

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

(ii) The determinations of provider-based status for payment purposes described in this section are not made as to whether the following facilities are provider-based:

* * * * *

(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.

(H) Facilities, other than those operating as parts of CAHs, furnishing only physical, occupational, or speech therapy to ambulatory patients, for as long as the $1,500 annual cap on coverage of physical, occupational, or speech therapy, as described in section 1833(g)(2) of the Act, remains suspended by the action of subsequent legislation.

* * * * *

(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).

(K) Ambulances.

(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 (n) 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) *Procedure 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), (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 a determination of provider-based status for a facility that is located on the 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 a determination would also be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS and to CMS contractors upon request.

(ii) If the facility is not located on the campus of the potential main provider, the provider seeking a 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.

(iii) Whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, as described in paragraph (b)(3)(i) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

(iv) Whenever a provider submits an attestation of provider-based status for an off-campus facility or organization, as described in paragraph (b)(3)(ii) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, consistency with the documentation submitted with the attestation and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

* * * * *

(c) *Reporting of material changes in relationships.* A main provider that has had one or more facilities or organizations considered provider-based also may report to CMS any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that would affect the provider-based status of the facility or organization.

(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 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.* In order for a facility or organization operated as a joint venture to be considered provider-based, the facility or organization must—

(1) Be partially owned by at least one provider'

(2) Be located on the main campus of a provider who is a partial owner;

(3) Be provider-based to that one provider whose campus on which the facility or organization is located; and

(4) Also meet all the requirements applicable to all provider-based facilities and organizations in paragraph (d) of this section. For example, where a provider 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 provider 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.*

(1) Hospital outpatient departments located either on or off the campus of the hospital that is the main provider must comply with the antidumping rules in §§ 489.20 (l), (m), (q), and (r) and § 489.24 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.

* * * * *

(7) When a Medicare beneficiary is treated in a hospital outpatient department or 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.

(iii) The hospital may furnish an estimate based on typical or average charges for visits to the facility, while stating that the patient's actual liability will depend upon the actual services furnished by the hospital.

(iv) If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, before the delivery of services, to the beneficiary's authorized representative.

(v) In cases where a hospital outpatient department provides examination or treatment that is required to be provided by the antidumping rules of § 489.24 of this chapter, notice, as described in this paragraph (g)(7), must be given as soon as possible after the existence of an emergency has been ruled out or the emergency condition has been stabilized.

* * * * *

(h) *Management contracts.* A facility or organization that is not located on the campus of the potential main provider and otherwise meets the requirements of paragraphs (d) and (e) of this section, but is operated under management contracts, must also meet all of the following criteria:

(1) 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 part 414 of this chapter. Other than staff that may be paid under such a Medicare fee schedule, the main provider may not utilize the services of ''leased'' employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) that are directly involved in the delivery of patient care.

(2) The administrative functions of the facility or organization are integrated with those of the main provider, as determined under criteria in paragraph (e)(2)(iii) of this section.

(3) The main provider has significant control over the operations of the facility or organization as determined under criteria in paragraph (e)(2)(ii) of this section.

(4) The management contract is held by the main provider itself, not by a parent organization that has control over both the main provider and the facility or organization.

(i) *Furnishing all services under arrangement.* A facility or organization may not qualify for provider-based status if all patient care services furnished at the facility or organization are furnished under arrangements.

(j) *Inappropriate treatment of a facility or organization as provider-based.—(1) Determination and review.* If CMS learns that a provider has treated a facility or organization as provider-based and the provider did not request a determination of provider-based status from CMS under paragraph (b)(3) of this section and CMS determines that the facility or organization did not meet the requirements for provider-based status under paragraphs (d) through (i) of this section, 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 will—

(i) Issue notice to the provider in accordance with paragraph (j)(3) of this section, adjust the amount of future payments to the provider for services of the facility or organization in accordance with paragraph (j)(4) of this section, and continue payments to the provider for services of the facility or organization only in accordance with paragraph (j)(5) of this section; and

(ii) Except as otherwise provided in paragraphs (b)(2), (b)(5), or (j)(2) of this section, recover the difference between the amount of payments that actually was made and the amount of payments that CMS estimates should have been made, in the absence of compliance with the provider-based requirements, to that provider for services at the facility or organization for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889 of this chapter.

(2) *Exception for good faith effort.* CMS will 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, if, during all of that period—

(i) The requirements regarding licensure and public awareness in paragraphs (d)(1) and (d)(4) of this section were met;

(ii) 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

(iii) All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described in paragraph (g)(2) of this section.

(3) *Notice to provider.* If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will issue written notice to the provider that payments for past cost reporting periods may be reviewed and recovered as described in paragraph (j)(1)(ii) of this section, and that future payments for services in or of the facility or organization will be adjusted as described in paragraph (j)(4) of this section.

(4) *Adjustment of payments.* If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will adjust future payments to the provider or the facility or organization, or both, to estimate the amounts that would be paid for the same services furnished by a freestanding facility.

(5) *Continuation of payment.* (i) The notice of denial of provider-based status sent to the provider will ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, of whether the provider intends to seek a determination of provider-based status for the facility or organization under this section 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 in a freestanding facility.

(ii) If the provider indicates that it will not be seeking a determination for the facility or organization under this section 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 payment under this paragraph (j)(5) will end as of the 30th day after the date of notice.

(iii) If the provider indicates that it will be seeking a determination for the facility or organization under this section 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 will continue, at the adjusted amounts described in paragraph (j)(4) of this section, for as long as is required for all billing requirements to be met (but not longer than 6 months) if the provider or the facility or organization or its practitioners—

(A) Submits, as applicable, a complete request for a determination of provider-based status or a complete enrollment application and provide all other required information within 90 days after the date of notice; and

(B) Furnishes all other information needed by CMS to make a determination regarding provider-based status or process the enrollment application, as applicable, and verifies that other billing requirements are met.

(v) If the necessary applications or information are not provided, CMS will 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.

(k) *Temporary treatment as provider-based.* If a provider submits a complete attestation of compliance with the requirements for provider-based status for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section, the provider may bill and be paid for services of the facility or organization as provider-based from the date it submits the attestation and any required supporting documentation until the date that CMS determines that the facility or organization does not meet the provider-based rules. If CMS subsequently 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 attestation of compliance with provider-based requirements was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements. For purposes of this paragraph (k), a complete attestation of compliance with provider-based requirements is one that includes all information needed to permit CMS to make a determination under paragraph (b)(3) of this section.

(l) *Correction of errors.* (1) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section 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 did report to CMS under paragraph (c) of this section, 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.

(2) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section 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 under paragraph (c) of this section, CMS will take the actions with respect to notice to the provider, adjustment of payments, and continuation of payment described in paragraphs (j)(3), (j)(4), and (j)(5) of this section, and will recover past payments to the provider to the extent described in paragraph (j)(1)(ii) of this section.

(m) *Status of Indian Health Service and Tribal facilities and organizations.* * * * * * *

(n) *FQHCs and ''look alikes.''* * * *

(o) *Effective date of provider-based status.*—(1) *General rule.* Provider-based status for a facility or organization is effective on the earliest date all of the requirements of this part have been met.

(2) *Inappropriate treatment as provider-based or not reporting material change.* Effective for any period on or after October 1, 2002 (or, in the case of facilities or organizations described in paragraph (b)(2) of this section, for cost reporting periods starting on or after July 1, 2003), if a facility or organization is found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section for those periods, or previously was determined by CMS to be provider-based but no longer qualifies as provider-based because of a material change occurring during those periods that was not reported to CMS under paragraph (c) of this section, CMS will not treat the facility or organization as provider-based for payment purposes until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under this part.

4. Section 413.70 is amended by revising paragraph (b)(3)(i) to read as follows:

§ 413.70 Payment for services of a CAH.

* * * * * *

(b) *Payment for outpatient services furnished by CAH.* * * *

(3) *Election to be paid reasonable costs for facility services plus fee schedule for professional services.* (i) A CAH may elect to be paid for outpatient services in any cost reporting period under the method described in paragraphs (b)(3)(ii) and (b)(3)(iii) of this section. This election must be made in writing, made on an annual basis, and delivered to the fiscal intermediary servicing the CAH at least 30 days before the start of each affected cost reporting period. An election of this

payment method, once made for a cost reporting period, remains in effect for all of that period and applies to all services furnished to outpatients during that period.

* * * * *

5. Section 413.86 is amended by—

A. Revising the definition of ''Affiliated group'' under paragraph (b).

B. Adding definitions of ''Affiliation agreement'' and ''Shared rotational arrangement'' in alphabetical order under paragraph (b).

C. Revising the last sentence of paragraph (e)(5)(i), introductory text.

D. Revising paragraph (e)(5)(i)(B).

E. Adding a new paragraph (e)(5)(i)(C).

F. Revising paragraph (f)(2).

G. Republishing the introductory text of paragraph (g)(4) and revising paragraph (g)(4)(iv).

H. Redesignating paragraphs (g)(7) through (g)(12) as paragraphs (g)(8) through (g)(13), respectively.

I. Adding a new paragraph (g)(7).

J. Amending the following cross-references:

i. In paragraph (g)(5)(vi), ''paragraph (g)(8)'' is removed and ''paragraph (g)(9)'' is added in its place.

ii. In paragraph (g)(6), ''paragraph (g)(12)'' is removed and ''paragraph (g)(13)'' is added in its place.

iii. In redesignated paragraphs (g)(8)(iv) and (g)(8)(v), ''paragraph (g)(7)'' is removed and ''paragraph (g)(8)'' is added in its place.

iv. In redesignated paragraph (g)(9)(i), ''paragraph (g)(8)'' is removed and ''paragraph (g)(9)'' is added in its place.

v. In the introductory text of redesignated paragraph (g)(9)(iii), ''paragraph (g)(8)(iii)(B)'' is removed and ''paragraph (g)(9)(iii)(B)'' is added in its place; and ''paragraph (g)(8)(iii)(A)'' is removed and ''paragraph (g)(9)(iii)(A)'' is added in its place.

vi. In redesignated paragraph (g)(9)(iii)(A)(*2*), ''paragraph (g)(8)(iii)(B)(*2*)'' is removed and ''paragraph (g)(9)(iii)(B)(*2*)'' is added in its place.

vii. In the introductory text of redesignated paragraph (g)(12), ''paragraph (g)(11)(i) through (g)(11)(vi)'' is removed and ''paragraph (g)(12)(i) through (g)(12)(vi)'' is added in its place.

The additions and revisions read as follows:

§ 413.86 Direct graduate medical education payments.

* * * * *

(b) *Definitions.* * * *

Affiliated group means—

(1) Two or more hospitals that are located in the same urban or rural area (as those terms are defined in § 412.62(f) of this subchapter) or in contiguous area and meet the rotation requirement in paragraph (g)(7)(ii) of this section.

(2) Two or more hospitals that are not located in the same or in a contiguous urban or rural area, but meet the rotation requirement in paragraph (g)(7)(ii) of this section, and are jointly listed—

(i) As the sponsor, primary clinical site or major participating institution for one or more programs as these terms are used in the most current publication of the *Graduate Medical Education Directory;* or

(ii) As the sponsor or is listed under ''affiliations and outside rotations'' for one or more programs in operation in *Opportunities, Directory of Osteopathic Postdoctoral Education Programs.*

(3) Two or more hospitals that are under common ownership and, effective for all affiliation agreements beginning July 1, 2003, meet the rotation requirement in paragraph (g)(7)(ii) of this section.

Affiliation agreement means a written, signed, and dated agreement by responsible representatives of each respective hospital in an affiliated group, as defined in this section, that specifies—

(1) The term of the agreement (which, at a minimum is one year), beginning on July 1 of a year;

(2) Each participating hospital's direct and indirect GME FTE caps in effect prior to the affiliation;

(3) The total adjustment to each hospital's FTE caps in each year that the affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect FTE caps that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect FTE caps of at least the same amount;

(4) The adjustment to each participating hospitals' FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the affiliated group for each year the affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's FTE caps (in accordance with paragraph (3) of this definition); and

(5) The names of the participating hospitals and their Medicare provider numbers.

* * * * *

Shared rotational arrangement means a residency training program under which a resident(s) participates in training at two or more hospitals in that program.

(e) *Determining per resident amounts for the base period.*

(5) Exceptions—(i) *Base period for certain hospitals.* * * * The per resident amount is based on the lower of the amount specified in paragraph (e)(5)(i)(A) or in paragraph (e)(5)(i)(B) of this section, subject to the provisions of paragraph (e)(5)(i)(C) of this section.

(B) Except as specified in paragraph (e)(5)(i)(C) of this section—

(*1*) For base periods that begin before October 1, 2002, the updated 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.

(*2*) For base periods beginning on or after October 1, 2002, the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

(C) If, under paragraph (e)(5)(i)(B)(*1*) or (e)(5)(i)(B)(*2*) of this section, there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in § 412.62(f)(1)(i) of this chapter.

* * * * *

(f) *Determining the weighted number of FTE residents.* * * *

(2) No individual may be counted as more than one FTE. A hospital cannot claim the time spent by residents training at another hospital. Except as provided in paragraphs (f)(3) and (f)(4) of this section, if a resident spends time in more than one hospital or in a nonprovider setting, the resident counts as partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of allowable time worked compared to the total time necessary to fill a full-time internship or residency slot.

* * * * *

(g) *Determining the weighted number of FTE residents.* * * *

(4) For purposes of determining direct graduate medical education payment—

* * * * *

(iv) Hospitals that are part of the same affiliated group (as described under paragraph (b) of this section) may elect to apply the limit on an aggregate basis as described under paragraph (g)(7) of this section.

* * * * *

(7) A hospital may receive a temporary adjustment to its FTE cap, which is subject to the averaging rules under paragraph (g)(5)(iii) of this section, to reflect residents added or subtracted because the hospital is participating in an affiliated group (as defined under paragraph (b) of this section). Under this provision—

(i) Each hospital in the affiliated group must submit the affiliation agreement, as defined under paragraph (b) of this section, 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.

(ii) Each hospital in the affiliated group must have a shared rotational arrangement, as defined in paragraph (b) of this section, with at least one other hospital within the affiliated group, and all of the hospitals within the affiliated group must be connected by a series of such shared rotational arrangements.

(iii) During the shared rotational arrangements under an affiliation agreement, as defined in paragraph (b) of this section, more than one of the hospitals in the affiliated group must count the proportionate amount of the time spent by the resident(s) in its FTE resident counts. No resident may be counted in the aggregate as more than one FTE.

(iv) The net effect of the adjustments (positive or negative) on the affiliated hospitals' aggregate FTE cap for each affiliation agreement must not exceed zero.

(v) If the affiliation agreement terminates for any reason, the FTE cap of each hospital in the affiliated group will revert to the individual hospital's pre-affiliation FTE cap that is determined under the provisions of paragraph (g)(4) of this section.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

D. Part 485 is amended as follows:

1. The authority citation for Part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Act (42 U.S.C. 1302 and 1396hh).

2. In § 485.645, the introductory text of paragraph (d) is republished and paragraph (d)(6) is revised, to read as follows.

§ 485.645 Special requirements for CAH providers of long-term care services (''swing-beds'').

* * * * *

(d) *SNF services.* The CAH is substantially in compliance with following SNF requirements contained in Subpart B of Part 483 of this chapter.

* * * * *

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§ 483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under § 483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in § 413.343(b) of this chapter).

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare— Hospital Insurance)

Dated: July 24, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 24, 2002.

Tommy G. Thompson,

Secretary.

[**Editorial Note:** The following Addendum and appendixes will not appear in the Code of Federal Regulations.]

Addendum—Schedule of Standardized Amounts Effective With Discharges Occurring On or After October 1, 2002 and Update Factors and Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning On or After October 1, 2002

I. Summary and Background

In this Addendum, we are setting forth the amounts and factors for determining prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs. We are also setting forth rate-of-increase percentages for updating the target amounts for hospitals and hospital units excluded from the acute care hospital inpatient prospective payment system.

For discharges occurring on or after October 1, 2002, except for SCHs, MDHs, and hospitals located in Puerto Rico, each hospital's payment per discharge under the acute care hospital inpatient prospective payment system will be based on 100 percent of the Federal national rate.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; or 75 percent of the updated hospital-specific rate based on FY 1996 costs per discharge, plus the greater of 25 percent of the updated FY 1982 or FY 1987 hospital-specific rate or 50 percent of the Federal DRG payment rate. Section 213 of Public Law 106–554 amended section 1886(b)(3) of the Act to allow all SCHs to rebase their hospital-specific rate based on their FY 1996 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever is higher. MDHs do not have the option to use their FY 1996 hospital-specific rate.

For hospitals in Puerto Rico, the payment per discharge is based on the sum of 50 percent of a Puerto Rico rate and 50 percent of a Federal national rate. (See section II.D.3. of this Addendum for a complete description.)

As discussed below in section II. of this Addendum, we are making changes in the determination of the prospective payment rates for Medicare inpatient operating costs for FY 2003. The changes, to be applied prospectively effective with discharges occurring on or after October 1, 2002, affect the calculation of the Federal rates. In section III. of this Addendum, we discuss our changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2003. Section IV. of this Addendum sets forth our changes for determining the rate-of-increase limits for hospitals excluded from the prospective payment system for FY 2003. The tables to which we refer in the preamble to this final rule are presented in section V. of this Addendum.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for FY 2003

The basic methodology for determining prospective payment rates for hospital inpatient operating costs is set forth at § 412.63. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico is set forth at §§ 412.210 and 412.212. Below, we discuss the factors used for determining the prospective payment rates.

In summary, the standardized amounts set forth in Tables 1A and 1C of section V. of this Addendum reflect—

- Updates of 2.95 percent for all areas (that is, the market basket percentage increase of 3.5 percent minus 0.55 percentage points);
- An adjustment to ensure the DRG recalibration and wage index update and changes are budget neutral, as provided for under sections 1886(d)(4)(C)(iii) and (d)(3)(E) of the Act, by applying new budget neutrality adjustment factors to the large urban and other standardized amounts;
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for in section 1886(d)(8)(D) of the Act, by removing the FY

2002 budget neutrality factor and applying a revised factor;

- An adjustment to apply the new outlier offset by removing the FY 2002 outlier offsets and applying a new offset; and
- An adjustment in the Puerto Rico standardized amounts to reflect the application of a Puerto Rico-specific wage index.

A. Calculation of Adjusted Standardized Amounts

1. Standardization of Base-Year Costs or Target Amounts

Section 1886(d)(2)(A) of the Act required the establishment of base-year cost data containing allowable operating costs per discharge of inpatient hospital services for each hospital. The preamble to the September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data were established in the initial development of standardized amounts for the acute care hospital inpatient prospective payment system.

Section 1886(d)(9)(B)(i) of the Act required us to determine the Medicare target amounts for each hospital located in Puerto Rico for its cost reporting period beginning in FY 1987. The September 1, 1987 final rule (52 FR 33043, 33066) contains a detailed explanation of how the target amounts were determined and how they are used in computing the Puerto Rico rates.

The standardized amounts are based on per discharge averages of adjusted hospital costs from a base period or, for Puerto Rico, adjusted target amounts from a base period, updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. Sections 1886(d)(2)(B) and (d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, indirect medical education costs, and costs to hospitals serving a disproportionate share of low-income patients.

Under sections 1886(d)(2)(H) and (d)(3)(E) of the Act, in making payments under the acute care hospital inpatient prospective payment system, the Secretary estimates from time to time the proportion of costs that are wages and wage-related costs. Since October 1, 1997, when the market basket was last revised, we have considered 71.1 percent of costs to be labor-related for purposes of the acute care hospital inpatient prospective payment system. As discussed in section IV. of the preamble to this final rule, we are not revising the labor share of the standardized amount (the proportion adjusted by the wage index). The average labor share in Puerto Rico is 71.3 percent. We are revising the discharge-weighted national standardized amount for Puerto Rico to reflect the proportion of discharges in large urban and other areas from the FY 2001 MedPAR file.

2. Computing Large Urban and Other Area Average Standardized Amounts

Sections 1886(d)(2)(D) and (d)(3) of the Act require the Secretary to compute two average standardized amounts for discharges occurring in a fiscal year: one for hospitals located in large urban areas and one for hospitals located in other areas. In addition, under sections 1886(d)(9)(B)(iii) and (d)(9)(C)(i) of the Act, the average standardized amount per discharge must be determined for hospitals located in large urban and other areas in Puerto Rico. In accordance with section 1886(b)(3)(B)(i) of the Act, the large urban average standardized amount is 1.6 percent higher than the other area average standardized amount.

Section 1886(d)(2)(D) of the Act defines ''urban area'' as those areas within a Metropolitan Statistical Area (MSA). A ''large urban area'' is defined as an urban area with a population of more than 1 million. In addition, section 4009(i) of Public Law 100–203 provides that a New England County Metropolitan Area (NECMA) with a population of more than 970,000 is classified as a large urban area. As required by section 1886(d)(2)(D) of the Act, population size is determined by the Secretary based on the latest population data published by the Bureau of the Census. Urban areas that do not meet the definition of a ''large urban area'' are referred to as ''other urban areas.'' Areas that are not included in MSAs are considered ''rural areas'' under section 1886(d)(2)(D) of the Act. Payment for discharges from hospitals located in large urban areas will be based on the large urban standardized amount. Payment for discharges from hospitals located in other urban and rural areas will be based on the other standardized amount.

Based on the latest available population estimates published by the Bureau of the Census, 63 areas meet the criteria to be defined as large urban areas for FY 2003. These areas are identified in Table 4A.

3. Updating the Average Standardized Amounts

Under section 1886(d)(3)(A) of the Act, we update the average standardized amounts each year. In accordance with section 1886(d)(3)(A)(iv) of the Act, we are updating the large urban areas' and the other areas' average standardized amounts for FY 2003 using the applicable percentage increases specified in section 1886(b)(3)(B)(i) of the Act. Section 1886(b)(3)(B)(i)(XVIII) of the Act specifies that the update factor for the standardized amounts for FY 2003 is equal to the market basket percentage increase minus 0.55 percentage points for hospitals in all areas.

The percentage change in the market basket reflects the average change in the price of goods and services purchased by hospitals to furnish inpatient care. The most recent forecast of the hospital market basket increase for FY 2003 is 3.5 percent. Thus, for FY 2003, the update to the average standardized amounts equals 2.95 percent for hospitals in all areas.

As in the past, we are adjusting the FY 2002 standardized amounts to remove the effects of the FY 2002 geographic reclassifications and outlier payments before applying the FY 2003 updates. That is, we are increasing the standardized amounts to restore the reductions that were made for the effects of geographic reclassification and outliers. We then apply the new offsets to the standardized amounts for outliers and geographic reclassifications for FY 2003.

We do not remove the prior budget neutrality adjustment because, in accordance with section 1886(d)(4)(C)(iii) of the Act, estimated aggregate payments after the changes in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year adjustment, we would not satisfy this condition.

Although the update factors for FY 2003 are set by law, we are required by section 1886(e)(3) of the Act to report to the Congress our initial recommendation of update factors for FY 2003 for both prospective payment hospitals and hospitals excluded from the prospective payment system. We have included our final recommendation on the update factors (which is required by sections 1886(e)(4)(A) and (e)(5)(A) of the Act) in Appendix B to this final rule.

4. Other Adjustments to the Average Standardized Amounts

a. Recalibration of DRG Weights and Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II. of the preamble, we normalized the recalibrated DRG weights by an adjustment factor, so that the average case weight after recalibration is equal to the average case weight prior to recalibration. However, 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, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

Section 1886(d)(3)(E) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index.

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. This provision is required by section 4410(b) of Public Law 105–33 to be budget neutral.

In addition, we are required to ensure that any add-on payments for new technology under section 1886(d)(5)(K) of the Act are budget neutral. As discussed in section II.D. of this final rule, we are approving one new technology for add-on payments in FY 2003. We estimate that the total add-on payments for this new technology will be $74.8 million.

To comply with the requirement of section 1886(d)(4)(C)(iii) of the Act that DRG

reclassification and recalibration of the relative weights be budget neutral, and the requirement in section 1886(d)(3)(E) of the Act that the updated wage index be budget neutral, we used FY 2001 discharge data to simulate payments and compared aggregate payments using the FY 2002 relative weights and wage index to aggregate payments using the FY 2003 relative weights and wage index, plus the additional add-on payments for the new technology. The same methodology was used for the FY 2002 budget neutrality adjustment, except for the new technology add-on budget neutrality adjustment. Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.993209. We also adjust the Puerto Rico-specific standardized amounts for the effect of DRG reclassification and recalibration. We computed a budget neutrality adjustment factor for Puerto Rico-specific standardized amounts equal to 0.994027. These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 2002 budget neutrality adjustments.

In addition, we will apply these same adjustment factors to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2002. (See the discussion in the September 4, 1990 final rule (55 FR 36073).)

Comment: One commenter questioned this budget neutrality calculation in the proposed rule and pointed out that the total numbers of cases in Table 7A, showing FY 2001 MedPAR records assigned to version 19 GROUPER DRGs, was different than the total number of cases in Table 7B, which shows FY 2001 MedPAR records assigned to version 20 GROUPER DRGs. The commenter noted that a similar discrepancy occurred in the FY 2002 final rule, yet there has been no discrepancy in the past. Based on the discrepancy in total cases, the commenter was concerned that the budget neutrality calculation may be incorrect.

Response: The commenter correctly points out a discrepancy in the source files used to produce Tables 7A and 7B for the FY 2002 final rule and the FY 2003 proposed rule. We have corrected this discrepancy in this final rule. The source of the discrepancy was the removal of statistical outliers for DRG recalibration. Statistical outliers are defined as cases with charges per case and charges per day beyond 3 standard deviations from the DRG mean. In the proposed rule, Table 7A had statistical outliers removed based on the GROUPER version 19 DRG assignment, and Table 7B had statistical outliers removed based on the GROUPER version 20 DRG assignment. In this final rule, we have removed only statistical outliers based on version 20 DRG assignment from both Table 7A and Table 7B.

This discrepancy did not affect the budget neutrality calculation, however. This calculation uses only cases remaining after trimming statistical outliers based on GROUPER version 20 DRG assignment. Payments for these remaining cases are then compared using first their version 19 GROUPER DRG assignment, then their version 20 DRG assignment.

b. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that, effective with discharges occurring on or after October 1, 1988, certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the standardized amount or the wage index, or both.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the acute care hospital inpatient prospective payment system after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. To calculate this budget neutrality factor, we used FY 2001 discharge data to simulate payments, and compared total prospective payments (including IME and DSH payments) prior to any reclassifications to total prospective payments after reclassifications. Based on these simulations, we are applying an adjustment factor of 0.991095 to ensure that the effects of reclassification are budget neutral.

The adjustment factor is applied to the standardized amounts after removing the effects of the FY 2002 budget neutrality adjustment factor. We note that the FY 2003 adjustment reflects FY 2003 wage index and standardized amount reclassifications approved by the MGCRB or the Administrator, and the effects of section 1886(d)(10)(D)(v) of the Act to extend wage index reclassifications for 3 years.

c. Outliers

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases, cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs above a fixed loss cost threshold amount. To determine whether the costs of a case exceed the fixed loss threshold, a hospital's cost-to-charge ratio is applied to the total covered charges for the case to convert the charges to costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the costs above the threshold.

Under section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year must be projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amounts by a factor to account for the estimated proportion of total DRG payments made to outlier cases. Similarly, section 1886(d)(9)(B)(iv) of the Act requires the Secretary to reduce the average standardized amounts applicable to hospitals in Puerto Rico to account for the estimated proportion of total DRG payments made to outlier cases.

i. FY 2003 outlier fixed loss cost thresholds. For FY 2002, the threshold is equal to the prospective payment rate for the DRG, plus any IME and DSH payments plus $21,025. The marginal cost factor (the percent of costs paid after costs for the case exceed the threshold) is 80 percent.

For FY 2003, we proposed to establish a fixed loss cost outlier threshold equal to the prospective payment rate for the DRG plus any IME and DSH payments, and any add-on payments for new technology, plus $33,450. This single threshold would be applicable for cases to qualify for both operating and capital outlier payments. We proposed to maintain the marginal cost factor at 80 percent.

To calculate the FY 2003 outlier thresholds, we simulated payments by applying FY 2003 rates and policies to the March 2002 update of the FY 2001 MedPAR file and the March 2002 update of the Provider-Specific File. Therefore, it was necessary to inflate the charges on the MedPAR claims by 2 years, from FY 2001 to FY 2003, in order to determine the appropriate FY 2003 thresholds.

Previously, inflation factors have been calculated by measuring the percent change in costs using the two most recent available cost report files. For example, the FY 2002 threshold was determined using the rate of cost increase measured using costs from hospitals' FY 1998 and FY 1999 cost reports. However, at the time of the proposed rule, the FY 2000 cost reports were not available to produce an updated cost inflation factor due to processing delays associated with implementing the hospital outpatient prospective payment system.

As discussed in the May 9, 2002 proposed rule, rather than use the rate of cost increase from hospitals' FY 1998 and FY 1999 cost reports to project the rate of increase from FY 2001 to FY 2003, we proposed to use a 3-year moving average of the rate of change in costs for prior years to estimate the annual rates of inflation from FY 2001 to FY 2003. The calculation was discussed thoroughly in the proposed rule (67 FR 31510).

Based on this methodology, we proposed a 2-year cost inflation factor of 15.0 percent to inflate FY 2001 charges to FY 2003, determined by multiplying the annual projected inflation factors for FYs 2002 and 2003 of 1.0655 and 1.0793.

We pointed out that, using actual FY 2001 cases, our analysis indicated that this 3-year moving average methodology would have resulted in FY 2002 outlier payments very close to 5.1 percent of total operating DRG payments and outlier payments.

Comment: Several commenters stated that the proposed 59 percent increase in the outlier threshold is an enormous increase based on old data and a new methodology, and as a result, puts hospitals at even greater risk for high-cost cases. One commenter wrote that this type of unpredictability makes sound management difficult.

The commenters also believed that the proposed outlier policy, if implemented in a budget neutral manner, has the effect of reducing hospital payments by 1.87 percent, nearly wiping out any inflationary increase paid through the market basket increase.The commenters stated that, without more recent data and better rationale, the outlier threshold should remain unchanged at the FY 2002 level of $21,025.

Response: Our objective in setting the outlier threshold is to set it at a level that is projected to result in outlier payments during the upcoming Federal fiscal year that are equal to 5.1 percent of operating DRG payments. In accordance with section 1886(d)(3)(B) of the Act, we reduce the standardized amounts by 5.1 percent to account for the projected 5.1 percent paid to outliers. This adjustment is intended to ensure that outlier payments are budget neutral: Total payments after making outlier payments are equal to what total payments would have been without making any outlier payments. Therefore, if our projections of outlier payments are perfectly accurate, there is no net change in total hospital payments related to outlier policy.

We believe the reference to reducing hospital payments by 1.87 percent relates to the fact that, for FY 2002, outlier payments will be greater than 5.1 percent of total DRG payments, and if outlier payments are projected to equal 5.1 percent of total DRG payments in FY 2003, hospitals will not receive the additional payments they otherwise would if outlier payments exceeded 5.1 percent. The statute requires that the outlier offset to the average standardized amounts equal the projected proportion of outlier payments relative to total operating DRG payments. Therefore, if we offset the average standardized amounts by 5.1 percent to account for outlier payments, we must set the outlier threshold at a level we project will result in outlier payments equal to 5.1 percent of total operating DRG payments.

Moreover, we believe that in order to maintain the fiscal integrity of the Medicare Trust Fund, we must set the FY 2003 outlier threshold so that, based on our best estimate, the proportion of FY 2003 outlier payments relative to total DRG payments is projected to equal the offset of the average standardized amounts.

As discussed in further detail below, we now estimate FY 2002 outlier payments to be 6.9 percent of total DRG payments, using the FY 2002 threshold of $21,025. Therefore, we estimate that we will be paying approximately $1.5 billion more in outlier payments during FY 2002 than we would have if our outlier projections had been perfectly accurate (outlier payments 1.9 percentage points higher relative to total DRG payments of approximately $76 billion). The table below demonstrates that actual outlier payments since 1997 have exceeded the 5.1 percent offset by an aggregate of 11.2 percentage points, equating with approximately $8.5 billion in higher than anticipated payments. However, analysis over a longer time period demonstrates that years in which CMS has paid more than projected in outlier payments are offset by years in which CMS has paid less than projected.

Year	Payments in excess of 5.1 percent (percentage points)
1997	0.4
1998	1.4
1999	2.5
2000	2.5
2001	2.6
2002	1.8

Based on available information (which was not available at the time we set the FY 2003 outlier thresholds), we now estimate that an outlier threshold of $30,525 would have resulted in outlier payments equal to 5.1 percent of total DRG payments for FY 2002. Therefore, barring any drastic reductions in hospital charges per case, maintaining the FY 2003 fixed loss outlier threshold at $21,025, while offsetting the standardized amount by only 5.1 percent, would almost certainly guarantee that FY 2003 total payments after outlier payments and the offset would exceed what total payments would have been without making any outlier payments or offset.

Comment: Numerous commenters added that the proposed methodology for determining the estimate of cost inflation is flawed and, as a result, the new threshold is too high. The commenters expressed concern that increasing the threshold too fast will seriously undermine hospitals' ability to continue to care for high-cost frail and elderly patients.

The commenters stated that the proposed 2-year cost inflation factor of 15.0 percent from FY 2001 to FY 2003 is more than triple the rate of change of cost inflation in FY 1999. The commenters also stated that this increase is also markedly different and significantly higher than all other government projections of cost inflation. For instance, they pointed out that, in its March 2002 report, MedPAC measured hospital cost inflation at 4.8 percent for the time period FY 2001 to FY 2003; the Office of Management and Budget has projected cost inflation for the overall economy at a rate of 2.2 percent for FY 2003; and CMS' market basket for that time period is a 6.6 percent increase.

Several commenters focused on the fact that, rather than proposing to calculate the inflation factor based on an annual rate of change, we proposed to calculate it using the difference in the annual rate of change (second derivative). The commenters submitted analysis indicating this proposed methodology was more volatile in its estimates than alternative approaches. In addition, the commenters stated that our data were outdated and therefore unreliable.

The commenters proposed using one of three alternatives:

- Three-year moving average of annual rates of change in costs rather than a 3-year average of the differences in the annual rates of change in costs (as proposed). The projected increase in hospital cost inflation from FY 2001 to FY 2003 using this method would be 4.1 percent.
- CMS' usual method in predicting cost inflation, but substituting a 4-year lag in data rather than the typical 3-year lag due to the lack of FY 2000 cost reports. The projected increase in hospital cost inflation from FY 2001 to FY 2003 would be 4.8 percent.
- Changes as measured in the hospital market basket index. The projected increase in hospital cost inflation from FY 2001 to FY 2003 would be 7.1 percent.

The commenters stated that the alternative that most closely approximates CMS' usual method is the 4-year lag approach. The commenters also recognized that the simulations of the market basket index approach they submitted tracks most closely with actual cost increases. The commenters stated that this method would result in a new outlier threshold between $26,254 and $27,810, which the commenters believe is a much more realistic increase.

One commenter noted that determining the outlier threshold is dependent not only on changes in costs per case, but is also dependent on hospital charges and cost-to-charge ratios.

Response: Our proposed methodology took into account that the most recent cost data we had available was approximately 3 years old by including a factor to measure the rate of growth in the annual change in costs per case. Using data from hospitals' cost reports, we calculated average annual rates of change to project cost growth from FYs 1999 through 2003. We believe this approach was preferable to a simple average rate of change when projecting over a 4-year time span because, by including a factor to measure the rate of change we account for the observed trend in cost growth over recent periods. We do not dispute that this methodology results in inflation factors higher than other estimates, including the market basket used to update the acute inpatient prospective payment system. However, we point out that our analysis in the proposed rule showed that, if this methodology had been used to estimate the threshold for FY 2002, it would have resulted in FY 2002 outlier payments much closer to 5.1 percent of total DRG payments than we are currently estimating (67 FR 31510).

Nevertheless, we understand the commenters' concerns that our methodology to estimate cost inflation for purposes of setting the outlier threshold is much higher than other, more established methodologies and we considered the alternatives suggested by the commenters. Each of the three alternative are based on projecting cost increases.

As noted above, commenters indicated they believe a FY 2003 threshold between $26,254 and $27,810 would be realistic. However, we believe, based on our analysis of MedPAR data, that this threshold would be significantly inaccurate. To illustrate, we used actual MedPAR data for the past 2.5 years to determine what thresholds would have resulted in a 5.1 percent outlier payout for FYs 2000, 2001 and 2002.

Fiscal year	Threshold actually applied	Threshold that would have paid out 5.1 percent	Actual payout percentage
2000	$14,050	$21,825	7.6
2001	17,550	26,200	7.7
2002*	21,025	30,525*	6.9

*Using March 2002 Update of Fiscal Year 2002 MedPAR Cases.

This table shows that, had we set the threshold each of the last 3 fiscal years at a level that would have paid out 5.1 percent based on data now available, the FY 2002 threshold would have actually been $30,525. Based on this analysis, we believe a threshold of no more than $27,810, as suggested by the commenters, would be likely to result in payments in excess of 5.1 percent.

Outlier payments are determined by multiple variables that change at different rates over time. As described above, to determine whether a case qualifies as an outlier, the hospital's cost-to-charge ratio is applied to the covered charges (which are adjusted for the area wage index applicable to the area where the hospital is located) of a case to estimate the costs. The estimated costs for the case are then compared to the outlier threshold to determine whether the case qualifies for outlier payments.

Based on our analysis above, we believe that, due to current trends in hospital charging practices, using inflation factors based on annual cost growth results in underestimating the percentage of outlier payments. That is, if charges are growing at a faster rate than costs, inflating FY 2001 charges by the observed rate of change in costs will underestimate FY 2003 charges, thereby resulting in outlier payments greater than 5.1 percent. Therefore, we analyzed the rate of change in covered charges per case over the past 3 years. Because charge data are available from claims data in the MedPAR file, they are more up-to-date than cost data taken from the cost reports.

FY	Covered charge/case	Percentage change in charge/case
1999	$15,215	
2000	16,376	7.63
2001	18,015	10.00

This table illustrates the substantial increase recently in the growth of charges, indicating that charges have indeed been increasing faster than costs. Because charges serve as the basis to estimate costs for purposes of identifying outlier cases, higher than expected increases in charges would lead to more cases qualifying for outlier payments than expected (and more of the costs of qualifying cases in excess of the threshold).

Over time, cost-to-charge ratios will reflect the differential increase in charges. However, due to the delay in processing the FY 2000 cost reports, combined with the dramatically different rates of change in charges and costs, we believe it is appropriate, at least as far as determining the outlier thresholds for FY 2003, to change from our past methodology of basing the inflation factor on the rate of change in costs, and instead rely on the rate of change in charges. Therefore, we are not adopting our proposed methodology.

Instead, we have determined that, for purposes of setting a FY 2003 outlier threshold that we project will result in outlier payments of 5.1 percent of total DRG payments, the most appropriate methodology to use is to inflate charges using a 2-year average annual rate of change in charges per case. The 2-year average annual rate of change in charges per case from FY 1999 to FY 2000, and from FY 2000 to FY 2001, is 8.8199 percent annually, or 17.6398 percent over 2 years. Applying this charge inflation factor to FY 2001 cases results in a fixed loss outlier threshold of $33,560.

We believe inflating charges by the 2-year average annual rate of change in charges per case is an appropriate revision to our prior inflation methodology used to set the threshold. That is, our analysis described above indicates that a 2-year average annual rate of change based on charges results in a threshold that is more consistent with what our analysis indicates recent thresholds would have resulted in actual outlier payments approximating 5.1 percent of actual total operating DRG payments. In addition, our analysis above demonstrates that charges have been growing at a much faster rate than recent estimates of cost growth, indicating that the average rate of change in charges will produce a more appropriate inflation factor at this time. We have selected a 2-year average rate of change in charges (from FY 1999 to FY 2000 and from FY 2000 to FY 2001) rather than simply a 1-year rate of change in order to account for the greater variability of charges (due to the fact that hospitals have greater latitude in setting their charges than they do over their costs). We would point out that this analysis is based on recent data and does not reflect upon previous analysis used to support the use of cost inflation factors used in the Medicare cost reports.

Using this revised methodology for setting the charge inflation factors for FY 2003, we are establishing a fixed loss cost outlier threshold equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $33,560. This single threshold would be applicable to qualify for both operating and capital outlier payments. We are also maintaining the marginal cost factor for cost outliers at 80 percent.

Comment: Two commenters recommended that we increase the FY 2002 threshold by the market basket inflation factor, then develop a new threshold using our previous cost inflation methodology when FY 2000 cost reports come available later this year.

Response: Based on our analysis of where prior years' thresholds would have been set if we knew at the time we set the thresholds what we know now, and our analysis showing the higher rate of change in charges than in costs, we are revising our methodology to establish the FY 2003 outlier thresholds to reflect the rate of change in charges. We believe this will establish the thresholds at an appropriate level using more recent data. Therefore, we are not accepting the commenters' recommendation.

Comment: Some commenters predicted that, as a result of the large increase in the threshold from FY 2002, outlier payments would fall well below 5.1 percent.

Response: We have taken the commenters' concerns and our further analysis into account in our methodology to set the FY 2003 threshold. Based on our analysis as described above, we disagree with the commenters' prediction.

Comment: One commenter attributed the high percentage of outlier payments relative to DRG payments to the increasing costs of medical technology, for which the commenter argued that there is no effective payment solution.

Response: Our analysis indicates the higher than estimated outlier payments are attributable to charges rising faster than our inflation estimates. This may be associated with increasing costs and utilization of medical technology, as the commenter suggested. This effect would eventually be reflected in the DRG weights and the market basket estimate.

However, we would point out that our analysis above indicates that charges are rising much faster than costs. This would indicate that costs estimated by applying cost-to-charge ratios from past periods to charges from current periods would result in estimated costs in excess of actual costs. Therefore, we disagree that rising costs due to new technology is the reason outlier payments have been higher than projected.

Comment: Some commenters argued that the delay in processing cost reports is interrupting the gradually declining trend in cost-to-charge ratios, leading to higher cost estimates than anticipated.

Response: Our analysis shows that, despite the delay in processing cost reports alluded to above, the average cost-to-charge ratios have continued to decline. We note there is always a lag between the timeframe from which the cost-to-charge ratios are taken and the period to which they are applied to charges. We do not have any evidence that the higher than expected outlier payments result from any extra lag in updating cost-to-

charge ratios due to the delay in processing the cost reports.

Comment: Some commenters referenced a joint letter from CMS' Center for Medicare Management, Office of Financial Management, issued April 22, 2002, on the issue of the correct calculation of hospital cost-to-charge ratios, as indicative of potential erroneous cost-to-charge ratios influencing the calculation of the outlier threshold.

Response: The joint letter clarified instructions to all fiscal intermediaries on calculating the cost-to-charge ratios in response to isolated instances where we were made aware they had been calculated incorrectly. We have examined the cost-to-charge ratios and do not believe the issue addressed in the joint letter is systemic, and therefore, it should not materially affect our outlier threshold calculations.

Comment: One commenter recommended increasing the estimated outlier payment percentage from 5.1 percent to 6.0 percent, the upper bound permissible under the statute. The commenter believed the proposed outlier change would cause an inequitable redistribution and that increasing the outlier target would address this inequity.

Response: Although reducing the outlier threshold would result in a higher outlier payout, and we have authority under section 1886(d)(5)(A)(iv) of the Act to set an outlier target of up to 6.0 percent, we do not believe this approach would be appropriate. As noted previously, section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amounts by the projected proportion of total DRG payments made to outlier cases. Therefore, adopting this suggestion would result in lower standardized amounts for all cases, reducing payments for hospitals that do not generally receive as high a proportion of outlier payments as other hospitals as a result of the lower standardized amount. These low-outlier hospitals would be negatively impacted by reducing the standardized amount without the benefit of continued high outlier payments.

Comment: Commenters also suggested reducing the marginal cost factor below 80 percent. One commenter suggested raising the marginal cost factor from 80 percent to 90 percent. This commenter stated such a change would redistribute the negative impact of increasing the threshold in a more equitable manner.

Response: Reducing the marginal cost factor would result in a lower outlier threshold (so more cases would qualify for outlier payments) but would also result in lower outlier payments per outlier case. While we considered this approach to alleviate the impact of the proposed increase in the outlier threshold, we decided not to adopt it without further analysis (the commenter presented no assessment of the impacts of such a change, for example). We note that the current 80 percent marginal cost factor was established for FY 1994 (from 75 percent) to further focus Medicare's cost outlier payments on the costliest cases (59 FR 45367). This change was consistent with a recommendation by the Prospective Payment Assessment Commission (MedPAC's predecessor) based on its analysis of outlier policy. We believe it would be necessary to conduct further analysis of the impacts of changing the marginal cost factor before making such a change in the marginal cost factor. Conversely, increasing the marginal cost factor would result in either raising the outlier threshold (which means fewer cases would qualify for outlier payments) or raising the offset to the standardized amount, or both. We believe that an 80 percent marginal cost factor and 5.1 percent outlier target appropriately target payments to extremely high cost cases and, at the same time, provide adequate compensation to nonoutlier cases.

ii. Other changes concerning outliers. In accordance with section 1886(d)(5)(A)(iv) of the Act, we calculated outlier thresholds so that outlier payments are projected to equal 5.1 percent of total operating DRG payments plus outlier payments. In accordance with section 1886(d)(3)(B), we reduced the FY 2003 standardized amounts by the same percentage to account for the projected proportion of payments paid to outliers.

As stated in the September 1, 1993 final rule (58 FR 46348), we establish outlier thresholds that are applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common set of thresholds resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2003 will result in outlier payments equal to 5.1 percent of operating DRG payments and 5.4 percent of capital payments based on the Federal rate.

The proposed outlier adjustment factors to be applied to the standardized amounts for FY 2003 were as follows:

	Operating standardized amounts	Capital federal rate
National	0.949004	0.945957
Puerto Rico	0.982910	0.980994

Based on simulations of payments using updated data, the final outlier adjustment factors applied to the standardized amounts for FY 2003 are as follows:

	Operating standardized amounts	Capital federal rate
National	0.948999	0.946924
Puerto Rico	0.981651	0.979669

As in the proposed rule, we apply the outlier adjustment factors after removing the effects of the FY 2002 outlier adjustment factors on the standardized amounts.

To determine whether a case qualifies for outlier payments, we apply hospital-specific cost-to-charge ratios to the total covered charges for the case. Operating and capital costs for the case are calculated separately by applying separate operating and capital cost-to-charge ratios, then these costs are combined to compare with the fixed-loss outlier threshold.

For those hospitals for which the fiscal intermediary computes operating cost-to-charge ratios lower than 0.194 or greater than 1.258, or capital cost-to-charge ratios lower than 0.012 or greater than 0.163, statewide average ratios would be used to calculate costs to determine whether a hospital qualifies for outlier payments.[1] Table 8A in section V. of this Addendum contains the updated statewide average operating cost-to-charge ratios for urban hospitals and for rural hospitals for which the fiscal intermediary is unable to compute a hospital-specific cost-to-charge ratio within the above range. These statewide average ratios replace the ratios published in the August 1, 2001 final rule (66 FR 40083). Table 8B contains comparable statewide average capital cost-to-charge ratios. We note that the cost-to-charge ratios in Tables 8A and 8B will be used during FY 2003 when hospital-specific cost-to-charge ratios based on the latest settled cost report are either not available or are outside the ranges noted above.

iii. FY 2001 and FY 2002 outlier payments. In the August 1, 2001 final rule (66 FR 39942), we stated that, based on available data, we estimated that actual FY 2001 outlier payments would be approximately 6.2 percent of actual total DRG payments. This was computed based on simulations using the March 2001 update of the Provider-Specific File and the March 2001 update of the FY 2000 MedPAR file (discharge data for FY 2000 bills). That is, the estimate of actual outlier payments did not reflect actual FY 2001 bills but instead reflected the application of FY 2001 rates and policies to available FY 2000 bills.

Our current estimate, using available FY 2001 bills, is that actual outlier payments for FY 2001 were approximately 7.7 percent of actual total DRG payments. Thus, the data indicate that, for FY 2001, the percentage of actual outlier payments relative to actual total payments is higher than we projected before FY 2001 (and thus exceeds the percentage by which we reduced the standardized amounts for FY 2001). Nevertheless, consistent with the policy and statutory interpretation we have maintained since the inception of the acute care hospital inpatient prospective payment system, we do not plan to recoup money and make retroactive adjustments to outlier payments for FY 2001.

We currently estimate that actual outlier payments for FY 2002 will be approximately 6.9 percent of actual total DRG payments, 1.8 percentage points higher than the 5.1 percent we projected in setting outlier policies for FY 2002. This estimate is based on simulations using the March 2001 update of the Provider-Specific File and the March 2001 update of the FY 2001 MedPAR file (discharge data for FY 2001 bills). We used these data to calculate an estimate of the actual outlier percentage for FY 2002 by applying FY 2002 rates and policies to available FY 2001 bills.

5. FY 2003 Standardized Amounts

The adjusted standardized amounts are divided into labor and nonlabor portions.

[1] This range represents 3.0 standard devitations (plus or minus) from the mean of the log distribution of cost-to-charge ratios for all hospitals.

Table 1A contains the two national standardized amounts that are applicable to all hospitals, except hospitals in Puerto Rico. As described in section II.A.1. of this Addendum, we are not revising the labor share of the national standardized amount from 71.1 percent.

Under section 1886(d)(9)(A)(ii) of the Act, the Federal portion of the Puerto Rico payment rate is based on the discharge-weighted average of the national large urban standardized amount and the national other standardized amount (as set forth in Table 1A). The labor and nonlabor portions of the national average standardized amounts for Puerto Rico hospitals are set forth in Table 1C. This table also includes the Puerto Rico standardized amounts. The labor share applied to the Puerto Rico standardized amount is 71.3 percent.

B. Adjustments for Area Wage Levels and Cost of Living

Tables 1A and 1C, as set forth in this Addendum, contain the labor-related and nonlabor-related shares that will be used to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national and Puerto Rico prospective payment rates, respectively, to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. In section III. of this preamble, we discuss the data and methodology for the FY 2003 wage index. The wage index is set forth in Tables 4A, 4B, 4C, and 4F of this Addendum.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act authorizes an adjustment to take into account the unique circumstances of hospitals in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. For FY 2003, we are adjusting the payments for hospitals in Alaska and Hawaii by multiplying the nonlabor portion of the standardized amounts by the appropriate adjustment factor contained in the table below.

TABLE OF COST-OF-LIVING ADJUSTMENT FACTORS, ALASKA AND HAWAII HOSPITALS

Alaska—All areas	1.25
Hawaii:	
County of Honolulu	1.25
County of Hawaii	1.165
County of Kauai	1.2325
County of Maui	1.2375
County of Kalawao	1.2375

(The above factors are based on data obtained from the U.S. Office of Personnel Management.)

C. DRG Relative Weights

As discussed in section II. of the preamble, we have developed a classification system for all hospital discharges, assigning them into DRGs, and have developed relative weights for each DRG that reflect the resource utilization of cases in each DRG relative to Medicare cases in other DRGs. Table 5 of section V. of this Addendum contains the relative weights that we will use for discharges occurring in FY 2003. These factors have been recalibrated as explained in section II. of the preamble.

D. Calculation of Prospective Payment Rates for FY 2003

General Formula for Calculation of Prospective Payment Rates for FY 2003

The operating prospective payment rate for all hospitals paid under the acute-care, short-term inpatient prospective payment system located outside of Puerto Rico, except SCHs and MDHs, equals the Federal rate based on the amounts in Table 1A.

The prospective payment rate for SCHs and MDHs equals the higher of the applicable Federal rate from Table 1A or the hospital-specific rate as described below. The prospective payment rate for Puerto Rico equals 50 percent of the Puerto Rico rate plus 50 percent of the national rate from Table 1C.

1. Federal Rate

For discharges occurring on or after October 1, 2002 and before October 1, 2003, except for SCHs, MDHs, and hospitals in Puerto Rico, payment under the acute-care inpatient prospective payment system is based exclusively on the Federal national rate.

The payment amount is determined as follows:

Step 1—Select the appropriate average standardized amount considering the location of the hospital (large urban or other) (see Table 1A in section V. of this Addendum).

Step 2—Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified (see Tables 4A, 4B, and 4C of section V. of this Addendum).

Step 3—For hospitals in Alaska and Hawaii, multiply the nonlabor-related portion of the standardized amount by the appropriate cost-of-living adjustment factor.

Step 4—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount (adjusted, if appropriate, under Step 3).

Step 5—Multiply the final amount from Step 4 by the relative weight corresponding to the appropriate DRG (see Table 5 of section V. of this Addendum).

2. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; or, for FY 2003, 75 percent of the updated hospital-specific rate based on FY 1996 costs per discharge, plus the greater of 25 percent of the updated FY 1982 or FY 1987 hospital-specific rate or 25 percent of the Federal DRG payment rate.

Section 1886(d)(5)(G) of the Act provides that MDHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate or the Federal rate plus 50 percent of the difference between the Federal rate and the greater of the updated hospital-specific rate based on FY 1982 and FY 1987 cost per discharge. MDHs do not have the option to use their FY 1996 hospital-specific rate.

Hospital-specific rates have been determined for each of these hospitals based on either the FY 1982 cost per discharge, the FY 1987 cost per discharge or, for SCHs, the FY 1996 cost per discharge. For a more detailed discussion of the calculation of the hospital-specific rates, we refer the reader to the September 1, 1983 interim final rule (48 FR 39772); the April 20, 1990 final rule with comment (55 FR 15150); the September 4, 1990 final rule (55 FR 35994); and the August 1, 2000 final rule (65 FR 47082). In addition, for both SCHs and MDHs, the hospital-specific rate is adjusted by the budget neutrality adjustment factor (that is, by 0.994027) as discussed in section II.A.4.a. of this Addendum. The resulting rate is used in determining the payment rate an SCH or MDH would be paid for its discharges beginning on or after October 1, 2002.

b. Updating the FY 1982, FY 1987, and FY 1996 Hospital-Specific Rates for FY 2003

We are increasing the hospital-specific rates by 2.95 percent (the hospital market basket percentage increase minus 0.55 percentage points) for SCHs and MDHs for FY 2003. Section 1886(b)(3)(C)(iv) of the Act provides that the update factor applicable to the hospital-specific rates for SCHs equal the update factor provided under section 1886(b)(3)(B)(iv) of the Act, which, for SCHs in FY 2003, is the market basket rate of increase minus 0.55 percentage points. Section 1886(b)(3)(D) of the Act provides that the update factor applicable to the hospital-specific rates for MDHs equals the update factor provided under section 1886(b)(3)(B)(iv) of the Act, which, for FY 2003, is the market basket rate of increase minus 0.55 percentage points.

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning On or After October 1, 2002 and Before October 1, 2003

a. Puerto Rico Rate

The Puerto Rico prospective payment rate is determined as follows:

Step 1—Select the appropriate adjusted average standardized amount considering the large urban or other designation of the hospital (see Table 1C of section V. of the Addendum).

Step 2—Multiply the labor-related portion of the standardized amount by the appropriate Puerto Rico-specific wage index (see Table 4F of section VI. of the Addendum).

Step 3—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount.

Step 4—Multiply the result in Step 3 by 50 percent.

Step 5—Multiply the amount from Step 4 by the appropriate DRG relative weight (see Table 5 of section V. of the Addendum).

b. National Rate

The national prospective payment rate is determined as follows:

Step 1—Multiply the labor-related portion of the national average standardized amount (see Table 1C of section V. of the Addendum) by the appropriate national wage index (see Tables 4A and 4B of section VI. of the Addendum).

Step 2—Add the amount from Step 1 and the nonlabor-related portion of the national average standardized amount.

Step 3—Multiply the result in Step 2 by 50 percent.

Step 4—Multiply the amount from Step 3 by the appropriate DRG relative weight (see Table 5 of section V. of the Addendum).

The sum of the Puerto Rico rate and the national rate computed above equals the prospective payment for a given discharge for a hospital located in Puerto Rico.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2003

The prospective payment system for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. Effective with that cost reporting period and during a 10-year transition period extending through FY 2001, acute care hospital inpatient capital-related costs were paid on the basis of an increasing proportion of the capital prospective payment system Federal rate and a decreasing proportion of a hospital's historical costs for capital.

The basic methodology for determining Federal capital prospective rates is set forth in regulations at §§ 412.308 through 412.352. Below we discuss the factors that we used to determine the capital Federal rate for FY 2003, which will be effective for discharges occurring on or after October 1, 2002. The 10-year transition period ended with hospital cost reporting periods beginning on or after October 1, 2001 (FY 2002). Therefore, for cost reporting periods beginning in FY 2002, all hospitals (except ''new'' hospitals under § 412.324(b) and under § 412.304(c)(2)) are paid based on 100 percent of the capital Federal rate.

For FY 1992, we computed the standard Federal payment rate for capital-related costs under the prospective payment system by updating the FY 1989 Medicare inpatient capital cost per case by an actuarial estimate of the increase in Medicare inpatient capital costs per case. Each year after FY 1992, we update the standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. Also, § 412.308(c)(2) provides that the Federal rate is adjusted annually by a factor equal to the estimated proportion of outlier payments under the Federal rate to total capital payments under the Federal rate. In addition, § 412.308(c)(3) requires that the Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for (regular and special) exceptions under § 412.348. Furthermore, § 412.308(c)(4)(ii) requires that the Federal rate be adjusted so that the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor are budget neutral. For FYs 1992 through 1995, § 412.352 required that the Federal rate also be adjusted by a budget neutrality factor so that aggregate payments for inpatient hospital capital costs were projected to equal 90 percent of the payments that would have been made for capital-related costs on a reasonable cost basis during the fiscal year. That provision expired in FY 1996. Section 412.308(b)(2) describes the 7.4 percent reduction to the rate that was made in FY 1994, and § 412.308(b)(3) describes the 0.28 percent reduction to the rate made in FY 1996 as a result of the revised policy of paying for transfers. In the FY 1998 final rule with comment period (62 FR 45966), we implemented section 4402 of Public Law 105–33, which requires that, for discharges occurring on or after October 1, 1997, and before October 1, 2002, the unadjusted standard Federal rate is reduced by 17.78 percent. As we explained in section VI.D. of the preamble of this final rule, a small part of that reduction will be restored effective October 1, 2002.

To determine the appropriate budget neutrality adjustment factor and the regular exceptions payment adjustment during the 10-year transition period, we developed a dynamic model of Medicare inpatient capital-related costs, that is, a model that projected changes in Medicare inpatient capital-related costs over time. With the expiration of the budget neutrality provision, the capital cost model was only used to estimate the regular exceptions payment adjustment and other factors. As we explained in the August 1, 2001 final rule (66 FR 39911), beginning in FY 2003 an adjustment for regular exceptions is no longer necessary because regular exception payments were only made for cost reporting periods beginning on or after October 1, 1991, and before October 1, 2001 (see § 412.348(b)). Since payments are no longer being made under the regular exceptions policy in FY 2003, we are no longer using the capital cost model. The capital cost model and its application during the transition period are described in Appendix B of the August 1, 2001 final rule (66 FR 40099).

In accordance with section 1886(d)(9)(A) of the Act, under the prospective payment system for acute care hospital inpatient operating costs, hospitals located in Puerto Rico are paid for operating costs under a special payment formula. Prior to FY 1998, hospitals in Puerto Rico were paid a blended rate that consisted of 75 percent of the applicable standardized amount specific to Puerto Rico hospitals and 25 percent of the applicable national average standardized amount. However, effective October 1, 1997, as a result of section 4406 of Public Law 105–33, operating payments to hospitals in Puerto Rico are based on a blend of 50 percent of the applicable standardized amount specific to Puerto Rico hospitals and 50 percent of the applicable national average standardized amount. In conjunction with this change to the operating blend percentage, effective with discharges on or after October 1, 1997, we compute capital payments to hospitals in Puerto Rico based on a blend of 50 percent of the Puerto Rico rate and 50 percent of the Federal rate.

Section 412.374 provides for the use of this blended payment system for payments to Puerto Rico hospitals under the prospective payment system for acute care hospital inpatient capital-related costs. Accordingly, for capital-related costs, we compute a separate payment rate specific to Puerto Rico hospitals using the same methodology used to compute the national Federal rate for capital.

A. Determination of Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

In the final rule published in the **Federal Register** on August 1, 2001 (66 FR 39947), we established a Federal rate of $390.74 for FY 2002. As a result of the changes to the factors used to establish the Federal rate that are explained in this addendum, the FY 2003 Federal rate is $407.01.

In the discussion that follows, we explain the factors that were used to determine the FY 2003 Federal rate. In particular, we explain why the FY 2003 Federal rate has increased 4.2 percent compared to the FY 2002 Federal rate. We also estimate aggregate capital payments will increase by 5.81 percent during this same period. This increase is primarily due to the increase in the number of hospital admissions and the increase in case-mix. This increase in capital payments is slightly more than last year (4.27 percent) mostly due to the restoration of the 2.1 percent reduction to the capital Federal rate (see section VI.D. of the preamble of this final rule).

Total payments to hospitals under the prospective payment system are relatively unaffected by changes in the capital prospective payments. Since capital payments constitute about 10 percent of hospital payments, a 1 percent change in the capital Federal rate yields only about 0.1 percent change in actual payments to hospitals. Aggregate payments under the capital prospective payment system are estimated to increase in FY 2003 compared to FY 2002.

1. Standard Federal Rate Update

a. Description of the Update Framework

Under § 412.308(c)(1), the standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and other factors. The update framework consists of a CIPI and several policy adjustment factors.

Specifically, we have adjusted the projected CIPI rate of increase as appropriate each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed rule reflected an update factor for FY 2003 under that framework of 1.1 percent, based on data available at that time. Under the update framework, the final update factor for FY 2003 is 1.1 percent. This update factor is based on a projected 0.7 percent increase in the CIPI, a 1.0 percent adjustment for intensity, a 0.0 percent adjustment for case-mix, a −0.3 percent adjustment for the FY 2001 DRG reclassification and recalibration, and a forecast error correction of −0.3 percent. We explain the basis for the FY 2003 CIPI projection in section III.C. of this Addendum. Below we describe the policy adjustments that have been applied.

The case-mix index is the measure of the average DRG weight for cases paid under the acute care hospital inpatient prospective payment system. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

- The average resource use of Medicare patients changes (''real'' case-mix change);
- Changes in hospital coding of patient records result in higher weight DRG assignments (''coding effects''); and
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients as opposed to changes in coding behavior that result in assignment of cases to higher weighted DRGs but do not reflect higher resource requirements. In the update framework for the prospective payment system for operating costs, we adjust the update upwards to allow for real case-mix change, but remove the effects of coding changes on the case-mix index. We also remove the effect on total payments of prior year changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than patient severity. (For example, we adjusted for the effects of the FY 2001 DRG reclassification and recalibration as part of our update for FY 2003.) We have adopted this case-mix index adjustment in the capital update framework as well.

For FY 2003, we are projecting a 1.0 percent total increase in the case-mix index. We estimate that real case-mix increase will equal 1.0 percent in FY 2003. Therefore, the net adjustment for case-mix change in FY 2003 is 0.0 percentage points.

We estimate that FY 2001 DRG reclassification and recalibration will result in a 0.3 percent change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are making a −0.3 percent adjustment for DRG reclassification and recalibration in the update for FY 2003 to maintain budget neutrality.

The capital update framework contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage points or more. There is a 2-year lag between the forecast and the measurement of the forecast error. A forecast error of −0.3 percentage points was calculated for the FY 2001 update. That is, current historical data indicate that the forecasted FY 2001 CIPI used in calculating the FY 2001 update factor (0.9 percent) overstated the actual realized price increases (0.6 percent) by 0.3 percentage points. This over-prediction was due to prices from municipal bond yields declining faster than originally expected. Therefore, we are making a −0.3 percent adjustment for forecast error in the update for FY 2003.

Under the capital prospective payment system framework, we also make an adjustment for changes in intensity. We calculate this adjustment using the same methodology and data as in the framework for the operating prospective payment system. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, changes in within-DRG severity, and expected modification of practice patterns to remove cost-ineffective services.

We calculate case-mix constant intensity as the change in total charges per admission, adjusted for price level changes (the CPI for hospital and related services), and changes in real case-mix. The use of total charges in the calculation of the intensity factor makes it a total intensity factor, that is, charges for capital services are already built into the calculation of the factor. Therefore, we have incorporated the intensity adjustment from the operating update framework into the capital update framework. Without reliable estimates of the proportions of the overall annual intensity increases that are due, respectively, to ineffective practice patterns and to the combination of quality-enhancing new technologies and within-DRG complexity, we assume, as in the revised operating update framework, that one-half of the annual increase is due to each of these factors. The capital update framework thus provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity to allow for within-DRG severity increases and the adoption of quality-enhancing technology.

For FY 2003, we have developed a Medicare-specific intensity measure based on a 5-year average, using FY 1997 through 2001 data. In determining case-mix constant intensity, we found that observed case-mix increase was 0.3 percent in FY 1997, −0.4 percent in FY 1998, −0.3 percent in FY 1999, −0.7 in FY 2000, and −0.3 percent in FY 2001. Past studies of case-mix change by the RAND Corporation (''Has DRG Creep Crept Up? Decomposing the Case Mix Index Change Between 1987 and 1988'' by G. M. Carter, J. P. Newhouse, and D. A. Relles, R–4098–HCFA/ProPAC (1991)) suggest that real case-mix change was not dependent on total change, but was usually a fairly steady 1.0 to 1.4 percent per year. We use 1.4 percent as the upper bound because the RAND study did not take into account that hospitals may have induced doctors to document medical records more completely in order to improve payment. Following that study, we consider up to 1.4 percent of observed case-mix change as real for FY 1997 through FY 2001. Since we did not find an increase in case-mix outside of the range of 1.0 to 1.4 percent, we believe that all of the observed case-mix increase for FYs 1997 through 2001 is real. Therefore, there was no need to employ the upper bound of 1.0 and 1.4 supported by the RAND study as we have done in the past since we did not find an increase in case-mix that was in excess of our estimate of real case-mix increase.

We calculate case-mix constant intensity as the change in total charges per admission, adjusted for price level changes (the CPI for hospital and related services), and changes in real case-mix. We estimate that case-mix constant intensity increased by an average of 1.0 percent during FYs 1997 through 2001, for a cumulative increase of 5.2 percent, given estimates of real case-mix of 0.3 percent for FY 1997, −0.4 percent for FY 1998, −0.3 percent for FY 1999, −0.7 percent for FY 2000, and −0.3 percent for FY 2001. Since we estimate that intensity has increased during that period, the intensity adjustment for FY 2003 is 1.0 percent.

Above we described the basis of the components used to develop the 1.1 percent final capital update factor for FY 2003 as shown in Table 1 below.

TABLE 1.—CMS'S FY 2003 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index	0.7
Intensity:	1.0
Case-Mix Adjustment Factors:	
Projected Case-Mix Change	−1.0
Real Across DRG Change	1.0
Subtotal	0.0
Effect of FY 2001 Reclassification and Recalibration	−0.3
Forecast Error Correction	−0.3
Total Update	1.1

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds is used to identify outlier cases for both inpatient operating and

inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related prospective payment system payments. The outlier thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating DRG payments.

In the August 1, 2001 final rule, we estimated that outlier payments for capital in FY 2002 would equal 5.76 percent of inpatient capital-related payments based on the Federal rate (66 FR 39948). Accordingly, we applied an outlier adjustment factor of 0.9424 to the Federal rate. Based on the thresholds as set forth in section II.A.4.c. of this Addendum, we estimate that outlier payments for capital will equal 5.31 percent of inpatient capital-related payments based on the Federal rate in FY 2003. Therefore, we are establishing an outlier adjustment factor of 0.9469 to the Federal rate. Thus, the projected percentage of capital outlier payments to total capital standard payments for FY 2003 is lower than the percentage for FY 2002.

The outlier reduction factors are not built permanently into the rates; that is, they are not applied cumulatively in determining the Federal rate. Therefore, the net change in the outlier adjustment to the Federal rate for FY 2003 is 1.0048 (0.9469/0.9424). The outlier adjustment increases the FY 2003 Federal rate by 0.48 percent compared with the FY 2002 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the Geographic Adjustment Factor

Section 412.308(c)(4)(ii) requires that the Federal rate be adjusted so that aggregate payments for the fiscal year based on the Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the geographic adjustment factor (GAF) are projected to equal aggregate payments that would have been made on the basis of the Federal rate without such changes.

Since we implemented a separate geographic adjustment factor for Puerto Rico, we apply separate budget neutrality adjustments for the national geographic adjustment factor and the Puerto Rico geographic adjustment factor. We apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. Separate adjustments were unnecessary for FY 1998 and earlier since the geographic adjustment factor for Puerto Rico was implemented in FY 1998.

In the past, we used the actuarial capital cost model (described in Appendix B of the August 1, 2001 final rule (66 FR 40099)) to estimate the aggregate payments that would have been made on the basis of the Federal rate with and without changes in the DRG classifications and weights and in the GAF to compute the adjustment required to maintain budget neutrality for changes in DRG weights and in the GAF. During the transition period, the capital cost model was also used to estimate the regular exceptions payment adjustment factor. As we explain in section III.A.4. of this Addendum, beginning in FY 2003 an adjustment for regular exceptions is no longer necessary. Therefore, we are no longer using the capital cost model. Instead, we are using historical data based on hospitals' actual cost experiences to determine the exceptions adjustment factor for special exception payments.

To determine the factors for FY 2003, we compared (separately for the national rate and the Puerto Rico rate) estimated aggregate Federal rate payments based on the FY 2002 DRG relative weights and the FY 2002 GAF to estimated aggregate Federal rate payments based on the FY 2003 relative weights and the FY 2003 GAF. For FY 2002, the budget neutrality adjustment factors were 0.9927 for the national rate and 0.9916 for the Puerto Rico rate (see the August 1, 2001 final rule (66 FR 40101)). In making the comparison, we set the regular and special exceptions reduction factors to 1.00.

To achieve budget neutrality for the changes in the national GAF, based on calculations using updated data, we are applying an incremental budget neutrality adjustment of 0.9991 for FY 2003 to the previous cumulative FY 2002 adjustment of (0.9927), yielding a cumulative adjustment of 0.9918 through FY 2003. For the Puerto Rico GAF, we are applying an incremental budget neutrality adjustment of 1.0081 for FY 2003 to the previous cumulative FY 2002 adjustment (0.9916), yielding a cumulative adjustment of 0.9997 through FY 2003.

We then compared estimated aggregate Federal rate payments based on the FY 2002 DRG relative weights and the FY 2002 GAF to estimated aggregate Federal rate payments based on the FY 2003 DRG relative weights and the FY 2003 GAF. The incremental adjustment for DRG classifications and changes in relative weights is 0.9966 both nationally and for Puerto Rico. The cumulative adjustments for DRG classifications and changes in relative weights and for changes in the GAF through FY 2003 are 0.9885 nationally and 0.9963 for Puerto Rico. The following table summarizes the adjustment factors for each fiscal year:

BUDGET NEUTRALITY ADJUSTMENT FOR DRG RECLASSIFICATIONS AND RECALIBRATION AND THE GEOGRAPHIC ADJUSTMENT FACTORS

Fiscal year	National			Cumulative	Puerto Rico			Cumulative
	Incremental adjustment				Incremental adjustment			
	Geographic adjustment factor	DRG Reclassifications and recalibration	Combined		Geographic adjustment factor	DRG Reclassifications and recalibration	Combined	
1992	.....	.....	.....	1.00000	.....	.....	.....	.....
1993	.....	.....	0.99800	0.99800	.....	.....	.....	.....
1994	.....	.....	1.00531	1.00330	.....	.....	.....	.....
1995	.....	.....	0.99980	1.00310	.....	.....	.....	.....
1996	.....	.....	0.99940	1.00250	.....	.....	.....	.....
1997	.....	.....	0.99873	1.00123	.....	.....	.....	.....
1998	.....	.....	0.99892	1.00015	.....	.....	.....	1.00000
1999	0.99944	1.00335	1.00279	1.00294	0.99898	1.00335	1.00233	1.00233
2000	0.99857	0.99991	0.99848	1.00142	0.99910	0.99991	0.99901	1.00134
2001[1]	0.99782	1.00009	0.99791	0.99933	1.00365	1.00009	1.00374	1.00508
2001[2]	[3]0.99771	[3]1.00009	[3]0.99780	0.99922	[3]1.00365	[3]1.00009	[3]1.00374	1.00508
2002	[4]0.99666	[4]0.99668	[4]0.99335	0.99268	[4]0.98991	[4]0.99668	[4]0.99662	0.99164
2003	0.99915	0.99662	0.99577	0.98848	1.00809	0.99662	1.00468	0.99628

[1] Factors effective for the first half of FY 2001 (October 2000 through March 2001).
[2] Factors effective for the second half of FY 2001 (April 2001 through September 2001).
[3] Incremental factors are applied to FY 2000 cumulative factors.
[4] Incremental factors are applied to the cumulative factors for the first half of FY 2001.

The methodology used to determine the recalibration and geographic (DRG/GAF) budget neutrality adjustment factor for FY 2003 is similar to that used in establishing budget neutrality adjustments under the prospective payment system for operating

costs. One difference is that, under the operating prospective payment system, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the DRG relative weights. Under the capital prospective payment system, there is a single DRG/GAF budget neutrality adjustment factor (the national rate and the Puerto Rico rate are determined separately) for changes in the GAF (including geographic reclassification) and the DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification has on the other payment parameters, such as the payments for serving low-income patients, indirect medical education payments, or the large urban add-on payments.

For FY 2002, we calculated a GAF/DRG budget neutrality factor of 0.9934. In the proposed rule, we proposed a GAF/DRG budget neutrality factor of 1.0024. For this final rule, based on updated data, we are establishing a GAF/DRG budget neutrality factor of 0.9957 for FY 2003. The GAF/DRG budget neutrality factors are built permanently into the rates; that is, they are applied cumulatively in determining the Federal rate. This follows from the requirement that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAF. The incremental change in the adjustment from FY 2002 to FY 2003 is 0.9957. The cumulative change in the rate due to this adjustment is 0.9885 (the product of the incremental factors for FY 1993, FY 1994, FY 1995, FY 1996, FY 1997, FY 1998, FY 1999, FY 2000, FY 2001, FY 2002, and FY 2003: $0.9980 \times 1.0053 \times 0.9998 \times 0.9994 \times 0.9987 \times 0.9989 \times 1.0028 \times 0.9985 \times 0.9979 \times 0.9934 \times 0.9957 = 0.9885$).

This factor accounts for DRG reclassifications and recalibration and for changes in the GAF. It also incorporates the effects on the GAF of FY 2003 geographic reclassification decisions made by the MGCRB compared to FY 2002 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors or in the large urban add-on.

4. Exceptions Payment Adjustment Factor

Section 412.308(c)(3) requires that the standard capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of additional payments for both regular exceptions and special exceptions under § 412.348 relative to total capital prospective payment system payments. In estimating the proportion of regular exceptions payments to total capital prospective payment system payments during the transition period, we used the actuarial capital cost model originally developed for determining budget neutrality (described in Appendix B of the August 1, 2001 final rule (66 FR 40099)) to determine the exception adjustment factor, which was applied to both the Federal and hospital-specific rates.

An adjustment for regular exceptions is no longer necessary in determining the FY 2003 capital Federal rate because, in accordance with § 412.348(b), regular exception payments were only made for cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001. Accordingly, as we explained in the August 1, 2001 final rule (66 FR 39949), in FY 2003 and subsequent fiscal years, no payments will be made under the regular exceptions provision. However, in accordance with § 412.308(c), we still need to compute a budget neutrality adjustment for special exception payments under § 412.348(g). We describe our methodology for determining the special exceptions adjustment used in establishing the FY 2003 capital Federal rate below.

Under the special exceptions provision specified at § 412.348(g)(1), eligible hospitals include SCHs, urban hospitals with at least 100 beds that have a disproportionate share percentage of at least 20.2 percent or qualify for DSH payments under § 412.106(c)(2), and hospitals with a combined Medicare and Medicaid inpatient utilization of at least 70 percent. An eligible hospital may receive special exception payments if it 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 as described at § 412.348(g)(4); (2) an age of assets test as described at § 412.348(g)(3); and (3) a project size requirement as described at § 412.348(g)(5).

As we explained in the August 1, 2001 final rule (66 FR 39912–39914), in order to determine the estimated proportion of special exceptions payments to total capital payments, we attempted to identify the universe of eligible hospitals that may potentially qualify for special exception payments. First, we identified hospitals that met the eligibility requirements at § 412.348(g)(1). Then we determined each hospital's average fixed asset age in the earliest available cost report starting in FY 1992 and subsequent fiscal years. For each of those hospitals, we calculated the average fixed asset age by dividing the accumulated depreciation by the current year's depreciation. In accordance with § 412.348(g)(3), a hospital must have an average age of buildings and fixed assets above the 75th percentile of all hospitals in the first year of the capital prospective payment system. In the September 1, 1994 final rule (59 FR 45385), we stated that, based on the June 1994 update of the cost report files in HCRIS, the 75th percentile for buildings and fixed assets for FY 1992 was 16.4 years. However, we noted that we would make a final determination of that value on the basis of more complete cost report information at a later date. In the August 29, 1997 final rule (62 FR 46012), based on the December 1996 update of HCRIS and the removal of outliers, we finalized the 75th percentile for buildings and fixed assets for FY 1992 as 15.4 years. Thus, we eliminated any hospitals from the potential universe of hospitals that may qualify for special exception payments if its average age of fixed assets did not exceed 15.4 years.

For the hospitals remaining in the potential universe, we estimated project-size by using the fixed capital acquisitions shown on Worksheet A7 from the following HCRIS cost reports updated through June 2002.

PPS year	Cost reporting periods beginning in . . .
IX	FY 1992
X	FY 1993
XI	FY 1994
XII	FY 1995
XIII	FY 1996
XIV	FY 1997
XV	FY 1998
XVI	FY 1999
XVII	FY 2000

Because the project phase-in may overlap 2 cost reporting years, we added together the fixed acquisitions from sequential pairs of cost reports to determine project size. Under § 412.348(g)(5), the hospital's project cost must be at least $200 million or 100 percent of its operating cost during the first 12-month cost reporting period beginning on or after October 1, 1991. We calculated the operating costs from the earliest available cost report starting in FY 1992 and later by subtracting inpatient capital costs from inpatient costs (for all payers). We did not subtract the direct medical education costs as those costs are not available on every update of the HCRIS minimum data set. If the hospital met the project size requirement, we assumed that it also met the project need requirements at § 412.348(g)(2) and the excess capacity test for urban hospitals at § 412.348(g)(4).

Because we estimate that so few hospitals will qualify for special exceptions, projecting costs, payments, and margins would result in high statistical variance. Consequently, we decided to model the effects of special exceptions using historical data based on hospitals' actual cost experiences. If we determined that a hospital may qualify for special exceptions, we modeled special exceptions payments from the project start date through the last available cost report (FY 1999). (Although some FY 2000 cost reports are available in HCRIS, only a few hospitals have submitted FY 2000 costs. Consequently, too few cost reports are available to reliably model FY 2000 special exceptions payments.) For purposes of modeling we used the cost and payment data on the cost reports from HCRIS assuming that special exceptions would begin at the start of the qualifying project. In other words, when modeling costs and payment data, we ignored any regular exception payments that these hospitals may otherwise have received as if there had not been regular exceptions during the transition period. In projecting an eligible hospital's special exception payment, we applied the 70-percent minimum payment level, the cumulative comparison of current year capital prospective payment system payments and costs, and the cumulative operating margin offset (excluding 75 percent of operating DSH payments).

Our modeling of special exception payments for FY 2003 produced the following results: