



Federal Register

**Friday,
May 4, 2001**

Part II

Department of Health and Human Services

Health Care Financing Administration

**42 CFR Parts 405, 412, 413, etc.
Medicare Program; Changes to the
Hospital Inpatient Prospective Payment
Systems and Fiscal Year 2002 Rates;
Proposed Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 412, 413, 485, and 486

[HCFA-1158-P]

RIN 0938-AK73

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2002 Rates

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems for operating and capital costs to: Implement applicable statutory requirements, including a number of provisions of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106-554); and implement changes arising from our continuing experience with these systems. In addition, in the Addendum to this proposed rule, we are describing proposed changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes would be applicable to discharges occurring on or after October 1, 2001. We also are setting forth proposed rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the prospective payment systems.

We also are proposing changes to the policies governing payments to hospitals for the direct costs of graduate medical education and critical access hospitals.

DATES: Comments will be considered if received at the appropriate address, as provided below, no later than 5 p.m. on July 3, 2001.

ADDRESSES: Mail written comments (an original and three copies) to the following address ONLY: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1158-P, P.O. Box 8010, Baltimore, MD 21244-1850.

If you prefer, you may deliver by courier your written comments (an original and three copies) to one of the following addresses:

Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5-14-03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments mailed to those addresses specified as appropriate for courier delivery may be delayed and could be considered late.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1158-P.

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

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

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Attn: John Burke, HCFA-1158-P; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

FOR FURTHER INFORMATION CONTACT:

Steve Phillips, (410) 786-4548, Operating Prospective Payment, Diagnosis-Related Groups (DRGs), Wage Index, Hospital Geographic Reclassifications, and Sole Community Hospital Issues
Tzvi Hefter, (410) 786-4487, Capital Prospective Payment, Excluded Hospitals, Graduate Medical Education and Critical Access Hospital Issues

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments

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

Availability of Copies and Electronic Access

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested

and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost for each copy is \$8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents home page address is http://www.access.gpo.gov/nara_docs/, by using local WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512-1661; type swais, then login as guest (no password required).

I. Background

A. Summary

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).

Under section 1886(d)(1)(B) of the Act in effect without consideration of the amendments made by the Balanced Budget Act of 1997 (Public Law 105-33), the Balanced Budget Refinement Act of 1999 (Public Law 106-113, and the recent Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106-554, enacted on December 21, 2000), certain specialty hospitals are excluded from the hospital inpatient prospective payment system: Psychiatric hospitals and units, rehabilitation hospitals and

units, children's hospitals, long-term care hospitals, and cancer hospitals. For these hospitals and units, Medicare payment for operating costs is based on reasonable costs subject to a hospital-specific annual limit, until the payment provisions of Public Laws 105-33, 106-113, and 106-554 that are applicable to three classes of these hospitals are implemented, as discussed below.

Various sections of Public Laws 105-33, 106-113, and 106-554 provide for the transition of rehabilitation hospitals and units, psychiatric hospitals and units, and long-term care hospitals from being paid on an excluded hospital basis to being paid on an individual prospective payment system basis. These provisions are as follows:

- **Rehabilitation Hospitals and Units.** Section 1886(j) of the Act, as added by section 4421 of Public Law 105-33 and amended by section 125 of Public Law 106-113 and section 305 of Public Law 106-554, authorizes the implementation of a prospective payment system for inpatient hospital services furnished by rehabilitation hospitals and units. Section 4421 of Public Law 105-33 amended the Act by adding section 1886(j). Section 1886(j) of the Act provides for a fully implemented prospective payment system for inpatient rehabilitation hospitals and rehabilitation units, effective for cost reporting periods beginning on or after October 2002, with payment provisions during a transitional period of October 1, 2000 to October 1, 2002 based on target amounts specified in section 1886(b) of the Act. Section 125 of Public Law 106-113 amended section 1886(j) of the Act to require the Secretary to use a discharge as the payment unit for inpatient rehabilitation services under the prospective payment system 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 hospitals to elect to be paid the full Federal prospective payment rather than the transitional period payments specified in the Act. A brief discussion of the November 3, 2000 proposed rule (65 FR 66304) that we issued to propose implementation of the prospective payment system for inpatient rehabilitation hospitals and rehabilitation units is included under section VI.A.4. of this preamble.

- **Psychiatric Hospitals and Units.** 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 of 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, effective for October 1, 2002.

- **Long-Term Care Hospitals.** Sections 123(a) and (c) of Public Law 106-113 provide for the development of a per discharge prospective payment system for payment for inpatient hospital services furnished by long-term care hospitals under the Medicare program, effective for cost reporting periods beginning on or after October 1, 2002. Section 307(b)(1) of Public Law 106-554 provides that payments under the long-term care prospective payment system will be made on a prospective payment basis rather than a cost basis. The long-term care hospital prospective payment system must include a patient classification system that reflects the differences in patient resource use and costs, and must maintain budget neutrality. We are planning to develop a proposed rule, to be followed by a final rule, to implement the prospective payment system for long-term care hospitals, effective for October 1, 2002. Section 307 of Public Law 106-554 provides that if the Secretary is unable to develop a prospective payment system for long-term care hospitals that can be implemented by October 1, 2002, the Secretary must implement a prospective payment system that bases payment under the system using the existing acute hospital DRGs, modified where feasible to account for resource use of long-term care hospital patients using the most recently available hospital discharge data for long-term care services.

Under sections 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 Parts 413 and 415.

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 regulations governing the hospital inpatient prospective payment system are located in 42 CFR Part 412. The regulations governing excluded hospitals and hospital units are located in Parts 412 and 413. The regulations governing GME payments and payments to CAHs are located in Part 413.

On August 1, 2000, we published a final rule in the **Federal Register** (65 FR 47054) that implemented both statutory requirements and other changes to the Medicare hospital inpatient prospective payment systems for both operating costs and capital-related costs, as well as changes addressing payment for excluded hospitals and payments for GME costs. Generally, these changes were effective for discharges occurring on or after October 1, 2000. On March 2, 2001, we published correction notices in the **Federal Register** (66 FR 13020) relating to the calculation of certain wage indexes and the labeling of certain DRGs.

Public Law 106-554 made a number of changes to the Act relating to prospective payments to hospitals for inpatient services and payments to excluded hospitals. This proposed rule would implement amendments enacted by Public Law 106-554 relating to FY 2002 payments for hospital inpatient services, new medical services and technology, GME costs, the payment adjustment for disproportionate share hospitals (DSHs), the indirect medical education (IME) adjustment for teaching hospitals, sole community hospitals (SCHs), and CAHs. It would also implement changes affecting hospitals' geographic reclassifications and wage index. These changes are addressed in sections II., III., IV., and VI. of this preamble.

Other provisions of Public Law 106-554 that relate to Medicare payments to hospitals effective prior to October 1, 2001 (that is, for FY 2001 or for the period between April 1, 2001 and September 30, 2001), are addressed in a separate interim final rule with comment period (HCFA-1178-IFC).

B. Major Contents of This Proposed Rule

In this proposed rule, we are setting forth proposed changes to the Medicare hospital inpatient prospective payment systems for operating costs and for capital-related costs in FY 2002. We also are proposing changes relating to payments for GME costs and payments to excluded hospitals and units and CAHs. The proposed changes would be

effective for discharges occurring on or after October 1, 2001.

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

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

As required by section 1886(d)(4)(C) of the Act, we adjust the DRG classifications and relative weights annually. Based on analyses of Medicare claims data, we are proposing to establish a number of new DRGs and make changes to the designation of diagnosis and procedure codes under other existing DRGs. Our proposed changes for FY 2002 are set forth in section II. of this preamble.

We also address the provisions of section 533 of Public Law 106-544 regarding development of a mechanism for adequate payment for new medical services and technologies and the required report to Congress on expeditiously introducing new medical services and technology into the DRGs.

2. Proposed Changes to the Hospital Wage Index

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

- The FY 2002 wage index update, using FY 1998 wage data.
- The transition to excluding from the wage index Part A physician wage costs that are teaching-related, as well as resident and Part A certified registered nurse anesthetist (CRNA) costs.
- The costs of contracted pharmacy and laboratory services.
- The collection of occupational mix data, as required by section 304(c) of Public Law 106-554.
- Revisions to the wage index based on hospital redesignations and reclassifications, including changes to reflect the provisions of sections 304(a) and (b) of Public Law 106-554 relating to 3-year wage index reclassifications by the MGCRB, the use of 3 years of wage data for evaluating reclassification requests for FYs 2003 and later, and the application of a statewide wage index for reclassifications beginning in FY 2003.
- Requests for wage data corrections and modification of the process and timetable for updating the wage index, and a proposed revision of that timetable.

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

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

- Sole community hospitals.
- Rural referral centers.
- Changes relating to the IME adjustment as a result of section 302 of Public Law 106-554.
- Changes relating to the DSH adjustment as a result of section 303 of Public Law 106-554.
- The establishment of policies relating to the 3-year application of wage index reclassifications by the MGCRB, the use of 3 years of wage data in evaluating reclassification requests to the MGCRB for FYs 2003 and later, and the use of a statewide wage index for reclassifications beginning in FY 2003, as required by sections 304(a) and (b) of Public Law 106-554.
- Proposed requirements for additional payments for new medical services and technology, as required by section 533(b) of Public Law 106-554.
- Changes relating to payment for the direct costs of GME, including changes as a result of section 511 of Public Law 106-554.

4. Prospective Payment System for Capital-Related Costs

In section V. of this preamble, we specify the proposed payment requirements for capital-related costs, including the special exceptions payment, beginning October 1, 2002.

5. Proposed Changes for Hospitals and Hospital Units Excluded from the Prospective Payment Systems

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

- Limits on and adjustments to the proposed target amounts for FY 2002.
- Revision of the methodology for wage neutralizing the hospital-specific target amounts using preclassified wage data.
- Updated caps for new excluded hospitals and units as well as changes in the effective date of classifications of excluded hospitals and units.
- The prospective payment system for inpatient rehabilitation hospitals and units.
- Payments to CAHs, including exclusion from the payment window requirements; the availability of CRNA pass-through payments; payment for

emergency room on-call physicians; treatment of ambulance services; the use of certain qualified practitioners for preanesthesia and postanesthesia evaluations; and clarification of location requirements for CAHs.

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

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the FY 2002 prospective payment rates for operating costs and capital-related costs. We also establish the proposed threshold amounts for outlier cases. In addition, we address update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2002 for hospitals and hospital units excluded from the prospective payment system.

7. Impact Analysis

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

8. Capital Acquisition Model

Appendix B contains the technical appendix on the proposed FY 2002 capital cost model.

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

Section 1886(e)(3) of the Act requires the Secretary to report to Congress on our initial estimate of a recommended update factor for FY 2002 for payments to hospitals included in the prospective payment systems, and hospitals excluded from the prospective payment systems. This report is included as Appendix C to this proposed rule.

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

As required by sections 1886(e)(4) and (e)(5) of the Act, Appendix D provides our recommendation of the appropriate percentage change for FY 2002 for the following:

- Large urban area and other area average standardized amounts (and hospital-specific rates applicable to sole community and Medicare-dependent, small rural hospitals) for hospital inpatient services paid for 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 prospective payment system.

11. Discussion of Medicare Payment Advisory Commission Recommendations

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

II. Proposed Changes to DRG Classifications and Relative Weights

A. Background

Under the 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 takes an individual hospital's payment rate per case and multiplies it by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG relative to the average resources used to treat cases in all DRGs.

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The proposed changes to the DRG classification system, and the proposed recalibration of the DRG weights for discharges occurring on or after October 1, 2001, are discussed below.

B. DRG Reclassification

1. General

Cases are classified into DRGs for payment under the 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). Medicare fiscal intermediaries enter the information into their claims processing systems and subject it 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 demographic information (that is, sex, age, and discharge status). It is used both to classify past cases in order to measure relative hospital resource consumption to establish the DRG weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the Medicare Provider Analysis and Review (MedPAR) file. The data in this file are used to evaluate possible DRG classification changes and to recalibrate the DRG weights.

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 August 1, approximately 8 months prior to the publication of the proposed rule, 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 the next year's proposed rule.

Currently, cases are assigned to one of 503 DRGs (including one DRG for a diagnosis that is invalid as a discharge diagnosis and one DRG for ungroupable diagnoses) in 25 major diagnostic categories (MDCs). Most MDCs are based on a particular organ system of the body (for example, MDC 6 (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 principal diagnosis, before assignment to a DRG. However, there are five DRGs to which cases are directly assigned on the basis of procedure codes. These are the DRGs for liver, bone marrow, and lung transplants (DRGs 480, 481, and 495, 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 (based on a surgical hierarchy that orders individual procedures or groups of procedures by resource intensity) and medical DRGs. 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, the GROUPER does not consider other procedures; that is, nonsurgical procedures or minor surgical procedures generally not performed in an operating room are not listed as operating room (OR) procedures in the GROUPER decision tables. However, there are a few non-OR 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.

The major changes we are proposing to make to the DRG classification system for FY 2002 are summarized in Charts 1, 2, and 3 below, followed by detailed discussions in individual sections according to MDC assignment. Other issues concerning DRGs are also set forth below. Unless otherwise noted, our DRG analysis is based on data from 100 percent of the FY 2000 MedPAR file containing hospital bills received through May 31, 2000 for discharges in FY 2000.

CHART 1.—SUMMARY OF PROPOSED CHANGES IN DRG ASSIGNMENTS

Diagnosis related groups (DRGs)	Added as new	Removed
Pre-MDC:		
DRG 512 (Simultaneous Pancreas/Kidney Transplant)	X	
DRG 513 (Pancreas Transplants)	X	
MDC 5 (Diseases and Disorders of the Circulatory System):		
DRG 112 (Percutaneous Cardiovascular Procedures)		X
DRG 514 (Cardiac Defibrillator Implant with Cardiac Catheterization)	X	
DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheterization)	X	
DRG 516 (Percutaneous Cardiovascular Procedures with Acute Myocardial Infarction (AMI))	X	
DRG 517 (Percutaneous Cardiovascular Procedures without AMI, with Coronary Artery Stent Implant)	X	
DRG 518 (Percutaneous Cardiovascular Procedures without AMI, without Coronary Artery Stent Implant)	X	
MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue):		
DRG 519 (Cervical Spinal Fusion with CC)	X	
DRG 520 (Cervical Spinal Fusion without CC)	X	
MDC 20 (Alcohol/Drug Use and Alcohol/Drug-Induced Organic Mental Disorders):		
DRG 434 Alcohol/Drug Abuse or Dependency, Detoxification or Other Symptomatic Treatment with CC)		X
DRG 435 (Alcohol/Drug Abuse or Dependency, Detoxification or Other Symptomatic Treatment without CC)		X
DRG 436 (Alcohol/Drug Dependence with Rehabilitation Therapy)		X
DRG 437 (Alcohol/Drug Dependence, Combined Rehabilitation and Detoxification Therapy)		X
DRG 521 (Alcohol/Drug Abuse or Dependence with CC)	X	
DRG 522 (Alcohol/Drug Abuse or Dependence without CC, with Rehabilitation Therapy)	X	
DRG 523 (Alcohol/Drug Abuse or Dependence without CC, without Rehabilitation Therapy)	X	

CHART 2.—SUMMARY OF PROPOSED ASSIGNMENT OR REASSIGNMENT OF DIAGNOSIS OR PROCEDURE CODES IN EXISTING DRGS

Diagnosis/procedure codes	Removed from DRG	Reassigned to DRG
MDC 5 (Diseases and Disorders of the Circulatory System):		
Principal Diagnosis Code:		
410.01 Acute myocardial infarction of anterolateral wall, initial episode of care.	116	516
410.11 Acute myocardial infarction of other anterior wall, initial episode of care.	116	516
410.21 Acute myocardial infarction of inferolateral wall, initial episode of care.	116	516
410.31 Acute myocardial infarction of inferoposterior wall, initial episode of care.	116	516
410.41 Acute myocardial infarction of other inferior wall, initial episode of care.	116	516
410.51 Acute myocardial infarction of other lateral wall, initial episode of care.	116	516
410.61 True posterior wall infarction, initial episode of care	116	516
410.71 Subendocardial infarction, initial episode of care	116	516
410.81 Acute myocardial infarction of other specified sites, initial episode of care.	116	516
410.91 Acute myocardial infarction of unspecified site, initial episode of care	116	516
Procedure Codes:		
37.94 Implantation or replacement of automatic cardioverter/defibrillation, total system (AICD).	104, 105	514, 515
37.95 Implantation of automatic cardioverter/defibrillator lead(s) only	104, 105	514, 515
37.96 Implantation of automatic cardioverter/defibrillator pulse generator only.	104, 105	514, 515
37.97 Replacement of automatic cardioverter/ defibrillator lead(s) only	104, 105	514, 515
37.98 Replacement of automatic cardioverter/defibrillator pulse generator only.	104, 105	514, 515
Operating Room Procedures:		
35.96 Percutaneous valvuloplasty	116	516, 517, 518
36.01 Single vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy without mention of thrombolytic agent.	116	516, 517, 518
36.02 Single vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy with mention of thrombolytic agent.	116	516, 517, 518
36.05 Multiple vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent.	116	516, 517, 518
36.09 Other removal of coronary artery obstruction	116	516, 517, 518
37.34 Catheter ablation of lesion or tissues of heart	116	516, 517, 518
92.27 Implantation or insertion of radioactive elements	Non-OR in MDC-5	517
Nonoperating Room Procedures:		
36.06 Insertion of coronary artery stent(s)	116	517
37.21 Right heart cardiac catheterization	104	514

CHART 2.—SUMMARY OF PROPOSED ASSIGNMENT OR REASSIGNMENT OF DIAGNOSIS OR PROCEDURE CODES IN EXISTING DRGs—Continued

Diagnosis/procedure codes		Removed from DRG	Reassigned to DRG
37.22	Left heart cardiac catheterization	104	514
37.23	Right and left heart cardiac catheterization	104	514
37.26	Cardiac electrophysiologic stimulation and recording studies	104, 112	514, 516, 517, 518
37.27	Cardiac mapping	112	516, 517, 518
88.52	Angiocardiology of right heart structures	104	514
88.53	Angiocardiology of left heart structures	104	514
88.54	Combined right and left heart angiocardiology	104	514
88.55	Coronary arteriography using a single catheter	104	514
88.56	Coronary arteriography using two catheters	104	514
88.57	Other and unspecified coronary arteriography	104	514
88.58	Negative-contrast cardiac roentgenography	104	514
MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue):			
Procedure Codes:			
81.02	Other cervical fusion, anterior technique	497, 498	519, 520
81.03	Other cervical fusion, posterior technique	497, 498	519, 520
MDC 15 (Newborns and Other Neonates with Conditions Originating in the Perinatal Period)			
Diagnosis Codes:			
773.0	Hemolytic disease due to RH isoimmunization	389	390
773.1	Hemolytic disease due to ABO isoimmunization	389	390
Secondary Diagnosis Codes:			
478.1	Other diseases of nasal cavity and sinuses	390	391
520.6	Disturbances in tooth eruption	390	391
623.8	Other specified noninflammatory disorders of vagina	390	391
709.00	Dyschroma, unspecified	390	391
709.01	Vitiglio	390	391
709.09	Dyschromia, Other	390	391
744.1	Accessory Auricle	390	391
754.61	Congenital pes planus	390	391
757.33	Congenital pigmentary anomalies of skin	390	391
757.39	Other specified anomaly of skin	390	391
764.08	"Light for dates" without mention of fetal malnutrition, 2,000–2,499 grams.	390	391
764.98	Fetal growth retardation, unspecified, 2,000–2,499 grams	390	391
772.6	Cutaneous hemorrhage	390	391
794.15	Abnormal and auditory function studies	390	391
796.4	Other abnormal clinical findings	390	391
V20.2	Routine infant or child health check	390	391
V72.1	Examination of ears and hearing	390	391

CHART 3.—SUMMARY OF PROPOSED RETITLED DRGs

MDC	DRG No.	Current name	Proposed name
MDC 5	DRG 116	Other Permanent Cardiac Pacemaker Implantation, or PTCA, with Coronary Artery Stent Implant.	Other Cardiac Pacemaker Implantation.
MDC 8	DRG 497	Spinal Fusion with CC	Spinal Fusion except Cervical with CC.
MDC 8	DRG 498	Spinal Fusion without CC	Spinal Fusion except Cervical without CC.

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

a. Removal of Defibrillator Cases From DRGs 104 and 105

DRGs 104 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization) and 105 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization) include the replacement or open repair of one or more of the four heart valves. These valves may be diseased or damaged, resulting in either leakage or restriction

of blood flow to the heart, compromising the ability of the heart to pump blood. This procedure requires the use of a heart-lung bypass machine, as the heart must be stilled and opened to repair or replace the valve.

Cardiac defibrillators are implanted to correct episodes of fibrillation (very fast heart rate) caused by malfunction of the conduction mechanism of the heart. Through implanted cardiac leads, the defibrillator mechanism senses changes in heart rhythm. When very fast heart rates occur, the defibrillator produces a burst of electric current through the

leads to restore the normal heart rate. An implanted defibrillator constantly monitors heart rhythm. The implantation of this device does not require the use of a heart-lung bypass machine, and would be expected to be very different in terms of resource usage, although both procedures currently group to DRGs 104 and 105.

As part of our ongoing review of DRGs, we examined Medicare claims data on DRG 104 and DRG 105. We reviewed 100 percent of the FY 2000 MedPAR file containing hospital bills received through May 31, 2000, for

discharges in FY 2000, and found that the average charges across all cases in DRG 104 were \$84,060, while the average charges across all cases in DRG 105 were \$66,348. Carving out code 37.94 (Implantation or replacement of automatic cardioverter/defibrillator, total system [AICD]) from DRGs 104 and 105 increased those average charges to \$91,366 for DRG 104 and \$67,323 for DRG 105. We identified 11,021 defibrillator cases in DRG 104 (out of 25,112 total cases), with average charges of \$74,719, and 2,434 defibrillator cases in DRG 105 (out of 20,094 total cases), with average charges of \$59,267.

We performed additional review on cases containing code 37.95 (Implantation of automatic cardioverter/defibrillator lead(s) only) with code 37.96 (Implantation of automatic cardioverter/defibrillator pulse generator only) and on cases containing code 37.97 (Replacement of automatic cardioverter/defibrillator lead(s) only) with code 37.98 (Replacement of automatic cardioverter/defibrillator pulse generator only). This subgrouping contained only 56 patients. The average charges for the 18 patients in DRG 104 were \$58,847. The average charges for the 38 patients in DRG 105 were \$54,891.

Because we believe the defibrillator cases are significantly different from other cases in DRGs 104 and 105, we are proposing to create two new DRGs: DRG 514 (Cardiac Defibrillator Implant with Cardiac Catheterization) and DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheterization).

We are proposing to remove procedure codes 37.94, 37.95 and 37.96, and 37.97 and 37.98 from DRGs 104 and 105 to form the new DRGs 514 and 515. The proposed new DRGs 514 and 515 would include principal diagnosis codes and procedure codes as reflected in Chart 4 below:

CHART 4.—COMPOSITION OF PROPOSED NEW DRGs 514 AND 515 IN MDC 5

Diagnosis and procedure codes	Included in proposed DRG 514	Included in proposed DRG 515
Principal Diagnosis Codes:		
All of the principal diagnosis codes assigned to MDC-5	X	X
Principal or Secondary Procedure Code:		
37.94 Implantation or replacement of automatic cardioverter/defibrillation, total system (AICD)	X	X
Combination Operating Procedure Codes:		
37.95 Implantation of automatic cardioverter/defibrillator lead(s) only; plus		
37.96 Implantation of automatic cardioverter/defibrillator pulse generator only;	X	X
Or		
37.97 Replacement of automatic cardioverter/defibrillator lead(s) only; plus		
37.98 Replacement of automatic cardioverter/defibrillator pulse generator only	X	X
Plus: One of the Following Nonoperating Room Procedure Codes:		
37.21 Right heart cardiac catheterization	X	
37.22 Left heart cardiac catheterization	X	
37.23 Combined right and left heart cardiac catheterization	X	
37.26 Cardiac electrophysiologic stimulation and recording studies	X	
88.52 Angiocardiology of right heart structures	X	
88.53 Angiocardiology of left heart structures	X	
88.54 Combined right and left heart angiocardiology	X	
88.55 Coronary arteriography using a single catheter	X	
88.56 Coronary arteriography using two catheters	X	
88.57 Other and unspecified coronary arteriography	X	
88.58 Negative-contrast cardiac roentgenography	X	

b. Percutaneous Cardiovascular Procedures

We reviewed other DRGs within MDC 5 in order to determine if there were also logic changes that could be made to these DRGs. The data was arrayed in a variety of ways displaying myriad permutations, resulting in the following proposed changes. A percutaneous transluminal coronary angioplasty (PTCA) is an acute intervention intended to minimize cardiac damage by restarting circulation to the heart. Some patients with an acute myocardial infarction (AMI) are now treated by performing a PTCA during the hospitalization for the AMI. Currently, PTCAs with a coronary stent implant are assigned to DRG 116 (Other Permanent Cardiac Pacemaker Implantation, or PTCA with Coronary Artery Stent Implant), along with

pacemaker implants. The remaining percutaneous cardiovascular procedures are assigned to DRG 112 (Percutaneous Cardiovascular Procedures).

The volume of percutaneous cardiovascular procedures has grown dramatically, with 186,669 cases identified in the FY 2000 MedPAR file containing hospital bills submitted through May 31, 2000. Because of the high volume, we decided to review the DRG for percutaneous cardiovascular procedures. As a first step in the evaluation, we combined the percutaneous cardiovascular procedures from DRGs 112 and 116. We then subdivided the combined percutaneous cardiovascular procedure group into two groups based on the principal diagnosis (Pdx) of AMI.

Group	Count	Average charge
With Pdx of AMI	50,442	\$31,722
Without Pdx of AMI	136,227	23,989

Each of these groups was further evaluated by subdividing them based on whether a coronary stent was implanted. The vast majority of patients with an AMI had a coronary stent implanted. Patients without an AMI were subdivided into two groups based on whether a coronary stent was implanted.

Group	Count	Average charge
Without Pdx of AMI with stent	111,441	\$24,745

Group	Count	Average charge
Without Pdx of AMI without stent	24,786	20,589

Based on this analysis, we are proposing to remove the PTCAs with coronary artery stent from DRG 116, thus limiting DRG 116 to permanent cardiac pacemaker implantation. This removal will leave approximately 68,000 non-PTCA cases in DRG 116.

In conjunction with this evaluation, we considered a new technology, intravascular brachytherapy, that is being used to treat coronary in-stent stenosis. A gamma-radiation-impregnated tape is threaded through the affected vessel for a specified amount of dwell time, and then the tape is removed. Intravascular brachytherapy was approved by the Food and Drug Administration in November 2000.

Intravascular brachytherapy is assigned to procedure code 92.27 (Implantation or insert of radioactive elements). With the use of angioplasty, these cases are currently assigned to DRG 112 (Percutaneous Cardiovascular Procedures). Therefore, cases involving this new technology will be implicated by these proposed changes.

We are proposing to retitle DRG 116 "Other Cardiac Pacemaker Implantation," remove DRG 112, and create three new DRGs: DRG 516 (Percutaneous Cardiovascular Procedures with Acute Myocardial Infarction (AMI)); DRG 517 (Percutaneous Cardiovascular Procedures without AMI, with Coronary Artery Stent Implant; and DRG 518 (Percutaneous Cardiovascular Procedures without AMI, without Coronary Artery Stent Implant). The principal diagnosis codes and operating room and nonoperating room procedure codes that are proposed to be included

in the new DRGs 516, 517, and 518 are reflected in Chart 5.

In order to be assigned to new DRG 516, cases must contain one of the principal diagnoses *plus* the operating room procedures listed in Chart 5. Because DRG 516 contains acute myocardial infarction, which is hierarchically ordered before DRGs 517 and 518, any AMI cases also containing codes 92.27 or 36.06 would automatically be assigned to DRG 516. We are proposing to assign patients with a percutaneous cardiovascular procedure and intravascular radiation treatment to new DRG 517. As more data become available, we will reassess the assignment of intravascular radiation treatment to DRG 517. Proposed new DRG 518 would contain the same operating room and nonoperating room procedures as new proposed DRG 517, with the exception of codes 92.27 and 36.06.

CHART 5.—COMPOSITION OF PROPOSED NEW DRGs 516, 517, AND 518 IN MDC 5

Diagnosis and procedure codes	Included in Proposed DRG 516	Included in Proposed DRG 517	Included in Proposed DRG 518
Principal Diagnosis Codes:			
410.01 Acute myocardial infarction of anterolateral wall, initial episode of care	X		
410.11 Acute myocardial infarction of other anterior wall, initial episode of care	X		
410.21 Acute myocardial infarction of inferolateral wall, initial episode of care	X		
410.31 Acute myocardial infarction of inferoposterior wall, initial episode of care	X		
410.41 Acute myocardial infarction of other inferior wall, initial episode of care	X		
410.51 Acute myocardial infarction of other lateral wall, initial episode of care	X		
410.61 True posterior wall infarction, initial episode of care	X		
410.71 Subendocardial infarction, initial episode of care	X		
410.81 Acute myocardial infarction of other specified sites, initial episode of care.	X		
410.91 Acute myocardial infarction of unspecified site, initial episode of care	X		
plus: Operating Room Procedures:			
35.96 Percutaneous valvuloplasty	X	X	X
and			
36.01 Single vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy without mention of thromolytic agent	X	X	X
or			
36.02 Single vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy with mention of thrombolytic agent	X	X	X
or			
36.05 Multiple vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent	X	X	X
and			
36.09 Other removal of coronary artery obstruction	X	X	X
and			
37.34 Catheter ablation of lesion or tissues of heart	X	X	X
92.27 Implantation or insertion of radioactive elements		X	
OR: Nonoperating Room Procedures:			
36.06 Insertion of coronary artery stent(s)		X	
37.26 Cardiac electrophysiologic stimulation and recording studies	X	X	X
37.27 Cardiac mapping	X	X	X

DRG 121 (Circulatory Disorders with AMI and Major Complication, Discharged Alive), DRG 122 (Circulatory Disorders with AMI without Major Complication, Discharged Alive), and DRG 123 (Circulatory Disorders with

AMI, Expired) are not affected by these changes.

c. Removal of Heart Assist Systems

The ICD-9-CM Coordination and Maintenance Committee considered the

nonoperative removal of heart assist systems at its November 17, 2000 meeting. A device called the intra-aortic balloon pump (IABP) is one of the most common types of ventricular assist systems. A balloon catheter is placed

into the patient's descending thoracic aorta, and inflates and deflates with each heartbeat. This device is timed with the patient's own heart rhythm, and inflates and circulates blood to the heart and other organs. This allows the heart to rest and recover. The IABP may be used preoperatively, intraoperatively, or postoperatively. It supports the patient from a few hours to several days.

Code 37.64 (Removal of heart assist system) already exists, and it is considered by the GROUPER to be an operative procedure. However, the nonoperative removal of a heart assist system can be done at the patient's bedside, is noninvasive, and requires no anesthesia. Therefore, the Committee created code 97.44 (Nonoperative removal of heart assist system) for use with discharges beginning on or after October 1, 2001.

In the past, we have assigned new ICD-9-CM codes to the same DRG to which the predecessor code was assigned. If this practice were to be followed, we would have proposed that code 97.44 be assigned to MDC 5, DRGs 478 (Other Vascular Procedures with CC) and 479 (Other Vascular Procedures without CC). After hospital charge data became available, we would have considered moving it to other DRGs. However, in accordance with section 533(a) of Public Law 106-554, which requires a more expeditious technique of recognizing new medical services or technology for the hospital inpatient prospective payment system, we will reconsider this longstanding practice when possible. Therefore, as code 97.44 was designed to capture heart assist system removal that is clearly nonoperative, we are not proposing to designate 97.44 as a code which the GROUPER recognizes as a procedure. This assignment can be found in Table 6B, New Procedure Codes in the addendum to this proposed rule. Therefore, these cases will be assigned by the GROUPER to a medical DRG based on the principal diagnosis, or to a surgical DRG if a surgical procedure recognized by the GROUPER is performed.

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

a. Refusions

We have received questions from correspondents regarding the appropriateness of the spinal fusion DRGs: DRG 496 (Combined Anterior/Posterior Spinal Fusion); DRG 497 (Spinal Fusion with CC); and DRG 498 (Spinal Fusion without CC). Several correspondents expressed concern about

the inclusion of all refusions of the spine into one procedure code, 81.09 (Refusion of spine, any level or technique). The correspondents pointed out that because all refusions using any technique or level are in this one code, all of these cases are assigned to DRG 497 and DRG 498. They also pointed out that fusion cases involving both an anterior and posterior technique are assigned to DRG 496. Although cases with the refusion code that involve anterior and posterior techniques would appear to be more appropriately assigned to DRG 496, this is not the case.

We recognized this limitation in the refusion codes and further acknowledged that this limitation in the ICD-9-CM coding system creates DRG problems by preventing the assignment to DRG 496 even when both anterior and posterior techniques are used for refusion cases. Therefore, we referred the issue to the ICD-9-CM Coordination and Maintenance Committee and requested the Committee to consider code revisions for the refusions of the spine during its year 2000 public meetings.

After its deliberations, the Committee approved a series of new procedure codes for refusion of the spine that could lead to improvements within DRGs 497 and 498. These new codes, listed below, go into effect on October 1, 2001.

- 81.30 Refusion of spine, not otherwise specified
- 81.31 Refusion of atlas-axis spine
- 81.32 Refusion of other cervical spine, anterior technique
- 81.33 Refusion of other cervical spine, posterior technique
- 81.34 Refusion of dorsal and dorsolumbar spine, anterior technique
- 81.35 Refusion of dorsal and dorsolumbar spine, posterior technique
- 81.36 Refusion of lumbar and lumbosacral spine, anterior technique
- 81.37 Refusion of lumbar and lumbosacral spine, lateral transverse process technique
- 81.38 Refusion of lumbar and lumbosacral spine, posterior technique
- 81.39 Refusion of spine, not elsewhere classified

As previously stated, all refusions of the spine and corrections of the pseudarthrosis of the spine are assigned to code 81.09. Code 81.09, which is always assigned to DRG 497 or DRG 498, includes refusions at any level of the spine using any technique. With the creation of the new procedure codes listed above, it will be possible to

determine the level of the spine at which the refusion is performed, as well as the technique used, and assign the case to a more appropriate DRG.

These new procedure codes should greatly improve our ability to determine the level and technique used in the refusion.

In the past, we have assigned new ICD-9-CM codes to the same DRG to which the predecessor code was assigned. If this practice were followed, these new codes would have been assigned to DRG 497 and 498 as they are currently. After data became available, we would have considered moving them to other DRGs. However, in accordance with section 533(a) of Public Law 106-554, which requires more expeditious methods of recognizing new medical services or technology under the inpatient hospital prospective payment system, we will reconsider this longstanding practice when possible. Since the new codes clearly allow us to identify cases where the technique was either anterior or posterior and these cases are clinically similar and, therefore, should be handled in the same fashion, we are proposing to immediately assign these cases on the same basis as the fusion codes (81.00 through 81.09). We would not wait for actual claims data before making this change. These proposed assignments are reflected in Chart 6 and also can be found in Table 6B, in section V. of the Addendum to this proposed rule.

b. Fusion of Cervical Spine

We have received an additional inquiry concerning the spinal DRGs that focused on fusions of the cervical spine. The inquirer stated that there was a significant difference between inpatients who undergo anterior cervical spinal fusion and other types of spinal fusion in regard to treatment, recovery time, costs, and risk of complications. Anterior cervical spinal fusions are assigned to procedure code 81.02, Other cervical fusion, anterior technique. The inquirer pointed out that anterior cervical fusions differ significantly from anterior techniques at other levels since the anatomic approach is far less invasive. Thoracic anterior techniques require working around the cardiac and respiratory systems in the chest cavity, while lumbar anterior working around bowel and digestive system and the abdominal muscles. The inquirer recommended that code 81.02 be removed from DRGs 497 and 498 and grouped separately.

We analyzed claims data from 100 percent of the FY 2000 MedPAR file containing hospital bills received through May 31, 2000, and confirmed

that charges are lower for fusions of the cervical spine than fusions of the thoracic and lumbar spine. This was true for both anterior and posterior cervical fusions of the spine. Our medical consultants agree that the data and their clinical analysis support the creation of new DRGs for cervical fusions of the spine. Therefore, we are

proposing to remove procedure codes 81.02 and 81.03 from the spinal fusion DRGs (currently, DRGs 497 and 498) and assign them to new DRGs for cervical spinal fusion with and without CC. We are proposing to make four groupings for fusion DRGs. We believe that the net effect of this proposal would be an increase in the weights for DRGs

497 and 498, since the lower charges for the cervical fusions would be removed. The average standardized charge for all spinal fusions with CCs was \$26,957. For all spinal fusions without CCs, the average charge was \$16,492. The table below also shows average standardized charges for these types of cases before and after the proposed revisions.

Proposed revised spinal fusion DRGs	Average charge before proposed revisions	Average charge after revisions
DRG 497 Spinal Fusion Except Cervical with CC	\$26,957	\$36,821
DRG 498 Spinal Fusion Except Cervical without CC	17,492	26,297
DRG 519 Cervical Spinal Fusion with CC	26,957
DRG 520 Cervical Spinal Fusion without CC	16,492

Based on the proposed groupings, we would create two new DRGs: DRG 519 (Cervical Spinal Fusion with CC); and DRG 520 (Cervical Spinal Fusion without CC). The procedure codes that would be included in the proposed DRGs 519 and 520 are reflected in Chart 6 below.

We are also proposing to add the new ICD-9-CM procedure codes for refusion of the cervical spine (81.32 and 81.33) to the new cervical spine fusion DRGs because they are clinically similar.

We are proposing to retitle DRG 497 "Spinal Fusion Except Cervical with CC" and DRG 498 "Spinal Fusion Except Cervical without CC." The retitled DRGs 497 and 498 would retain fusion codes 81.00, 81.01, and 81.04 through 81.08 and include the proposed new refusion codes 81.30, 81.31, and

81.34 through 81.39, as reflected in Chart 6 below.

c. Posterior Spinal Fusion

We received other correspondence regarding the current DRG assignment for code 81.07, Lumbar and lumbosacral fusion, lateral transverse process technique. The correspondent stated that physicians consider code 81.07 to be a posterior procedure. The patient is placed prone on the operating table and the spine is exposed through a vertical midline incision. The correspondent pointed out that code 81.07 is not classified as a posterior procedure within DRG 496 (Combined Anterior/Posterior Spinal Fusion). Therefore, when 81.07 is reported with one of the anterior techniques fusion codes, it is not assigned to DRG 496. The

correspondent recommended that code 81.07 be added to the list of posterior spinal fusion codes for use in determining assignment to DRG 496.

We have consulted with our clinical advisors and they agree that this addition should be made. Since we are proposing to handle the new refusion codes in the same manner as the fusion codes, we also are proposing to assign DRG 496 when 81.37 is used with one of the anterior technique fusion or refusion codes. This would be similar to the manner in which code 81.07 is classified. For assignment to DRG 496, we would consider codes 81.01, 81.04, 81.06, 81.32, 81.34, and 81.36 to be anterior techniques and codes 81.03, 81.05, 81.07, 81.08, 81.33, 81.35, and 81.38 to be posterior techniques.

CHART 6.—PROPOSED REVISED COMPOSITION OF DRGS 496, 497, AND 498 AND PROPOSED COMPOSITION OF PROPOSED DRG 519 AND 520 IN MDC 8

Diagnosis and procedure codes	Existing DRG 496		Proposed to be retained in or added to existing DRG 497	Proposed to be retained in or added to existing DRG 498	Included in proposed DRG 519	Included in proposed DRG 520
	Proposed to be assigned as anterior techniques	Proposed to be assigned as posterior techniques				
Principal or Secondary Procedure Codes:						
81.00 Spinal fusion, not otherwise specified			X	X		
81.01 Atlas-axis fusion			X	X		
81.02 Other cervical fusion, anterior technique	X				X	X
81.03 Other cervical fusion, posterior technique		X			X	X
81.04 Lumbar and lumbosacral fusion, anterior technique	X		X	X		
81.05 Lumbar and lumbosacral fusion, posterior technique		X	X	X		
81.06 Lumbar and lumbosacral fusion, anterior technique	X		X	X		
81.07 Lumbar and lumbosacral fusion, lateral transverse process technique		X	X	X		
81.08 Lumbar and lumbosacral fusion, posterior technique		X	X	X		
81.30 Refusion of spine, not otherwise specified ..			X	X		
81.31 Refusion of atlas-axis spine			X	X		
81.32 Refusion of other cervical spine, anterior technique	X				X	X

CHART 6.—PROPOSED REVISED COMPOSITION OF DRGS 496, 497, AND 498 AND PROPOSED COMPOSITION OF PROPOSED DRG 519 AND 520 IN MDC 8—Continued

Diagnosis and procedure codes	Existing DRG 496		Proposed to be retained in or added to existing DRG 497	Proposed to be retained in or added to existing DRG 498	Included in proposed DRG 519	Included in proposed DRG 520
	Proposed to be assigned as anterior techniques	Proposed to be assigned as posterior techniques				
81.33 Refusion of other cervical spine, posterior technique		X			X	X
81.34 Refusion of dorsal and dorsolumbar spine, anterior technique	X		X	X		
81.35 Refusion of dorsal and dorsolumbar spine, posterior technique		X	X	X		
81.36 Refusion of lumbar and lumbosacral spine, anterior technique	X		X	X		
81.37 Refusion of lumbar and lumbosacral spine, posterior technique		X	X	X		
81.38 Refusion of lumbar and lumbosacral spine, posterior technique		X	X	X		
81.39 Refusion of spine, not elsewhere classified			X	X		

d. Spinal Surgery

The California Division of Workers' Compensation notified us of a possible problem with the following spinal DRGs:

- DRG 496 (Combined Anterior/Posterior Spinal Fusion)
- DRG 497 (Spinal Fusion with CC)
- DRG 498 (Spinal Fusion without CC)
- DRG 499 (Back & Neck Procedures except Spinal Fusion with CC)
- DRG 500 (Back & Neck Procedures except Spinal Fusion without CC)

The Division of Workers' Compensation uses the DRG categories developed by HCFA to classify types of hospital care. However, instead of using HCFA's weights for determining reimbursement for inpatient services, the Division sets a global fee for all inpatient medical services not otherwise exempted. This fee is established by multiplying the product of the DRG weight (or revised DRG weight for a small number of categories) and the health facility's composite factor by 1.20 to get the maximum amount for worker compensation admissions.

The Division of Workers' Compensation has received reports that the formula it uses for reimbursing cases may be providing inadequate reimbursement. California hospitals and orthopedists have reported that certain spinal surgery DRGs (DRGs 496 through 500) may involve different types of care and/or technologies than those in use at the time these groups were formulated. Health care providers in California report "recent increased use of the new implantation devices, hardware, and instrumentation, coupled with requirements for intensive hospital services accompanying use of new procedures, has led to inadequate

reimbursement in these DRGs." As a short-term response to these concerns, the California Division of Workers' Compensation is exempting the costs of hardware and instrumentation from the global fee of the fee schedule for DRGS 496 through 500. The Division also requested that HCFA examine these DRGs for any potential problem under the Medicare reimbursement system.

The ICD-9-CM coding system does not capture specific types of implantation devices, hardware, and instrumentation. Therefore, we were not able to verify the claim that these new devices have led to increased costs in specific cases. As discussed in section II.D. of this preamble, we believe that the adoption of a more detailed coding system, such as ICD-10-PCS, would supply greater amounts of detail on these items. However, in the short term, it is not possible to identify a specific problem that involves implantation devices, hardware, and instrumentation.

4. MDC 12 (Diseases and Disorders of the Male Reproductive System)

At its May 11, 2000 public meeting, the ICD-9-CM Coordination and Maintenance Committee considered a request from a manufacturer to create a unique code for the procedure, Penile plethysmography with nerve stimulation, in DRG 334 (Major Male Pelvic Procedures with CC). The penile plethysmography is a test that can be performed during a radical prostatectomy procedure. During the course of the procedure, the physician places a probe within an area where the prostatic nerves are thought to be located and is able to detect minor changes in penile tumescence or detumescence. This reaction tells the

physician that the nerve bundles have been located, which may aid the physician in performing a nerve-sparing radical prostatectomy procedure with precision. The nerve bundles can also be restimulated at the conclusion of the procedure, providing immediate feedback as to whether erectile function will be restored after surgery.

After a presentation on the nerve identifying procedure and review of existing ICD-9-CM codes, the ICD-9-CM Coordination and Maintenance Committee determined that the existing code 89.58 (Plethysmogram) adequately describes this test.

Radical prostatectomies for patients with cancer of the prostate are grouped in either DRG 334 (Major Male Pelvic Procedures with CC) or DRG 335 (Major Male Pelvic Procedures without CC). We have received a request from a manufacturer of a nerve-identifying device to assign cases containing code 89.58 into DRG 334 only, not into DRG 335, resulting in higher payments to hospitals. During FY 2001, DRG 334 had a relative weight of 1.5591, and DRG 335 had a relative weight of 1.1697. The manufacturer requested that we designate code 89.58 as an operating room procedure code that would be recognized by the GROUPER software, and make that code applicable only to DRG 334. The manufacturer believed that this would serve to take any cases of nerve sparing out of the lower paying DRG 335, and would make the technology more attractive to hospitals. As paired DRGs 334 and 335 are currently structured, they differ only in whether or not a secondary diagnosis identified as a CC is recorded.

Using 100 percent of the FY 2000 MedPAR file which contains hospital

bills for FY 2000 through May 31, 2000, we examined those cases in DRG 334 to which the procedure code for prostatectomy was assigned. Of the total 7,241 cases in DRG 334 identified, 5,611 of these cases contained procedure code 60.5 (Radical prostatectomy). Only three of the prostatectomy cases included code 89.58. There is not a sufficient number of cases on which to base an assessment of the payment for this procedure. Therefore, we are not proposing to modify the assignment of code 89.58.

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

DRG 390 (Neonate with Other Significant Problems) contains newborn or neonate cases with other significant problems, not assigned to DRGs 385 through 389, DRG 391, or DRG 469. To be assigned to DRG 389 (Full Term Neonate with Major Problems), the neonate must have one of the principal or secondary diagnosis listed under this DRG. A neonate is assigned to DRG 390 when the neonate has a principal or secondary diagnosis of newborn or neonate with other significant problems that are not assigned to DRG 385 through 389, 391, or 469.

We have received correspondence suggesting a number of changes to be made to DRGs 398 and 391. These changes involve removing two codes from DRG 389 and adding 17 codes to DRG 391, as described below.

a. DRG 389 (Full Term Neonate With Major Problems)

The correspondent suggested removing the following codes from DRG 389 and assigning them to DRG 390:

773.0 Hemolytic disease due to RH isoimmunization
773.1 Hemolytic disease due to ABO isoimmunization

The correspondent stated that hemolytic disease due to RH isoimmunization or due to ABO isoimmunization should not be considered a major problem. The correspondent recommended that these two conditions be classified as significant problems instead and thus assigned to DRG 390.

Our medical consultants sought additional advice from the National Association of Children's Hospitals and Related Institutions (NACHRI). (HCFA contracts with the 3M Health Information Systems to maintain the DRG system. The medical experts at 3M evaluate proposed DRG changes from a clinical perspective. These medical consultants assist HCFA in evaluating

alternative proposals.) NACHRI and our medical consultants agree that it is appropriate to remove codes 773.0 and 773.1 from DRG 389. Therefore, we are proposing to remove 773.0 and 773.1 from DRG 389 so that neonates with these conditions are assigned to DRG 390.

b. DRG 391 (Normal Newborn)

We also have received correspondence with recommendations for changes to DRG 391. The correspondent pointed out that the following secondary codes currently lead to the assignment of the neonate to DRG 390 (Neonate with Other Significant Problems). The correspondent believed that the conditions described by these codes should not cause the neonate to be classified under DRG 390 when reported as a secondary diagnosis. The correspondent recommended that these conditions be listed under DRG 391 (Normal Newborn).

478.1 Other diseases of nasal cavity and sinuses
520.6 Disturbances in tooth eruption
623.8 Other specified noninflammatory disorders of vagina
709.00 Dyschroma, unspecified
709.01 Vitiglio
709.09 Dyschromia, Other
744.1 Accessory auricle
754.61 Congenital pes planus
757.33 Congenital pigmentary anomalies of skin
757.39 Other specified anomaly of skin, Other
764.08 "Light for dates" without mention of fetal malnutrition, 2,000–2,499 grams
764.98 Fetal growth retardation, unspecified, 2,000–2,499 grams
772.6 Cutaneous hemorrhage
794.15 Abnormal and auditory function studies
796.4 Other abnormal clinical findings
V20.2 Routine infant or child health check
V72.1 Examination of ears and hearing

Our medical consultants also sought the advice of NACHRI on this recommendation. NACHRI reviewed the list of codes and agreed that none of these conditions should be considered to be a significant problem for a neonate. NACHRI concurred that neonates with these secondary diagnoses should be classified as normal newborns. Therefore, we are proposing to add the codes listed above to DRG 391 and not classify them to DRG 390 when reported as a secondary diagnosis.

c. Medicare Code Editor Changes

The Medicare Code Editor (MCE) is a front-end software program that detects

and reports errors in the coding of claims data. The age conflict edit detects inconsistencies between a patient's age and any diagnosis on the patient's record. A subset of diagnoses is considered valid only for patients over the age of 14 years. These diagnoses are identified as "adult" diagnoses and range in age from 15 through 124 years. Therefore, any codes included on the Newborn Diagnoses edit are valid only for patients under age 14.

It has come to our attention that cases including the ICD-9-CM code 770.7, Chronic respiratory disease arising in the perinatal period, are being rejected. However, a condition such as bronchopulmonary dysplasia always originates in the perinatal period, so regardless of the patient's age, this condition is always coded as 770.7. The age at which the diagnosis was established or the age at continuing treatment does not affect the assignment of code 770.7.

Because correct coding is causing these claims to be rejected, we are proposing to remove code 770.7 from the Newborn Diagnoses edit in the MCE, as well as remove it from DRG 387 (Prematurity with Major Problems) and DRG 389 (Full Term Neonate with Major Problems). Clinical conditions in code 770.7, such as pulmonary fibrosis, would group to DRG 92 (Interstitial Lung Disease with CC) and DRG 93 (Interstitial Lung Disease without CC). Therefore, we are proposing the addition of code 770.7 to DRGs 92 and 93, as they are most similar clinically. We will monitor these cases in upcoming MedPAR data to ascertain that the cases consume similar resources.

6. MDC 20 (Alcohol/Drug Use and Alcohol/Drug-Induced Organic Mental Disorders)

DRG 434 (Alcohol/Drug Abuse or Dependency, Detoxification or Other Symptomatic Treatment with CC) is assigned when the patient has a principal diagnosis of alcohol or drug abuse or dependence along with a secondary diagnosis classified as a CC. If these patients do not have a CC, they are assigned to DRG 435 (Alcohol/Drug Abuse or Dependency, detoxification or Other Symptomatic Treatment without CC). When the patients receive rehabilitation and detoxification therapy during the stay, they are assigned to DRG 437 (Alcohol/Drug Dependence, Combined Rehabilitation and Detoxification Therapy). If the patients receive only rehabilitation therapy, they are assigned to DRG 436 (Alcohol/Drug Dependence with Rehabilitation Therapy).

We have received inquiries as to why the relative weight for DRG 437, which includes both rehabilitation and detoxification (for FY 2001, the relative weight is .6606, with a geometric mean length of stay of 7.5) is lower than the FY 2001 relative weight for DRG 434, which includes only detoxification (.7256, with a geometric mean length of stay of 3.9). Likewise, the FY 2001 relative weight for DRG 436, which includes only rehabilitation (.7433), is higher than the FY 2001 relative weight for DRG 437, which includes combined

rehabilitation and detoxification therapy (.6606). The inquirers indicated that those patients receiving the combination therapy would be expected to have a longer length of stay, require more services, and, therefore, be more costly to treat.

We analyzed data from 100 percent of the FY 2000 MedPAR file which contains hospital bills received through May 31, 2000, and did not find support for the inquirers' assertion that combination therapy is more costly to treat. The relative weights indicate that

the presence of a CC in DRG 434 leads to a significantly higher weight than is found in DRG 435, which does not have a CC. Therefore, we analyzed the alcohol/drug DRGs and focused on eliminating the distinction between rehabilitation and rehabilitation with detoxification and assessing the impact of CCs. We combined data on DRGs 436 and 437 and then subdivided the data based on the presence or absence of a CC. The following table contains the results of the analysis.

AVERAGE CHARGES FOR CASES—WITH AND WITHOUT CCs

DRGs	With CC			Without CC		
	Count	Charge	Length of stay	Count	Charge	Length of stay
Detoxification Cases—DRG 434 and DRG 435	3,298	\$8,548	5.0	9,689	\$5,111	4.1
All Rehabilitation Cases—DRG 436 and DRG 437	3,298	8,117	10.1	4,473	7,407	9.6

We found that, for both the detoxification and rehabilitation DRGs, the with-CC group has higher charges than the without-CC group. However, the with-CC groups still contain the anomaly that the detoxification DRG 434 has a slightly higher average charge than the combined rehabilitation DRGs 436 and 437. It appears that any significant medical problems as indicated by the presence of a CC dominate the cost incurred by hospitals for treating alcohol and drug abuse patients. For the without-CC groups, the detoxification DRG 435 has substantially lower average charges than the combined rehabilitation DRGs 436

and 437. Because the average charges of the with-CC for both the detoxification DRG 434 and combined rehabilitation DRGs 436 and 437 have similar average charges, we are proposing to combine these two groups.

Based on the results of our analysis, we are proposing to restructure MDC 20 as follows. We first identified those cases with a principal diagnosis within MDC 20 where the patient left against medical advice. These cases are found in DRG 433 (Alcohol/Drug Abuse or Dependence, Left Against Medical Advice (AMA)). We next identified all remaining cases with a principal diagnosis within MDC 20 where there

was a CC. We assigned these cases to a proposed new DRG, Alcohol/Drug Abuse or Dependence with CC). The remaining cases (without CC and did not leave against medical advice) were then divided into two proposed new DRGs based on whether or not the patient received rehabilitation (Alcohol/Drug Abuse or Dependence without CC, with Rehabilitation Therapy; and Alcohol/Drug Abuse or Dependence without CC, without Rehabilitation Therapy).

The following table illustrates the number of patients and average charges for each of the four proposed DRGs.

FREQUENCIES AND AVERAGE CHARGES FOR NEW DRGs

DRG	Group title	Number of cases	Average charges
433	Alcohol/Drug Abuse or Dependence, Left Against Medical Advice	3,509	\$3,855
521	Alcohol/Drug Abuse or Dependence with CC	18,235	8,470
522	Alcohol/Drug Abuse or Dependence without CC, with Rehabilitation Therapy	4,473	7,407
523	Alcohol/Drug Abuse or Dependence without CC, without Rehabilitation Therapy	9,689	5,111

This table illustrates that groups based first on the presence of CC and then on whether or not the patient receives rehabilitation therapy provide a

much better explanation of differences in charges. Therefore, we are proposing to retain DRG 433, make DRGs 434 through 437 invalid, and create new

DRGs 521, 522, and 523 to include the diagnosis and procedure codes reflected in Chart 7 below.

CHART 7.—PROPOSED RESTRUCTURE OF MDC 20
[Alcohol/drug use and alcohol/drug-induced organic mental disorders]

Diagnosis and procedure code	Included in existing DRG 433	Included in proposed DRG 521	Included in proposed DRG 522	Included in proposed DRG 523
Principal diagnosis: All principal diagnosis within existing MDC 20 involving cases in which patients left against medical advice (AMA)	X			

CHART 7.—PROPOSED RESTRUCTURE OF MDC 20—Continued
 [Alcohol/drug use and alcohol/drug-induced organic mental disorders]

Diagnosis and procedure code	Included in existing DRG 433	Included in proposed DRG 521	Included in proposed DRG 522	Included in proposed DRG 523
All principal diagnoses within existing MDC 20 where there is a CC and where patient did not leave against medical advice (AMA)		X		
All principal diagnoses within existing MDC 20 without CC and where patient did not leave against medical advice (AMA)			X	
All principal diagnoses in existing MDC 20 involving cases where patients did not leave against medical advice (AMA)				X
Procedure Codes:				
94.61 Alcohol rehabilitation			X	
94.63 Alcohol rehabilitation and detoxification			X	
94.64 Drug rehabilitation			X	
94.66 Drug rehabilitation and detoxification			X	
94.67 Combined alcohol and drug rehabilitation			X	
94.69 Combined alcohol and drug rehabilitation and detoxification			X	

7. MDC 25 (Human Immunodeficiency Virus Infections)

Effective October 1, 2000, ICD-9-CM diagnosis codes 783.2 (Abnormal loss of weight) and 783.4 (Lack of expected normal physiological development) were made invalid (65 FR 47171). These two old diagnosis codes were expanded to five digits and the following new diagnosis codes were created:

- 783.21 Loss of weight
- 783.22 Underweight
- 783.40 Unspecified lack of normal physiological development
- 783.41 Failure to thrive
- 783.42 Delayed milestones
- 783.43 Short stature

These six revised codes were created in response to an industry request. Specifically, code 783.2 did not differentiate between whether the patient had lost weight recently or whether the patient was underweight. Code 783.4 was expanded to capture concepts such as failure to thrive, delayed milestones, and short stature. None of these concepts were captured in the old codes.

We listed these new codes in the August 1, 2000 final rule on the hospital inpatient prospective payment system in Table 6A—New Diagnosis Codes (65 FR 47169). At the time the final rule was published, all of these codes were assigned to DRGs 296 through 298. After the final rule was published, we received an inquiry as to why these new diagnosis codes were not included in MDC 25 as human immunodeficiency virus (HIV)-related conditions. The inquirer pointed out that the predecessor codes (783.2 and 783.4) were included in MDC 25 as HIV-related conditions and suggested that the new codes be added to MDC 25. These cases will be assigned to other MDCs if the patient does not have HIV.

We agree that the expanded codes should have been placed in the MDC 25 as HIV-related conditions. The omission was an oversight. Therefore, we are proposing to add diagnosis codes 783.21, 783.22, 783.40, 783.41, 783.42, and 783.43 as HIV-related conditions within MDC 25. When these six revised codes are reported with code 042 HIV, the patient will be classified within MDC 25.

8. 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 by which these cases are assigned to a single DRG. The surgical hierarchy, an ordering of surgical classes from resource intensive most to least, 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 recalibration, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications, to determine if the ordering of classes coincided with the intensity of resource utilization, as measured by the same billing data used to compute the DRG relative weights.

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 each DRG for frequency to determine the 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 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 OR procedures” as discussed below.

This methodology may occasionally result in a case involving multiple procedures being assigned 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 relative weight is ordered above a surgical class with a higher average relative weight. For example, the “other OR procedures” surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the relative weight for the DRG or

DRGs in that surgical class may be higher than that for other surgical classes in the MDC. The "other OR procedures" class is a group of procedures that are least likely to be related to the diagnoses in the MDC but are occasionally performed on patients 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 weights for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy since, by virtue of the hierarchy change, the relative weights are likely to shift such that the higher-ordered surgical class has a lower average weight than the class ordered below it.

Based on the preliminary recalibration of the DRGs, we are proposing to modify the surgical hierarchy as set forth below. As we stated in the September 1, 1989 final rule (54 FR 36457), we are unable to test the effects of proposed revisions to the surgical hierarchy and to reflect these changes in the proposed relative weights due to the unavailability of the revised GROUPER software at the time the proposed rule is prepared. Rather, we simulate most major classification changes to approximate the placement of cases under the proposed reclassification and then determine the average charge for each DRG. These average charges then serve as our best estimate of relative resource use for each surgical class. We test the proposed surgical hierarchy changes after the revised GROUPER is received and reflect the final changes in the DRG relative weights in the final rule. Further, as discussed in section II.C. of this preamble, we anticipate that the final recalibrated weights will be somewhat different from those proposed, because they will be based on more complete data. Consequently, further revision of the hierarchy, using the above principles, may be necessary in the final rule.

At this time, we are proposing to revise the surgical hierarchy for the pre-MDC DRGs, MDC 5 (Diseases and Disorders of the Circulatory System), MDC 8 (Diseases and Disorders of the Musculoskeletal System & Connective Tissue) and MDC 20 (Alcohol/Drug Use & Alcohol/Drug Induced Organic Mental Disorders), as these are proposed to be revised under sections II.B.2., II.B.3., and II.B.6. of this preamble, as follows:

- In the pre-MDC DRGs, we are proposing to reorder Lung Transplant

(DRG 495) above Bone Marrow Transplant (DRG 481). We are also proposing to reorder Simultaneous Pancreas/Kidney Transplant (DRG 512) and Pancreas Transplant (DRG 513) above Lung Transplant (DRG 495).

- In MDC 5, we are proposing to reorder Cardiac Defibrillator Implants (DRGs 514 and 515) above Other Cardiothoracic Procedures (DRG 108).

We are also proposing to reorder Percutaneous Cardiovascular Procedures (DRGs 516, 517, and 518) above Other Vascular Procedures (DRGs 478 and 479).

- In MDC 8, we are proposing to reorder Cervical Spinal Fusion (DRGs 519 and 520) above Back & Neck Procedures Except Spinal Fusion (DRGs 499 and 500).

- In MDC 20, we are proposing to order as follows: Alcohol/Drug Abuse or Dependence, Left AMA (DRG 433) above Alcohol/Drug Abuse or Dependence With CC (DRG 521); Alcohol/Drug Abuse or Dependence With CC (DRG 521) above Alcohol/Drug Abuse or Dependence With Rehabilitation Therapy Without CC (DRG 522); and Alcohol/Drug Abuse or Dependence With Rehabilitation Therapy Without CC (DRG 522) above Alcohol/Drug Abuse or Dependence Without Rehabilitation Therapy Without CC (DRG 523).

9. 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 a valid CC in combination with a particular principal diagnosis. Thus, we created the CC Exclusions List. We made these changes for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative coding or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. We developed this standard list of diagnoses using physician panels to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity. In previous years, we have made changes to the standard list of CCs, either by adding new CCs or deleting CCs already on the list. At this time, we do 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 a condition should not be considered CCs for one another.
- Conditions that may not coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another.
- 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 complications or comorbidities 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, and the August 1, 2000 final rule (65 FR 47064) for the FY 2001 revisions. In the July 30, 1999 final rule (64 FR 41490) we did not modify the CC Exclusions List for FY 2000 because we

did not make any changes to the ICD-9-CM codes for FY 2000.

We are proposing a limited revision of the CC Exclusions List to take into account the changes that will be made in the ICD-9-CM diagnosis coding system effective October 1, 2001. (See section II.B.11. below, for a discussion of ICD-9-CM changes.) These proposed changes are being made in accordance with the principles established when we created the CC Exclusions List in 1987.

Tables 6F and 6G in section V. of the Addendum to this proposed rule contain the proposed revisions to the CC Exclusions List that would be effective for discharges occurring on or after October 1, 2001. Each table shows the principal diagnoses with proposed 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, 2001, 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, 2001, 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, and 1999) and those in Tables 6F and 6G of this document 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, 2001. (Note: There was no CC Exclusions List in FY 2000 because we

did not make changes to the ICD-9-CM codes for FY 2000.)

Alternatively, the complete documentation of the GROUPER logic, including the current CC Exclusions List, is available from 3M/Health Information Systems (HIS), which, under contract with HCFA, is responsible for updating and maintaining the GROUPER program. The current DRG Definitions Manual, Version 18.0, is available for \$225.00, which includes \$15.00 for shipping and handling. Version 19.0 of this manual, which includes the final FY 2002 DRG changes, will be available in October 2001 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.

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

Each year, we review cases assigned to DRG 468 (Extensive OR Procedure Unrelated to Principal Diagnosis), DRG 476 (Prostatic OR Procedure Unrelated to Principal Diagnosis), and DRG 477 (Nonextensive OR 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 OR procedures performed is 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 OR 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); or in FY 2001, as noted in the August 1, 2000 final rule (65 FR 47064).

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.

Using 100 percent of the FY 2000 MedPAR file containing bills submitted through May 31, 2000 for discharges in FY 2000, we determined that the quantity of cases in DRG 477 totaled 17,153. There were 106 instances where the major operative procedure appeared only once (6.4 percent of the time), resulting in assignment to DRG 477.

Using the same 100 percent sample of the FY 2000 MedPAR file, we reviewed DRG 468. There were a total of 40,429 cases, with one major operative code causing the DRG assignment 311 times (or 8 percent) and 230 instances where the major operative procedure appeared only once (or 6 percent of the time).

Our medical consultants then identified those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical DRGs for the MDC in which the

diagnosis falls. Based on this year's review, we did not identify any necessary changes in procedures under DRG 477 and, therefore, are not

proposing to move any procedures from DRG 477 to one of the surgical DRGs. However, our medical consultants have identified a number of procedure codes

that should be removed from DRG 468 and put into more clinically coherent DRGs. The movement of these codes are specified in the charts below:

MOVEMENT OF PROCEDURE CODES FROM DRG 468

Procedure code	Description	Included in DRG	Description
MDC 1—Diseases and Disorders of the Nervous System			
5495	Peritoneal Incision	7	Peripheral and Cranial Nerve and Other Nervous System Procedures with CC
5495	Peritoneal Incision	8	Peripheral and Cranial Nerve and Other Incision Nervous System Procedures without CC
MDC 3—Diseases and Disorders of the Ear			
3821	Blood Vessel Biopsy	63	Other Ear, Nose, Mouth and Throat OR Procedure
MDC 4—Diseases and Disorders of the Respiratory System			
3821	Blood Vessel Biopsy	76	Other Respiratory System OR Procedures with CC
3821	Blood Vessel Biopsy	77	Other Respiratory System OR Procedures without CC
3929	Vascular Shunt & Bypass NEC	76	Other Respiratory System OR Procedures with CC
3929	Vascular Shunt & Bypass NEC	77	Other Respiratory System OR Procedures without CC
3931	Suture of Artery	76	Other Respiratory System OR Procedures with CC
3931	Suture of Artery	77	Other Respiratory System OR Procedures without CC
5411	Exploratory Laparotomy	76	Other Respiratory System OR Procedures with CC
5411	Exploratory Laparotomy	77	Other Respiratory System OR Procedures without CC
7749	Bone Biopsy NEC	76	Other Respiratory System OR Procedures with CC
7749	Bone Biopsy NEC	77	Other Respiratory System OR Procedures without CC
8669	Free Skin Graft NEC	76	Other Respiratory System OR Procedures with CC
8669	Free Skin Graft NEC	77	Other Respiratory System OR Procedures without CC
MDC 5—Diseases and Disorders of the Circulatory System			
3402	Exploratory Thoracotomy	120	Other Circulatory System OR Procedures
3403	Reopen Thoracotomy Site	120	Other Circulatory System OR Procedures
3421	Transpleura Thoracoscopy	120	Other Circulatory System OR Procedures
3422	Mediastinoscopy Circulatory	120	Other Circulatory System OR Procedures
3426	Open Mediastinal Biopsy	120	Other Circulatory System OR Procedures
436	Distal Gastrectomy	120	Other Circulatory System OR Procedures
437	Partial Gastrectomy with Jejunal Anastomosis.	120	Other Circulatory System OR Procedures
4389	Partial Gastrectomy	120	Other Circulatory System OR Procedures
4399	Total Gastrectomy	120	Other Circulatory System OR Procedures
14561	Multiple Segment Small Bowel Excision.	120	Other Circulatory System OR Procedures
4562	Partial Small Bowel Resectomy NEC.	120	Other Circulatory System OR Procedures
4572	Cecectomy	120	Other Circulatory System OR Procedures
4573	Right Hemicolectomy	120	Other Circulatory System OR Procedures
4574	Transverse Colon Resectomy	120	Other Circulatory System OR Procedures
4575	Left Hemicolectomy	120	Other Circulatory System OR Procedures
4579	Partial Large Bowel Excision NEC ..	120	Other Circulatory System OR Procedures
458	Total Intra-Abdominal Colectomy ...	120	Other Circulatory System OR Procedures
4593	Small-to-Large Bowel NEC	120	Other Circulatory System OR Procedures
4603	Large Bowel Exteriorization	120	Other Circulatory System OR Procedures
4613	Permanent Colostomy	120	Other Circulatory System OR Procedures
4709	Other Appendectomy	120	Other Circulatory System OR Procedures
4862	Anterior Rectal Resction With Colostomy.	120	Other Circulatory System OR Procedures
4863	Anterior Rectal Resection NEC	120	Other Circulatory System OR Procedures
4869	Rectal Resection	120	Other Circulatory System OR Procedures
5012	Open Liver Biopsy	120	Other Circulatory System OR Procedures
540	Abdominal Wall Incision	120	Other Circulatory System OR Procedures
MDC 6—Diseases and Disorders of the Digestive System			
5122	Cholecystectomy	170	Other Digestive System OR Procedures with CC
5122	Cholecystectomy	171	Other Digestive System OR Procedures without CC
5123	Laparoscopic Cholecystectomy	170	Other Digestive System OR Procedures with CC
5132	GB-To-Intestine Anastomy	170	Other Digestive System OR Procedures with CC
5136	Choledochoenterostomy	170	Other Digestive System OR Procedures with CC

MOVEMENT OF PROCEDURE CODES FROM DRG 468

Procedure code	Description	Included in DRG	Description
5136	Choledochoenterostomy	171	Other Digestive System OR Procedures without CC
5137	Hepatic Duct-GI Anastomy	170	Other Digestive System OR Procedures with Anastomy CC
5137	Hepatic Duct-GI Anastomy	171	Other Digestive System OR Procedures without CC
5159	Bile Duct Incision NEC	170	Other Digestive System OR Procedures with CC
5159	Bile Duct Incision NEC	171	Other Digestive System OR Procedures without CC
MDC 7—Diseases and Disorders of the Hepatobiliary System and Pancreas			
540	Abdominal Wall Incision	201	Other Hepatobiliary and Pancreas Procedure
MDC 8—Diseases and Disorders of the Musculoskeletal System and Connective Tissue			
3479	Other Chest Wall Repair	233	Other Musculoskeletal System & Connective Tissue OR Procedure with CC
3479	Other Chest Wall Repair	234	Other Musculoskeletal System & Connective Tissue OR Procedure without CC
MDC 11—Diseases and Disorders of the Kidney and Urinary Tract			
540	Abdominal Wall Incision	315	Other Kidney & Urinary Tract OR Procedure
5451	Laparoscopic Periton Adhesiolysis ..	315	Other Kidney & Urinary Tract OR Procedure
5459	Other Periton Adhesiolysis	315	Other Kidney & Urinary Tract OR Procedure

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 moved 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 our medical consultants were to find these shifts, we would propose moving cases to keep the DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data. Based on our review this year, we are not proposing to move any procedures from DRG 468 to DRGs 476 or 477, from DRG 476 to DRGs 468 or 477, or from DRG 477 to DRGs 468 or 476.

c. Adding Diagnosis Codes to MDCs

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

11. 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 HCFA, charged with maintaining and updating the ICD-9-CM system. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD-9-CM to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

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

The Committee encourages participation in the above process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA) (formerly American Medical Record Association (AMRA)), the American Hospital Association (AHA), and various physician specialty groups as

well as physicians, medical record administrators, health information management professionals, and other members of the public to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2002 at public meetings held on May 11, 2000 and November 17, 2000, and finalized the coding changes after consideration of comments received at the meetings and in writing by January 8, 2001.

Copies of the Coordination and Maintenance Committee minutes of the 2000 meetings can be obtained from the HCFA home page at: <http://www.hcfa.gov/medicare/icd9cm.htm>. Paper copies of these minutes are no longer available and the mailing list has been discontinued. We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson; ICD-9-CM Coordination and Maintenance Committee; NCHS; Room 1100; 6525 Belcrest Road; Hyattsville, MD 20782. Comments may be sent by E-mail to: dfp4@cdc.gov.

Questions and comments concerning the procedure codes should be addressed to: Patricia E. Brooks, Co-Chairperson; ICD-9-CM Coordination and Maintenance Committee; HCFA, Center for Health Plans and Providers, Purchasing Policy Group, Division of Acute Care; C4-07-07; 7500 Security

Boulevard; Baltimore, MD 21244-1850. Comments may be sent by E-mail to: pbrooks@hcfa.gov.

The ICD-9-CM code changes that have been approved will become effective October 1, 2001. The new ICD-9-CM codes are listed, along with their proposed DRG classifications, in Tables 6A and 6B (New Diagnosis Codes and New Procedure Codes, respectively) in section V. of the Addendum to this proposed rule. As we stated above, the code numbers and their titles were presented for public comment at the ICD-9-CM Coordination and Maintenance Committee meetings. Both oral and written comments were considered before the codes were approved. Therefore, we are soliciting comments only on the proposed DRG classification of these new codes.

Further, the Committee has approved the expansion of certain ICD-9-CM codes to require an additional digit for valid code assignment. Diagnosis codes that have been replaced by expanded codes or other codes or have been deleted are in Table 6C (Invalid Diagnosis Codes). These invalid diagnosis codes will not be recognized by the GROUPER beginning with discharges occurring on or after October 1, 2001. 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). There were no procedure codes that were replaced by expanded codes or other codes, or were deleted. Revisions to diagnosis code titles are in Table 6E (Revised Diagnosis Code Titles), which also include the proposed DRG assignments for these revised codes. Revisions to procedure code titles are in Table 6F (Revised Procedure Codes Titles).

In September 2000, the Department implemented a policy of paying for inpatient hospital stays for Medicare beneficiaries participating in clinical trials (HCFA Program Memorandum AB 00-89, September 19, 2000). Hospitals were encouraged to identify the patients involved by reporting an ICD-9-CM code. This would allow the examination of data on the patients involved in clinical trials. However, there was no clear ICD-9-CM diagnosis code for patients who took part in a clinical trial. There was a code for patients receiving an examination as part of the control group for clinical trials. This control group code was V70.7 (Examination for normal comparison or control in clinical research). Hospitals were instructed to use V70.5 (Health examination of defined subpopulations), for patients participating in a clinical trial.

This coding directive has created some confusion because of the title and description of the two codes. Hospitals also have requested that all clinical patients be captured under one code. They indicated that the use of one code would be especially useful because patients frequently do not know if they are part of the control group or are receiving new therapy.

To help alleviate the confusion, the ICD-9-CM Coordination and Maintenance Committee revised code V70.7. Effective October 1, 2001, the new title of code V70.7 is "Examination of patient in clinical trial." This revision will make it easier to capture data on Medicare beneficiaries who are participating in a clinical trial.

12. Other Issues

a. Pancreas Transplant

Effective July 1, 1999, Medicare covers whole organ pancreas transplantation if the transplantation is performed simultaneously with or after a kidney transplant (procedure codes 55.69 (Other kidney transplantation), or diagnosis code V42.0 (Organ or tissue replaced by transplant, Kidney), along with 52.80 (Pancreatic transplant, not otherwise specified), or 52.82 (Homotransplant of pancreas)). A discussion of the history of these coverage decisions and codes can be found in the August 1, 2000 final rule on the prospective payment system for FY 2001 (65 FR 47067).

We discussed the appropriate DRG classification for these cases in both the July 30, 1999 final rule (64 FR 41497) and the August 1, 2000 final rule (65 FR 47067). Currently, cases can be assigned to one of two major DRGs depending on principal diagnosis. If a kidney transplant and a pancreas transplant are performed simultaneously on a patient with chronic renal failure secondary to diabetes with renal manifestations (diagnosis codes 250.40 through 250.43), the cases will be assigned to DRG 302 (Kidney Transplant). If a pancreas transplant is performed following a kidney transplant (during a different hospital admission) on a patient with chronic renal failure secondary to diabetes with renal manifestations, the case is assigned to DRG 468 (Extensive OR Procedure Unrelated to Principal Diagnosis). This is because pancreas transplant is not assigned to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract), the MDC to which a principal diagnosis of chronic renal failure secondary to diabetes is assigned.

In the August 1, 2000 final rule, we noted that we would continue to

monitor these transplant cases to determine the appropriateness of establishing a new DRG. For this proposed rule, using 100 percent of the data in the FY 2000 MedPAR file (which contains hospital bills received for FY 2000 through May 31, 2000), we analyzed the cases for which procedure codes 52.80 and 52.82 were reported. (Our data showed that 15 of the cases were coded using 52.83 (Heterotransplant of pancreas), which is not a covered procedure under any circumstances.) We identified a total of 221 cases for this time period. The United Network for Organ Sharing (UNOS) reported it had identified 270 cases through September 2000.

These 221 MedPAR cases were distributed over 6 DRGs, with the majority (158 cases or 72 percent) assigned to DRG 302, and 23 cases (10 percent) assigned to DRG 468. The remaining 40 cases were distributed between 4 other DRGs, with the majority (25 cases) being assigned to DRG 292 (Other Endocrine, Nutritional and Metabolic OR Procedures with CC). Four cases were assigned to DRG 483 (Tracheostomy with Principal Diagnosis except Face, Mouth and Neck Diagnoses) in the Pre-MDC grouping, which took precedence over any other DRG assignment.

We arrayed the data based on the presence or absence of kidney transplant; that is, pancreas transplant codes with or without 55.69. The majority of cases (166 or 75 percent) had the combined kidney-pancreas transplant in one operative episode, with 55 (25 percent) of the cases having pancreas transplant subsequent to the kidney transplant. Differences in hospital charges were significantly higher for a pancreas transplant plus a kidney transplant (\$138,809) than a pancreas transplant alone (\$85,972), and both were higher than average standardized charges in DRG 302 (\$64,760) or DRG 468 (\$39,707), although it must be noted that these figures do reflect the resource intensive patients assigned to DRG 483. Those patients in DRG 483 had average standardized charges of \$377,934.

Because these categories of patients do not fit into existing DRGs from either a clinical or resource perspective, we are proposing to create two new DRGs that would reflect these patients' unique clinical profiles: DRG 512 (Simultaneous Pancreas/Kidney Transplant) and DRG 513 (Pancreas Transplants). Cases grouped to either proposed DRGs 512 or 513 must have a principal or secondary diagnosis code and procedure code or combination of

procedure codes as indicated in the chart below:

COMPOSITION OF PROPOSED DRGs 512 AND 513

Diagnosis and procedure codes	Included in proposed DRG 512	Included in proposed DRG 513
Principal or Secondary ICD-9-CM Diabetes Mellitus Code:		
250.00 Diabetes mellitus without mention of complication, Type II or unspecified type, not stated as uncontrolled	X	X
250.01 Diabetes mellitus without mention of complication, Type I, not stated as uncontrolled	X	X
250.02 Diabetes mellitus without mention of complication, Type I,	X	X
250.03 Diabetes mellitus without mention of complication, Type I, uncontrolled	X	X
250.10 Diabetes with ketoacidosis, Type II or Unspecified type, not stated as uncontrolled	X	X
250.11 Diabetes with ketoacidosis, Type I, not stated as uncontrolled	X	X
250.12 Diabetes with ketoacidosis, Type II or unspecified type, uncontrolled	X	X
250.13 Diabetes with ketoacidosis, Type I, controlled	X	X
250.20 Diabetes with hyperosmolarity, Type II or unspecified type, not stated as uncontrolled	X	X
250.21 Diabetes with hyperosmolarity, Type I, not stated as uncontrolled	X	X
250.22 Diabetes with hyperosmolarity, Type II or unspecified type, uncontrolled	X	X
250.23 Diabetes with hyperosmolarity, Type I, uncontrolled	X	X
250.30 Diabetes with other coma, Type II or unspecified type, not stated as uncontrolled.		
250.31 Diabetes with other coma, Type I, not stated as uncontrolled	X	X
250.32 Diabetes with other coma, Type II or unspecified type, uncontrolled	X	X
250.33 Diabetes with other coma, Type I, uncontrolled	X	X
250.40 Diabetes with renal manifestations, Type II or unspecified type, not stated as uncontrolled	X	X
250.41 Diabetes with renal manifestations, Type I, not stated as uncontrolled	X	X
250.42 Diabetes with renal manifestations, Type II unspecified type, uncontrolled	X	X
250.43 Diabetes with renal manifestations, Type I, uncontrolled	X	X
250.50 Diabetes with ophthalmic manifestations, Type II or unspecified type, not stated as uncontrolled	X	X
250.51 Diabetes with ophthalmic manifestations, Type I, not stated as uncontrolled	X	X
250.52 Diabetes with ophthalmic manifestations, Type II or unspecified type, uncontrolled	X	X
250.53 Diabetes with ophthalmic manifestations, Type I, uncontrolled	X	X
250.60 Diabetes with neurological manifestations, Type II or unspecified type, not stated as uncontrolled	X	X
250.61 Diabetes with neurological manifestations, Type I, not stated as uncontrolled	X	X
250.62 Diabetes with neurological manifestations, Type II or unspecified type, uncontrolled	X	X
250.63 Diabetes with neurological manifestations, Type I uncontrolled	X	X
250.70 Diabetes with peripheral circulatory disorders, Type II or unspecified type, not stated as uncontrolled	X	X
250.71 Diabetes with peripheral circulatory disorders, Type I, not stated as uncontrolled	X	X
250.72 Diabetes with peripheral circulatory disorders, Type II or unspecified type, uncontrolled	X	X
250.73 Diabetes with peripheral circulatory disorders, Type I, uncontrolled	X	X
250.80 Diabetes with other specified manifestations, Type II or unspecified type, not stated as uncontrolled ...	X	X
250.81 Diabetes with other specified manifestations, Type I, not stated as uncontrolled	X	X
250.82 Diabetes with other specified manifestations, Type II or unspecified type, uncontrolled	X	X
250.83 Diabetes with other specified manifestations, Type I, uncontrolled	X	X
250.90 Diabetes with unspecified complication, Type II or unspecified type, not stated as uncontrolled	X	X
250.91 Diabetes with unspecified complication, Type I, not stated as uncontrolled	X	X
250.92 Diabetes with unspecified complication, Type II or unspecified type, uncontrolled	X	X
250.93 Diabetes with unspecified complication, Type I, uncontrolled	X	X
Principal or Secondary Diagnosis Code:		
585 Chronic renal failure	X	X
403.01 Hypertensive renal disease, malignant, with renal failure	X	X
403.11 Hypertensive renal disease, benign, with renal failure	X	X
403.91 Hypertensive renal disease, unspecified, with renal failure	X	X
404.02 Hypertensive heart & renal disease, malignant, with renal failure	X	X
404.03 Hypertensive heart & renal disease, malignant, with congestive heart failure and renal disease	X	X
404.12 Hypertensive heart & renal disease, benign, with renal failure	X	X
404.13 Hypertensive heart & renal disease, benign, with congestive heart failure and renal disease	X	X
404.92 Hypertensive heart & renal disease, unspecified, with renal failure	X	X
404.93 Hypertensive heart & renal disease, unspecified, with congestive heart failure and renal failure	X	X
V42.0 Organ or tissue replaced by transplant, kidney	X	X
V43.89 Organ or tissue replaced by other means, other (Kidney)	X	X
Procedure Code:		
52.80 Pancreatic transplant, not otherwise specified		X
52.82 Homotransplant of pancreas		X
Combination Procedure Codes:		
52.80 Pancreatic transplant, not otherwise specified, plus		
55.69 Other kidney transplantation	X	
or		
52.82 Homotransplant of pancreas plus		
55.69 Other kidney transplantation	X	

The logic for the proposed DRG 512 accepts the pair of diagnosis codes in any position (principal/secondary or secondary/secondary). The pair of procedure codes must be present along with the two diagnosis codes. This DRG would be placed in the Pre-MDC GROUPER logic immediately following DRG 480 (Liver Transplant).

The logic for DRG 513 accepts the pair of diagnosis codes in any position (principal/secondary or secondary/secondary). Only one procedure code must be used along with the two diagnosis codes. This DRG would be placed in the Pre-MDC GROUPER logic immediately following proposed new DRG 512 (Simultaneous Pancreas/Kidney Transplant).

b. Intestinal Transplantation

Effective April 1, 2001, Medicare covers intestinal transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure (Medicare Program Memorandum Transmittal No. AB-00-130, December 22, 2000). This procedure is covered only when performed for patients who have failed total parenteral nutrition (TPN) and only when performed in centers that meet approval criteria.

Intestinal failure is defined as the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome. Intestinal failure prevents oral nutrition and may be associated with both mortality and profound morbidity.

If an intestinal transplantation alone is performed on a patient with an intestinal principal diagnosis, the case would be assigned to either DRG 148 (Major Small & Large Bowel Procedures With CC) or DRG 149 (Major Small & Large Bowel Procedures Without CC). If an intestinal transplantation and a liver transplantation are performed simultaneously, the case would be assigned to DRG 480 (Liver Transplant).

If an intestinal transplantation and a pancreas transplantation are performed simultaneously, currently the case would be assigned to either DRG 148 or DRG 149. As we have proposed in section II.B.12.A. of this proposed rule, effective October 1, 2001, the case would be assigned to DRG 513 (Pancreas Transplant). We are proposing to make a conforming change to the regulations at § 412.2(e)(4) and § 486.302 to include intestines (and multivisceral organs) in the list of organs for which Medicare pays for the acquisition costs on a reasonable cost basis.

Effective October 1, 2000, procedure code 46.97 (Transplant of intestine) was

created. We have examined our Medicare claims data to determine whether it is appropriate to propose a new intestinal transplant DRG. We examined 100 percent of the data in the FY 2000 MedPAR file containing bills submitted through May 31, 2000. Therefore, we focused our examination on the previous code assignment for intestinal transplant, code 46.99 (Other operations on intestines), and facilities that are currently performing intestinal transplantation. We were able to identify only one case, with an average charge of approximately \$10,738 as compared to the average standardized charges for DRGs 148 and 149, which are approximately \$37,961, and \$16,965, respectively. We will continue to monitor these cases to determine whether it may be appropriate in the future to establish a new DRG.

C. Recalibration of DRG Weights

We are proposing to use the same basic methodology for the FY 2002 recalibration as we did for FY 2001 (August 1, 2000 final rule (65 FR 47069)). That is, we would recalibrate the weights based on charge data for Medicare discharges. However, we propose to use the most current charge information available, the FY 2000 MedPAR file. (For the FY 2001 recalibration, we used the FY 1999 MedPAR file.) The MedPAR file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills.

The proposed recalibrate DRG relative weights are constructed from FY 2000 MedPAR data (discharges occurring between October 1, 1999 and September 30, 2000), based on bills received by HCFA through December 31, 2000, from all hospitals subject to the prospective payment system and short-term acute care hospitals in waiver States. The FY 2000 MedPAR file includes data for approximately 11,008,302 Medicare discharges.

The methodology used to calculate the proposed DRG relative weights from the FY 2000 MedPAR file is as follows:

- To the extent possible, all the claims were regrouped using the proposed DRG classification revisions discussed in section II.B. of this preamble. As noted in section II.B.8., due to the unavailability of the revised GROUPER software, we simulated most major classification changes to approximate the placement of cases under the proposed reclassification. However, there are some changes that cannot be modeled.

- 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.

- 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. 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 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 HCFA 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 proposed new DRGs 512 (Simultaneous Pancreas/Kidney Transplant) and 513 (Pancreas Transplant). Because these costs are paid separately from the prospective payment rate, it is necessary to make an adjustment to prevent the relative weights for these DRGs from including the acquisition costs. 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 propose to use that same case threshold in recalibrating the DRG weights for FY 2002. Using the FY 2000 MedPAR data set, there are 39 DRGs that contain fewer than 10 cases. We computed the weights for these 39 low-volume DRGs by adjusting the FY 2001 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 (1.44813) 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, and accounts for the gradual shift in cases toward higher-weighted DRGs over time.

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 payment to hospitals is affected by factors other than average case weight. Therefore, as we have done in past years and as discussed in section II.A.4.b. of the Addendum to this proposed rule, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

D. Incorporating New Medical Services and Technologies in the Inpatient Hospital Prospective Payment System

Much attention recently has focused on how well Medicare incorporates the cost of new medical services and technologies into its payment systems. Of particular concern is the adequacy of Medicare's payment systems in facilitating access to new technologies for Medicare beneficiaries. Section 533 of Public Law 106-554 directs the Secretary to develop a mechanism for ensuring adequate payment under the hospital inpatient prospective payment system for new medical services and technologies, and to report to Congress on ways to more expeditiously

incorporate new services and technologies into that system. This discussion addresses the requirements of section 533 of Public Law 106-554.

1. Overview

Medicare payment for an inpatient hospital discharge under the inpatient prospective payment system is determined by multiplying the relative weight associated with a particular DRG by the national average standardized amount (adjusted for other hospital characteristics such as a geographic wage index, teaching status, and treating a high percentage of low-income patients). Cases are classified into DRGs for payment under the 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). The DRG relative weights are recalculated each year to reflect the average resources expended across all hospitals to treat patients within a particular DRG.

In general, the inpatient prospective payment system makes payments for new medical services and technologies as soon as these items are payable. New items or services generally fit within existing DRGs, and hospitals using these items and services will be paid at established payment rates for the applicable DRGs. Payment rates may subsequently be adjusted through the annual process of evaluating the assignment of cases within DRGs and recalculating the relative weights associated with each DRG based on average charges. These annual changes are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

Since the prospective payment system was first implemented in October 1983, the pace of innovation in medical technology has been rapid. Generally speaking, the system appears to have accommodated these innovations without occasioning significant concerns regarding access to new technologies. In its March 2001 report to the Congress, the Medicare Payment Advisory Commission stated "the design of the inpatient PPS (prospective payment system) makes it easier to ensure an appropriate distribution of payments while accommodating technological advances" (page 44).

2. Current Practice—Coding and Payment

A number of issues arise relating to present methods of incorporation of new technologies in the inpatient hospital prospective payment system. One issue is the appropriate ICD-9-CM code to be assigned to the new technology. This issue is discussed in detail below. Assuming the new technology is or can be covered by Medicare, a determination must be made concerning to which DRG should the new technology be assigned. The DRG (and the value of the relative weight associated with that DRG) to which the new technology is assigned determines the payment rate for the new technology. Under the DRG system, the condition of the patient is the primary consideration in the decision to assign a new technology to a DRG. Therefore, a new technology generally will be assigned to the same DRG as the DRG's predecessor technologies and treatment modalities. In this way, hospitals can receive payment for new technology under the inpatient hospital prospective payment system quickly. As use of the new technology diffuses among hospitals, HCFA will gradually and largely automatically recalibrate 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 recalibrated DRG weights. Considering the actual costs as reflected in the claims data, HCFA may also reassign new technologies to different DRGs. However, because a new technology is often more costly initially than the predecessor technologies, the adequacy of the initial payment rate occasionally becomes an issue.

At present, if payment is to be made other than by routine assignment of the new technology to an existing DRG, it is necessary to establish a new ICD-9-CM code. The lag between application for a new code and its being made effective for payment is at least a year. Because we use actual charge data from hospitals, additional costs or savings from the new technology are not reflected in the DRG weight for 2 years after a new code is effective. For example, the costs or savings attributable to any new technologies that were assigned new ICD-9-CM codes effective October 1, 1999, will be reflected in the DRG relative weights effective for discharges on or after October 1, 2001.

The lag before new technology affected payment has been viewed by some observers as a useful check on payment changes, helping to ensure that

these changes reflect the benefit of a new technology. Hospitals would adopt and utilize the new technology, it was reasoned, with a speed and to a degree commensurate with its medical advantages. Any differences in the resource requirements between the new and existing technologies would then be reflected over time in claims data and in changes in the DRG weights. To the extent particular new technologies may have been initially given relatively low payment, the design of the system provided incentives to compensate by achieving efficiencies elsewhere. Conversely, if a particular new technology reduced costs compared to existing technologies, hospitals would reap the payment benefits until such time as the DRG weights began to reflect the lower costs.

3. Current Practice—Data

Recently, HCFA provided an explicit avenue to permit more rapid payment adjustment through use of additional data. The Conference Report that accompanied the Balanced Budget Act of 1997 (Public Law 105–33) stated that “in order to ensure that Medicare beneficiaries have access to innovative new drug therapies, the conferees believe that HCFA should consider, to the extent feasible, reliable, validated data other than Medicare Provider Analysis and Review (MedPAR) data in annually recalibrating and reclassifying the DRGs” (H.R. Conf. Rep. No. 105–217, 105th Cong., 1st Sess., at 734 (1997)). The MedPAR contains records for all Medicare hospital discharges and is the source data used for DRG recalibration. Although we had never precluded the use of non-MedPAR data, we established an explicit process for the submission of such data in a manner consistent with the annual recalibration of the DRG weights. We stated in the July 30, 1999 **Federal Register** that, in the case of external data, a significant sample of the data should be submitted by August 1, approximately 8 months prior to the publication of the proposed rule. This would allow us to verify and test the data and make a preliminary assessment as to the feasibility of the data’s use (64 FR 41499). Subsequently, a complete database must be submitted no later than December 1, approximately 4 months prior to the publication of the proposed rule. On the issue of the use of sample data, we stated in the **Federal Register** that we were not establishing specific criteria regarding sample sizes or data collection methodologies prior to gaining experience that would enable us to realistically reflect the availability of external data based on actual

experience. We also encouraged anyone interested in submitting such data in the future to contact us to discuss the specific data they wish to submit and whether the data may be adequate.

4. New Legislation

Section 533 of Public Law 106–554 addresses the issue of how new technologies are introduced into the DRGs, and how DRG payment rates must be adapted to accommodate them. Specifically, the provision requires that the Secretary:

- Not later than April 1, 2001, submit a report to Congress on methods of expeditiously incorporating new medical services and technologies into the clinical coding system.
- Not later than October 1, 2001, implement the preferred methods described in the report.
- Effective October 1, 2001, establish a mechanism to recognize the costs of new medical services and technologies after notice and opportunity for public comment.
- Establish criteria to identify new medical services or technologies after notice and an opportunity for public comment.

5. DRG Assignment Issues

As background for discussion of how the DRGs should be changed to better accommodate new technology, this section will discuss the rationale for basing the initial DRG assignment on patient condition. The underlying assumption of the prospective payment system is that because hospitals are responsible for the delivery of care they can respond to the incentives to control costs inherent in the system. The success of any payment system that is predicated on providing incentives for cost control is almost totally dependent on the effectiveness with which the incentives are communicated. The DRGs were designed to be a management tool that is used also as the basis for prospective payments. The key distinction between a management tool and payment method is the ability of the hospital to use the information to take action in response to the incentives in the system. Thus, a management tool communicates information in a form and at a level of detail that can lead to specific actions. The effectiveness of any incentive-based payment system is enhanced if the payment method is simultaneously a management tool.

Because the DRGs were developed to group clinically similar patients, an extremely important means of communication between the clinical and financial aspects of care was created. DRGs provided administrators

and physicians with a meaningful basis for evaluating both the process of providing care and the associated financial impacts. Development of care pathways by DRG and profit-and-loss reports by DRG product lines became commonplace. With the adoption of these new management methods, length of stay and the use of ancillary services dropped dramatically.

The DRGs not only provided a communications tool for hospital management, but they also provided an effective means for hospitals and Medicare to communicate. Instead of accountants and lawyers arguing the fine points of cost accounting, the focus of payment deliberations became the determination of a fair payment rate for patients with specific clinical problems. The vast majority of modifications to the DRGs since the inception of the Medicare inpatient hospital prospective payment system have resulted from recommendations from hospitals. The recommendations have almost always been the result of clinicians identifying specific types of patients with unique needs. A recent example of such a clinical dialogue relates to the DRGs for burns. The FY 1999 update to the DRGs included a major restructuring of the burn DRGs. This restructuring was the direct result of detailed and specific clinical recommendations provided to HCFA by burn specialists.

Central to the success of the Medicare inpatient hospital prospective payment system is that DRGs have remained a clinical description of why the patient required hospitalization. We believe it would be undesirable to transform DRGs into detailed descriptions of the technology and processes used by the hospital to treat the patient. If such a transformation were to happen, the DRGs would become largely a repackaging of fee-for-service without the management and communication benefits. A fundamental assumption underlying 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. The separation of the clinical and payment weight methodologies allows a stable clinical methodology to be maintained while the payment weights evolve in response to changing practice patterns. The packaging of all services associated with the care of a particular type of patient into a single payment amount provides the incentive for efficiency inherent in a DRG-based prospective payment system. Substantial disaggregation of the DRGs

into smaller units of payment, or a substantial number of cases receiving extra payments, would undermine the incentives and communication value in the DRG system.

6. Coding Issues

To permit us to identify use of a new technology on hospital claims and hence to make different payments than would otherwise be applicable, we would require a code that can be used to specify when that technology is used.

a. Process for Establishing New Codes

The ICD-9-CM Coordination and Maintenance Committee is responsible for discussing potential changes to ICD-9-CM. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS) and HCFA. The NCHS has lead responsibility for the ICD-9-CM diagnosis codes, while HCFA has lead responsibility for the ICD-9-CM procedure codes. The committee holds meetings twice a year, usually in May and November. Agendas for the discussions about procedure codes are published on HCFA's Internet website a month before the meeting. A **Federal Register** notice is also published listing topics to be discussed. The meetings are open to the public and are held usually in Baltimore, Maryland. Shortly afterwards, an extensive summary of the meeting is published on HCFA's website and the public is given an additional opportunity to comment. Final comments are due by early January. A complete, current timeline is included in the Summary Report of the Committee at: www.hcfa.gov/medicare/icd9cm.htm.

For a topic to be discussed at one of the two yearly meetings of the committee, the committee must receive a request 2 months prior to the meeting. This timeframe allows HCFA to publish the agendas in the **Federal Register** notices and allows individuals and organizations to review the agenda and to determine if they wish to attend the public meetings. The timeframe is also necessary to allow the committee to research the topic and prepare a draft solution in time for the meeting. During the meetings, the committee provides a brief description of the topic (such as a new technology that may not be adequately identified by the current code) and then describes the technology or procedure through a formal presentation. Frequently, medical experts who perform the procedure make a presentation to describe the procedure and how it might be different from other procedures in the current code. Proposals are made to either

continue capturing the procedure in the existing code, revise existing codes, or create a new code. The public then discusses the merits of the proposals and offers any alternate suggestions.

The ICD-9-CM is updated once a year, effective October 1. This date coincides with the annual updates to the DRGs within the inpatient hospital prospective payment system. Each spring HCFA publishes a proposed rule that includes proposed changes to the inpatient hospital prospective payment system. This notice also includes final decisions on changes to ICD-9-CM codes. By August 1, HCFA publishes the new codes in the Addendum to the final rule, which is a technical presentation of actual changes to be made in both the index and tabular sections of the ICD-9-CM coding books. The Addendum is available on HCFA's website and is also sent to organizations such as the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) to distribute to their members. By October 1 of each year, the Department of Health and Human Services also produces a CD-ROM version of the ICD-9-CM, which may be purchased at the Government Printing Office. Since the ICD-9-CM is not a copyrighted system, many publishers and organizations distribute and sell books or other publications that include the changes to ICD-9-CM.

Although the committee's process for discussing proposed changes to the ICD-9-CM fully involves and informs the public, the deliberative nature of the process does require some time. Topics discussed at the May and November 2000 meetings of the Committee are for changes to ICD-9-CM in October 2001. Therefore, depending on whether a request is considered at the May or November meeting, resulting changes may not be effective for approximately a year to a year-and-a-half later.

b. Options To Expedite the Implementation of Coding Changes

Several constraints upon the system would complicate implementing extensive changes. One significant complication is the interaction between the DRG system and the ICD-9-CM diagnosis and procedure codes (in the case of new services and technologies, the discussion focuses on procedure rather than diagnosis codes). When a new procedure code is created, a decision must be made as to whether the new code affects DRG assignment (for example, resulting in a case being assigned to a surgical rather than a medical DRG). Currently, new technology is generally assigned to the

same DRG as its predecessor codes. Even if new codes do not affect DRG assignment, the GROUPER software (used to assign cases to DRGs) must be reprogrammed to recognize and classify all the new codes. This is necessary to allow Medicare's claims processing systems to process the claim.

In addition to the changes to the GROUPER software, implementing changes to ICD-9-CM codes is a detailed and far-reaching process involving modifications to code books and software coding systems, as well as changes to hospitals' claims processing systems. As described above, the current process is organized around the annual publication of coding changes in the **Federal Register** as part of the updates and changes to the inpatient hospital prospective payment system. The changes are made available during the summer, and communicated via multiple channels to hospitals. This process allows for the necessary processing changes to be thoroughly tested prior to implementation, both by HCFA and by the hospitals. This testing procedure is essential given the volume (generally 11 million claims annually) and dollar impact (approximately \$75 billion during FY 2001) of Medicare inpatient discharges.

Another important issue when considering expediting the process of making coding changes is that 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 (section 1886(d)(4)(C)(iii) of the Act). If ICD-9-CM changes were made at multiple times during the year, the budget neutrality requirement would mean the standardized amounts, and potentially the cost outlier thresholds, would change as well. These changes would compromise the prospective nature of the payment system, whereby hospitals are able to project their revenues for the year and plan accordingly. Because we do not believe the requirement in section 533 of Public Law 106-554 to explore ways to expedite coding changes was intended to disrupt the prospective nature of the payment system, we did not consider options that would require revising the DRG weights and the standardized amounts more than once a year.

With these considerations in mind, we explored the potential for shortening the current process.

First, we are proposing to move the November meeting of the Coordination and Maintenance Committee to December without significant disruption. To move it further would

disrupt the process for production of the annual inpatient prospective payment system regulation. This step would shorten the code assignment process by a month and permit coding changes resulting in payment changes to be implemented in a year.

Second, we are proposing to expedite the process by issuing new coding decisions resulting from the spring meeting of the Committee (currently in May) that would be effective the following October 1. It may be necessary to move the May meeting to April to accommodate this procedure. Because the timing of this process would not allow the coding changes to be incorporated into the proposed rule published in the spring, cases with the new codes would have to be assigned to the same DRG to which they would have been assigned without the new code and no other payment adjustments would be possible. These coding changes would thus not affect the DRG weights or the budget neutrality calculations. However, more rapid introduction of new codes would permit reflection of the codes in claims data more quickly, and thus would permit eventual adjustment of payment rates sooner than otherwise possible. This capability could be of particular use where otherwise available data were not sufficient to support an immediate payment change, because hospital claims data permitting identification of use of the new technology would be available more quickly.

This change would reduce the time between discussion of a proposed code and its implementation from a minimum of 11 months to 6 months. It would allow for the collection of MedPAR data a full year earlier than under the current process, providing the possibility that DRG revisions based on new codes could be expedited by up to 1 year.

There would be significant challenges to making this proposed process work. Because the changes would not be published in the proposed rule, the public would be given less opportunity to consider the merits of the proposals, and it would have to either attend the spring meeting of the Committee or respond to the summary report within a few weeks. The decisions from the spring meeting must be finalized by the middle of June in order for us to include the changes in the Addendum of the final rule and in order to make changes in the GROPER software to be effective October 1; it may be necessary to schedule the spring meeting earlier to meet this deadline. The opportunity to solicit additional input from industry groups and experts would be curtailed

because of the short time lines. There would be an increased risk of errors related to revisions in the procedure code index (a manual process performed by HCFA), as there would be less time available to review and revise the procedure index to ensure that all changes are accurately reflected.

For example, we are creating a new procedure code to capture percutaneous gastrojejunostomy (code 44.32). All coding instructions (indexing, inclusion terms, and exclusion terms) must be verified so that the procedure is appropriately indexed. If one of the many index entries for gastrojejunostomy is not correctly updated, percutaneous gastrojejunostomy would be assigned to another gastroenterostomy (code 44.39), which is an operating room procedure. This can have a significant impact on national health care data. Coders at different hospitals may follow different entries and arrive at different codes. To limit the potential for confusion in the hospital and coding communities resulting from two separate schedules for implementing code changes, we would limit these changes to those that meet our definition of new technology eligible for special treatment as proposed below. It would not be necessary, however, to demonstrate that the cases involving the new technology would be inadequately paid, since there would be no payment impacts of these changes.

The changes would be included in the Addendum of the proposed rule for the inpatient hospital prospective payment system, and placed on the website for use by the industry in updating books and software systems. They also would be published in the final rule, and included in the CD-ROM version of ICD-9-CM that is distributed by the Government Printing Office. We are requesting public comments on this proposal.

c. Limitations of ICD-9-CM

While the updating process currently in use may not lend itself to expeditiously incorporating new medical services and technologies into the ICD-9-CM coding system, another important factor is the dated and limited structure of the ICD-9-CM system. The ICD-9-CM system was developed in the 1970s and implemented in 1979. Dramatic advances have occurred in medicine since that time. Although the ICD-9-CM Coordination and Maintenance Committee has attempted to make coding modifications to capture new technology, it has sometimes been difficult to achieve a reasonable result.

The ICD-9-CM procedure codes are made up of four digits: two numerical characters followed by a decimal, and then two additional numerical characters. The first two digits indicate a category, such as 36—Operations on the vessels of the heart. The third digit provides additional breakdown, such as 36.0—Removal of coronary artery obstruction and insertion of stents. When the fourth digit is added, the code is fully described. There are only 10 codes available within each category (fourth digits 0–9). Once a category is full, we must either combine types of similar procedures under one code, or find a place in another section of the codebook for a new code. The benefit of such a system is that we can collapse the codes into categories when analyzing claims data to capture a wide range of similar procedures. However, if similar codes are placed in separate sections of the code book, coders may not easily find them. Errors may occur when trying to identify particular types of cases when codes are not carefully placed within a system such as the current ICD-9-CM.

ICD-9-CM is 22 years old and the premises on which the coding system was established are dated. A number of approaches and techniques used for procedures such as lasers and the use of scopes were not anticipated when the structure of ICD-9-CM was developed. Consequently, the basic categories were established on technology that is now outdated. Making needed coding changes each year has been quite difficult and involves making compromises that effect the precision of the coding.

d. Short-Term Solutions Within the ICD-9-CM Structure

To consider how we might better respond to requests for new codes in the short term, we examined ICD-9-CM to attempt to identify an open series of codes that could be used for new procedures and technologies. There are currently 16 chapters of procedure codes. However, codes 17.00 through 17.99 are not in use. These codes are found between Chapter 3, "Operations on the Eye," and Chapter 4, "Operations on the Ear." This series of 100 codes could be used to provide codes for new procedures and technology. To fully utilize this new series of codes, we would assign new procedures to the next available code.

A limitation of this approach would be that this new chapter would capture a diverse group of procedures potentially affecting all body systems. Assigning procedure codes to this new chapter would undoubtedly create

considerable confusion for coders. Currently, procedures are grouped by body system, and similar procedures are placed in categories. This arrangement assists the coder in choosing the most appropriate code because he or she can quickly review closely related codes that are together. Using Chapter 17 for new technology codes, on the other hand, would mean that closely related codes would be widely separated.

Use of Chapter 17 would also require a major revision of coding rules since coders are taught to identify codes within a group of similar procedures. They are not accustomed to looking for a list of unrelated procedures in a separate section of the coding book.

To supplement the Chapter 17 codes, the Coordination and Maintenance Committee may be able to assign vacant codes in other chapters. However, large numbers of sequences are already fully or nearly fully occupied, and this strategy would only provide limited availability of new codes.

e. Alternative Short-Term Approaches

Some observers have expressed concern that the additional codes available within the ICD-9-CM code set may not be adequate to accommodate both routine changes in coding and the new technologies under consideration here, particularly if a long-term change, such as adoption of ICD-10-PCS, is significantly delayed. We have examined several alternative short-term options in the event the additional available codes are used before a long-term solution is reached. In evaluating these alternatives, one must consider the changes each entails to hospitals' and HCFA's coding and claims processing systems, and the time necessary to implement such changes (balanced against the timeframe for adopting a long-term coding solution).

Expanding ICD-9-CM procedure codes by making them alphanumeric or adding a fifth digit would make available a substantial number of new codes for new technology but would require substantial system changes and create standards issues. This approach was extensively discussed in meetings of the ICD-9-CM Coordination and Maintenance Committee prior to the development of ICD-10-PCS. Input from the public indicated that such a significant modification to a limited and dated system would only make the system worse. The time it would take to make this system work well would be longer than that required to build a new system and the resources needed for system changes would be significant. Such a modification of the ICD-9-CM standard code set would require the

formal standards setting process prescribed by the regulations implementing the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). We solicit comments from the public about the desirability of pursuing expansion and modification of the ICD-9-CM standards for this purpose.

Using the V-code section of ICD-9-CM diagnosis codes to report new technology would not require any systems changes or create any standards issues and would create a moderate number of codes for new technology. We have discussed this recommendation with NCHS. NCHS opposed this option as an inappropriate use of diagnosis codes. While "V" codes are used for the classification of factors influencing health status and contact with health services, they are not a substitute for procedure coding. By adding procedure coding concepts to the diagnosis coding system, confusion could easily lead to increased errors. Furthermore, the V-code section has only a limited number of available spots.

We also considered using HCFA Common Procedure Coding System (HCPCS) codes to report use of new technology for inpatient cases. However, using HCPCS would require a moderate amount of systems change and may require the formal standards setting process prescribed by Public Law 104-191, since the HCPCS code set is not the standard for inpatient services. However, it would make a substantial number of codes available for new technology. Alphanumeric HCPCS codes are currently used in outpatient departments and physician offices for reporting services, and they are used on a limited basis by hospitals in reporting specific inpatient services. For instance, alphanumeric HCPCS codes are used for reporting the use of hemophilia clotting factors used during an inpatient stay.

Use of HCPCS codes would require that a new service or technology either be assigned a code through otherwise applicable processes for HCPCS coding or that HCFA assign a specific, temporary code for use in connection with new technology payments for inpatient hospital services. Specifically assigned codes could be assigned relatively quickly. However, use of such codes would run the risk of confusion if other codes were assigned to the same service or items when used in other settings. More generally, HCPCS coding would duplicate information found in the ICD-9-CM procedure codes. Careful attention to integration of coding across the two systems would be necessary, and dissemination of information about

correct coding to hospital coders would present challenges. Even with excellent integration and dissemination, the risk of confusion by hospital coders would be high.

The use of HCPCS codes would also raise questions on how the accuracy of claims data will be assessed. HCFA contracts with Peer Review Organizations (PROs) to validate the accuracy of coded data. Consideration would need to be given to how the accuracy of these data could be verified. If two separate coding systems with overlapping information are used, considerable variations in reporting practices might arise.

Similar to the option of using alphanumeric ICD-9-CM procedure codes, changes in systems and in hospital coding procedures that would be associated with this approach would take time and resources to implement for hospitals, HCFA, and potentially other payers such as Medicare secondary insurers.

In recognition of these considerations, we do not propose to proceed with use of HCPCS codes for this purpose at the present. We believe this possibility should be revisited later if the ICD-9-CM codes in fact prove inadequate and if a longer term solution is not yet available. However, we are encouraging public comments on the concept of using HCPCS codes to identify specific new technologies on inpatient hospital claims.

f. Development of ICD-10-PCS; A Possible Long-Term Solution

While acknowledging the limitations of the ICD-9-CM system, the Secretary designated the ICD-9-CM system as the national standard in a final rule in the **Federal Register** on August 17, 2000 (65 FR 50311) following notice and comment rulemaking in accordance with Public Law 104-191. In that same final rule, the public was advised that there would be a need in the near future to replace this dated coding system with a system that could better capture today's health care information. At that time, work was proceeding on an updated variant of the ICD system, ICD-10, that could replace ICD-9-CM, but this system was not yet completed. The World Health Organization developed ICD-10 as an international diagnosis coding system. NCHS has been modifying ICD-10 to replace the diagnosis section of ICD-9-CM. This system is being referred to as ICD-10-CM. At the same time, HCFA has been developing the ICD-10-Procedure Coding System (ICD-10-PCS) as a possible replacement for the ICD-9-CM procedure codes.

Criteria for the development of a new procedure coding system were established by the National Committee on Vital and Health Statistics (NCVHS). The criteria included the following:

- Completeness—all substantially different procedures have a unique code.
- Expandability—the structure of the system allows incorporation of new procedures and technologies as unique codes.
- Standardized terminology—the coding system includes definitions of the terminology used. While the meaning of the specific words can vary in common usage, the coding scheme does not include multiple meanings for the same term. Each term is assigned a specific meaning.
- Multiaxial—the system has a multiaxial structure with each code character having the same meaning within the specific procedure section and across procedure sections to the extent possible.
- Diagnostic information is not included in the procedure description.

The ICD-10-PCS was developed using these criteria by HCFA through a contract with 3M Health Information Systems. The ICD-10-PCS system provides much greater code capacity because all substantially different procedures have a unique code. While the ICD-9-CM procedure coding system is limited to a maximum of 10,000 codes, the current draft of ICD-10-PCS contains 197,769 codes and the number could be expanded further.

g. Public Meeting on Implementing ICD-10-PCS

The Department of Health and Human Services is starting the process of soliciting public comments on whether it should proceed to adopt ICD-10-PCS as the national standard for coding inpatient hospital services to replace ICD-9-CM procedures. A public meeting on this issue has been scheduled for May 17, 2001, in the HCFA Auditorium in Baltimore, Maryland. Information on this meeting can be found in the Summary Report of the November 2000 meeting of the ICD-9-CM Coordination and Maintenance Committee at: www.hcfa.gov/medicare/icd9cm.htm. The public is encouraged to attend and participate in the discussion on whether ICD-10-PCS should become a national standard. Organizations and groups will be given the opportunity to make a brief presentation on their members' behalf. Groups wishing to be scheduled to present should contact Pat Brooks, HCFA, at (410) 786-5318. This meeting will begin the process of evaluating

ICD-10-PCS as a future national standard.

h. Proposed Methods of Expediently Incorporating New Medical Services and Technologies Into the Coding System

In summary, we are proposing a two-part strategy for expediently incorporating new medical services and technologies into the clinical coding system used with respect to payment for inpatient hospital services. First, we are proposing to shorten the timeframe for implementing new codes by processing changes that do not have payment implications without first publishing them in the proposed rule in the spring. This means new codes approved at the spring meeting of the ICD-9-CM Coordination and Maintenance Committee could be implemented by October of the same year. We also are proposing to move the November meeting to December. These proposed changes would reduce the time it currently takes to implement new codes, as well as reduce the time required to collect data through the MedPAR by up to a year in many cases.

Second, to make more codes available to identify new technology, we will immediately begin to work with the public to use Chapter 17 of ICD-9-CM procedures. This will provide room for 100 additional procedure codes. We also will continue the current process of adding and revising codes within the current chapters as room and structure allow. Our long-range strategy is to consider the implementation of ICD-10-PCS as a replacement system for ICD-9-CM. However, because of the need to address any such change through notice and public rulemaking procedures (a proposed and final rule), in addition to the need to revise both our payment systems and those of hospitals, this could occur no earlier than October 2003.

7. New Requirements Relative to New Services and Technologies

Section 533 of Public Law 106-554 addresses the process by which new technologies and services are introduced into the DRGs and how DRG payment rates are to be adapted to accommodate them. Section 533(b) added new section 1886(d)(5)(K) to the Act, which specifies that the Secretary must establish criteria to use to identify a new technology after notice and an opportunity for public comment. Under new section 1886(d)(5)(K)(ii)(I) of the Act, effective for discharges occurring on or after October 1, 2001, the Secretary is required to apply a mechanism to recognize the costs of

new technologies if, "based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate." Further, new section 1886(d)(5)(K)(v) stipulates that the requirement for an additional payment for a new medical service or technology may be satisfied by means of "an add-on payment, a payment adjustment, or any other similar mechanism for increasing the amount otherwise payable with respect to a discharge under this subsection." Section 533(b) also added a new section 1886(d)(5)(L) to the Act which states that the requirement for an additional payment for a new medical service or technology may also be met through establishing "new-technology groups into which a new medical service or technology will be classified."

In section IV.F. of this preamble, we are setting forth, for public comment, our policy proposals to implement section 1886(d)(5)(K) of the Act, as added by section 533(b) of Public Law 106-554. In summary, the proposed policies include—

- Proposed criteria for identifying new medical services and technologies for additional payments beyond the DRG prospective payment system payment.
- The proposed methodology for determining the adequacy of current payments for new services and technology.
- The proposed methodology for determining the amount of the additional payment and for payment mechanism for new medical services and technologies.

III. Proposed Changes to the Hospital Wage Index

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts "for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level." In accordance with the broad discretion conferred under the Act, we currently define hospital labor market areas based on the definitions of Metropolitan Statistical Areas (MSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs) issued by the Office of Management and Budget

(OMB). The 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.

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.

B. FY 2002 Wage Index Update

The proposed FY 2002 wage index values in section V of the Addendum to this proposed rule (effective for hospital discharges occurring on or after October 1, 2001 and before October 1, 2002) are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 1998 (the FY 2001 wage index was based on FY 1997 wage data).

The proposed FY 2002 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 2001 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 2001, the proposed wage index for FY 2002 also continues to exclude the direct and overhead salaries and hours for services not paid through the inpatient prospective payment system such as skilled nursing facility (SNF) services, home health services, or other subprovider components that are not subject to the 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 2002 Wage Index Proposal

Because it is used to adjust payments to hospitals under the prospective payment system, the hospital wage index should, to the extent possible, reflect the wage costs associated with the areas of the hospital included under the hospital inpatient prospective payment system. In response to concerns within the hospital community related to the removal, from the wage index calculation, of costs related to graduate medical education (GME) (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), which are paid by Medicare separately from the prospective payment system, the American Hospital Association (AHA) convened a workgroup to develop a consensus recommendation on this issue. The workgroup 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. In keeping with the decision to phase-out costs related to GME and CRNAs, the proposed FY 2002 wage index is based on a blend of

40 percent of an average hourly wage including these costs, and 60 percent of an average hourly wage excluding these costs.

Beginning with the FY 1998 cost reports, we revised the Worksheet S-3, Part II so that hospitals can separately report teaching physician Part A costs on lines 4.01, 10.01, 12.01, and 18.01. Therefore, it is no longer necessary for us to conduct the special survey we used for the FY 2000 and FY 2001 wage indexes (64 FR 41505 and 65 FR 47071).

1. Health Insurance and Health-Related Costs

In the August 1, 2000 final rule, we clarified our definition of "purchased health insurance costs" and "self-insurance" for hospitals that provide health insurance to employees (65 FR 47073). For purposes of the wage index, purchased or self-funded health insurance plan costs include the hospitals' insurance premium costs, external administration costs, and the share of costs for services delivered to employees.

In response to a comment received concerning this issue, we stated that, for self-funded health insurance costs, personnel costs associated with hospital staff that deliver the services to the employees must continue to be excluded from wage-related costs if the costs are already included in the wage data as salaries on Worksheet S-3, Part II, Line 1. However, after further consideration of this policy, particularly with respect to concerns expressed by our fiscal intermediaries about the level of effort required during the wage index desk review process to ensure hospitals are appropriately identifying and excluding these costs, we are proposing a revision. Effective with the calculation of the FY 2003 wage index, for either purchased or self-funded health insurance, we would allow health insurance personnel costs, associated with hospital staff that deliver services to employees, to be included as part of the wage-related costs. We believe this proposed revised policy will ensure that health insurance costs are consistently reported by hospitals. Health insurance costs would continue to be developed using generally accepted accounting principles.

In the August 1, 2000 final rule (65 FR 47073), we further clarified that health-related costs (including employee physical examinations, flu shots, and clinic visits, and other services that are not covered by employees' health insurance plans but are provided at no cost or at discounted rates to employees of the hospital) may be included as "other" wage-related costs if, among

other criteria, the combined cost of all such health-related costs is greater than one percent of the hospital's total salaries (less excluded area salaries).

For purposes of calculating the FY 2003 wage index (which will be based on data for cost reporting periods beginning in FY 1999), we are proposing to revise this policy to allow hospitals to include health-related costs as allowable core wage-related costs.

2. Costs of Contracted Pharmacy and Laboratory Services

Our policy concerning inclusion of contract labor costs for purposes of calculating the wage index has evolved over the years. We recognize the 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 of direct patient care contract services in the wage index calculation. The FY 1999 wage index included the costs and hours of certain management contract services, and the FY 2000 wage index included the costs for contract physician Part A services. (The 1996 proposed rule (61 FR 27456) provided an in-depth background to the issues related to the inclusion of contract labor costs in the wage index calculation.)

We revised the 1998 cost report to collect the data associated with contract pharmacy, Worksheet S-3, Part II, Line 9.01, and contract laboratory, Worksheet S-3, Part II, Line 9.02. The cost reporting instructions for these line numbers followed that for all contract labor lines; that is, to include the amount paid for services furnished under contract for direct patient care, and not include cost for equipment, supplies, travel expenses, and other miscellaneous or overhead items (Medicare Provider Reimbursement

Manual, Part 2, Cost Reporting Forms and Instructions, Chapter 36, Transmittal 6, page 36-32). Effective with the FY 2002 wage index, which uses FY 1998 wage data, we are proposing to include the costs and hours of contract pharmacy and laboratory.

3. Collection of Occupational Mix Data

Section 304(c) of Public Law 106-554 amended section 1886(d)(3)(E) of the Act to require that the Secretary must 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.

Currently, the wage data collected by HCFA on the cost report reflect the sum of wages, hours, and wage-related costs for all hospital employees. There is no separate collection by occupational categories of employees, such as registered nurses or physical therapists. Total salaries and hours reflect management decisions made by hospitals in terms of how many employees within a certain occupation to employ to treat different types of patients. For example, a large academic medical center may tend to hire more high-cost specialized employees to treat its more acutely ill patient population. The argument is that the higher labor costs incurred to treat this patient population are reflected in the higher case mix of these hospitals, and therefore, reflecting these costs in the wage index is essentially counting them twice.

An occupational mix adjustment can be used to account for hospital management decisions about how many employees to hire in each occupational

category. Occupational mix data measure the price the hospital must pay for employees within each category. A wage index that reflected only these market prices would remove the impact of management decisions about the mix of employees needed and, therefore, better capture geographic variations in the labor market.

We have examined this issue previously. In the May 27, 1994 **Federal Register** (59 FR 27724), we discussed the outcome of consideration of this issue by a hospital workgroup. At that time, the workgroup's consensus was that the data required to implement an occupational mix adjustment were not available and the likelihood of obtaining such data would be minimal. There seemed to be little support among hospital industry representatives for developing a system that would create additional reporting burdens with an unproven or minimal impact on the distribution of payments. Also, in the August 30, 1991 **Federal Register** (56 FR 43219), we stated our belief that the collection of these data would be costly and difficult.

In considering the format to collect occupational mix data, we looked to data currently being collected by the Bureau of Labor Statistics (BLS), which conducts an annual mail survey to produce estimates of employment and wages for specific occupations. This program, Occupational Employment Statistics (OES), collects data on wage and salary workers in nonfarm establishments in order to produce employment and wage estimates for over 700 occupations.

The OES survey collects wage data in 12 hourly rate intervals. Employers report the number of employees in an occupation per each wage range. To illustrate, the wage intervals used for the 1999 survey are as follows:

Interval	Hourly wages	Annual wages
Range A	Under \$6.75	Under \$14,040
Range B	6.75 to 8.49	14,040 to 17,659
Range C	8.50 to 10.74	17,660 to 22,359
Range D	10.75 to 13.49	22,360 to 28,079
Range E	13.50 to 16.99	28,080 to 35,359
Range F	17.00 to 21.49	35,360 to 44,719
Range G	21.50 to 27.24	44,720 to 56,679
Range H	27.25 to 34.49	56,680 to 71,759
Range I	34.50 to 43.74	71,760 to 90,999
Range J	43.75 to 55.49	91,000 to 115,439
Range K	55.50 to 69.99	115,440 to 145,599
Range L	70,000 and over	145,600 and over

It should be noted that this table is for illustrative purposes, and we may

update the data ranges in our actual collection instrument.

Although we initially considered using the OES data, section 304(c) of Public Law 106-554 requires us to

collect data from every short-term, acute care hospital. The OES data are a sample survey and, therefore, as currently conducted, are not consistent with the statutory requirement to include data from every hospital. Another issue with using OES data is that, for purposes of the Medicare wage index, the hospitals' data must be reviewed and verified by the fiscal intermediaries. The OES survey is a voluntary survey.

Although we decided to pursue a separate data collection effort than OES, we propose to model our format after the one used by OES. In this way,

hospitals participating in the OES survey, should have no additional recordkeeping and reporting requirements beyond those of the OES survey.

The OES survey of the hospital industry is designed to capture all occupational categories within the industry. For purposes of adjusting the wage index for occupational mix, we do not believe it is necessary to collect data from such a comprehensive scope of categories. Furthermore, because the data must be audited, a comprehensive list of categories would be excessively burdensome.

In deciding which job categories to include, we reviewed the occupational categories collected by OES and identified those with at least 35,000 hospital employees. Our goal is to collect data from a sample of job categories that provides a valid measure of wage rates within a geographical area. Using this threshold of at least 35,000 employees within a category nationally, we are proposing to collect the number of employees by wage range as illustrated in the above table, for the occupational categories listed below. The following data are based on the 1999 OES survey:

OES code	Category	Employees	Percent of total hospital employees	Mean hourly wage
15008	Medicine and Health Services Managers	93,680	1.9	\$27.38
27302	Social Workers, Medial and Psychiatric	53,360	1.1	16.33
32102	Physicians and Surgeons	125,640	2.6	43.76
32308	Physical Therapists	39,840	0.8	26.14
32502	Registered Nurses	1,231,980	25.0	21.12
32505	Licensed Practical Nurses	206,360	4.2	13.39
32517	Pharmacists	46,860	1.0	28.62
32911, 32928, 32931	Clinical Technologists and Technicians	122,380	2.50	11.69
51002, 55105, 55108, 55305	First-Line Supervisors and Clerical Workers	445,730	9.5	11.39
55332, 55347				
65038, 67002, 67005	Food Preparation Workers and House-keeping	218,440	4.5	8.17
66008	Nursing Aides, Orderlies, and Attendants	301,240	6.2	8.67

We believe this list of occupational categories provides a good representation of the employee mix at most hospitals. Definitions for each occupational category are available on the BLS website at http://stats.bls.gov/oes/1999/oes_alpha.htm.

We have yet to settle on the methodology on how to use the occupational mix index. One option would be to weight each hospital's wage index by its occupational mix index. This requires calculating a national occupational mix index and then breaking it down by MSA and by hospital, similar to how the wage index is broken down. In this way, the wage index would capture geographic differences in wage rates. The decision about how to apply the occupational mix index to the wage index depends on the quality of the data collected, since this effort will be the first time wage and hour data by occupation are collected in this audited manner.

Section 304(c) directs the Secretary to provide for the collection of these data by September 30, 2003, and to apply them in the wage index by October 1, 2004. Therefore, the data are to be incorporated in the FY 2005 wage index. Under our current timetable, the FY 2005 wage index will be based on wage data collected from hospitals' cost

reporting periods beginning during FY 2001. In order to facilitate the fiscal intermediaries' review of these data, we believe the occupational mix data should coincide with the data otherwise used to calculate the cost report. Therefore, we will conduct a special survey of all short-term acute-care hospitals that are required to report wage data to collect these data coinciding with hospitals' FY 2001 cost reports. More specific procedural information regarding this survey will be included in the FY 2002 final rule scheduled to be published by August 1, 2001.

D. Verification of Wage Data From the Medicare Cost Report

The data for the proposed FY 2002 wage index were obtained from Worksheet S-3, Parts II and III of the FY 1998 Medicare cost reports. The data file used to construct the proposed wage index includes FY 1998 data submitted to HCFA as of mid-February 2001. As in past years, we performed an intensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our fiscal intermediaries to revise or verify data elements that resulted in specific edit failures. Some unresolved data elements are included

in the calculation of the proposed FY 2002 wage index pending their resolution before calculation of the final FY 2002 wage index. We have instructed the intermediaries to complete their verification of questionable data elements and to transmit any changes to the wage data no later than April 9, 2001. We expect that all unresolved data elements will be resolved by that date. The revised data will be reflected in the final rule.

Also, as part of our editing process, we removed data for 47 hospitals that failed edits. For 23 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 or are in bankruptcy status. Twenty-four hospitals had incomplete or inaccurate data resulting in zero or negative average hourly wages. Therefore, they were removed from the calculation. The data for these hospitals will be included in the final wage index if we receive corrected data that pass our edits. As a result, the proposed FY 2002 wage index is calculated based on FY 1998 wage data for 4,868 hospitals.

E. Computation of the Proposed FY 2002 Wage Index

We note a proposed technical change to the FY 2002 calculation. For the FY 2001 wage index calculation, we initially proposed to subtract Line 13 of Worksheet S-3, Part III from total hours when determining the excluded hours ratio used to estimate the amount of overhead attributed to excluded areas (65 FR 26299). However, the formula resulted in large and inappropriate increases in the average hourly wages for some hospitals (65 FR 47074), particularly hospitals that have large overhead and excluded area costs. Therefore, for the final FY 2001 wage index calculation, we reverted to the FY 2000 excluded hours ratio formula, which did not subtract Line 13.

We, and others in the hospital community, continued to believe that subtracting Part III, Line 13 from total hours is the correct formula for determining the excluded hours ratio. We analyzed how the application of this formula resulted in overstated average hourly wages for some hospitals and how we could improve the overall accuracy of the overhead allocation methodology. We became aware that the problem was not in the excluded hours ratio formula. Rather, our wage index calculation did not also remove the overhead wage-related costs associated with excluded areas, an amount that must be estimated before it can be subtracted from the calculation. The combined effect of applying the excluded hours ratio formula, which appropriately removes salaries of lower-wage, overhead employees, and not subtracting overhead wage-related costs associated with excluded areas, resulted in overstated salary costs and average hourly wages.

For the FY 2002 wage index calculation, we are proposing to apply the excluded hours ratio formula that subtracts Part III, Line 13 from total hours. Additionally, for the first time in the wage index calculation, we estimated and subtracted overhead wage-related costs allocated to excluded areas.

After we applied this new calculation, there were still a few hospitals that experienced large increases in their average hourly wages. The intermediaries verified that the hospitals' wage data were accurate, so we kept the data in the wage index calculation. These hospitals primarily function as SNFs, psychiatric hospitals, or rehabilitation hospitals that have few acute care beds. The hospitals' higher average hourly wages reflect the costs of the higher salaried employees that

remain in the wage index calculation after we subtract the costs of excluded area and associated overhead employees.

The method used to compute the proposed FY 2002 wage index follows.

Step 1—As noted above, we are proposing to base the FY 2002 wage index on wage data reported on the FY 1998 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, 1997 and before October 1, 1998. In addition, we included data from any hospital that had cost reporting periods beginning before October 1997 and reported a cost reporting period covering all of FY 1998. 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 1998 data. We note that, if a hospital had more than one cost reporting period beginning during FY 1998 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 1997 and before October 1, 1998), 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—The method used to compute a hospital's average hourly wage is a blend of 40 percent of the hospital's average hourly wage including all GME and CRNA costs, and 60 percent of the hospital's average hourly wage after eliminating all GME and CRNA costs.

In calculating a hospital's average salaries plus wage-related costs, including all GME and CRNA costs, we subtracted from Line 1 (total salaries) 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 skilled nursing facility services, home health services, and other subprovider components not subject to the prospective payment system). We also subtracted from Line 1 the salaries for which no hours were reported on Lines 2, 4, and 6. 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 physician Part A services (Lines 9, 9.01, 9.02, 10, and 10.01), home office salaries and wage-related costs reported by the hospital on Lines 11, 12, and 12.01, and nonexcluded area wage-related costs (Lines 13, 14, 16, 18, 18.01, and 20).

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 specific categories of employees (Lines 16, 18, 18.01, and 20) are excluded if no corresponding salaries are reported for those employees (Lines 2, 4, 4.01, and 6, respectively).

We then calculated a hospital's salaries plus wage-related costs by subtracting from total salaries the salaries plus wage-related costs for teaching physicians, Lines (4.01, 10.01, 12.01, and 18.01), Part A CRNAs (Lines 2 and 16), and residents (Lines 6 and 20).

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 3, 5, 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 3, 5, 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, 16, 18, 18.01, and 20; 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. Using the above method for computing overhead salaries, wage-related costs, and hours to allocate to

excluded areas, we also computed these costs excluding all costs associated with GME and CRNAs (Lines 2, 4.01, 6, 10.01, 12.01, and 18.01).

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, 1997 through April 15, 1999 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
12/14/97	01/15/98	1.03292
01/14/98	02/15/98	1.03048
02/14/98	03/15/98	1.02828
03/14/98	04/15/98	1.02621
04/14/98	05/15/98	1.02411
05/14/98	06/15/98	1.02200
06/14/98	07/15/98	1.01973
07/14/98	08/15/98	1.01714
08/14/98	09/15/98	1.01424
09/14/98	10/15/98	1.01137
10/14/98	11/15/98	1.00885
11/14/98	12/15/98	1.00669
12/14/98	01/15/99	1.00462
01/14/99	02/15/99	1.00239
02/14/99	03/15/99	1.00000
03/14/99	04/15/99	0.99746

For example, the midpoint of a cost reporting period beginning January 1, 1998 and ending December 31, 1998 is June 30, 1998. An adjustment factor of 1.01973 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 1998 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 (with and without GME and CRNA costs) 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.

Because the proposed FY 2002 wage index is based on a blend of average hourly wages, we then added 40 percent of the average hourly wage calculated without removing GME and CRNA costs, and 60 percent of the average hourly wage calculated with these costs excluded.

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 same blending methodology described in Step 7). Using the data as described above, the national average hourly wage is \$22.0545.

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

Step 10—Following the process set forth above, we developed a separate Puerto Rico-specific wage index for purposes of adjusting the Puerto Rico standardized amounts. (The national Puerto Rico standardized amount is adjusted by a wage index calculated for all Puerto Rico labor market areas based on the national average hourly wage as described above.) We added the total adjusted salaries plus wage-related costs (as calculated in Step 5) for all hospitals in Puerto Rico and divided the sum by the total hours for Puerto Rico (as calculated in Step 4) to arrive at an overall average hourly wage of \$10.8100 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 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 2002, this change affects 240 hospitals in 41 MSAs. The MSAs affected by this provision are identified in Table 4A by a footnote.

F. Revisions to the Wage Index Based on Hospital Redesignation

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 MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the prospective payment system.

1. Provisions of Public Law 106-554

Section 304 of Public Law 106-554 made changes to several provisions of section 1886(d)(10) of the Act relating to hospital reclassifications and the wage index:

- Section 304(a) amended section 1886(d)(10)(D) of the Act by adding a clause (v) to provide that, beginning with FY 2001, an MGCRB decision on a hospital reclassification for purposes of the wage index is effective for 3 years, unless the hospital elects to terminate the reclassification. Section 304(a) also 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 1886(d)(10)(D)(vi) of the Act).

- Section 304(b) 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. Section 304(b) further requires that, if the Secretary applies a statewide wage index to an area, an application by an individual hospital in that area would not be considered.

We address our policy proposals relating to implementation of these three provisions of sections 304(a) and (b) of Public Law 106-554 in section IV. of this proposed rule. The following

discussion of the proposed revisions to the wage index based on hospital redesignations reflects these proposed policies.

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.

- Currently, the wage index value for an urban area is calculated exclusive of the wage data for hospitals that have been reclassified to another area.

For the FY 2002 wage index, we are proposing to include the wage data for a reclassified urban hospital in both the area to which it is reclassified and the MSA where the hospital is physically located. We believe this will improve consistency and predictability in hospital reclassification and wage indices, as well as alleviate the fluctuations in the wage indexes due to reclassifications. For example, hospitals applying to reclassify into another area will know which hospitals' data will be included in calculating the wage index, because even if some hospitals in the area are reclassified, their data will be included in the calculation of the wage index of the area where they are geographically located. Also, in some cases, excluding the data of hospitals reclassified to another MSA could have a large downward impact on the wage index of the MSA in which the hospital is physically located. The negative impact of removing the data of the reclassified hospitals from the wage index calculation could lead to large wage disparities between the reclassified hospitals and other hospitals in the MSA, as the remaining hospitals would receive reduced payments due to a lower wage index. Our proposed approach would promote consistency, and simplify our rules, with respect to how we construct the wage indexes of rural and urban areas. As noted above, in the case of rural hospitals redesignated to another area, the wage index of the rural area where the hospitals are geographically located is calculated by including the wage data of the redesignated hospitals (unless doing so would result in a lower wage index).

Finally, we note that the Medicare Payment Advisory Commission (MedPAC), in its March 2001 "Report to the Congress: Medicare Payment Policy," recommended this policy (p. 82). (Section VII. of this preamble includes a discussion of MedPAC's recommendations and our responses.) To illustrate the potential negative impact on hospitals in an area where reclassifications of some hospitals to another area results in a decline in the wage index after the reclassified hospitals are excluded from the wage index calculation, MedPAC points out that hospitals in several MSAs have organized to pay qualifying hospitals not to reclassify. Our proposed policy change would remove this distorted incentive.

The proposed wage index values for FY 2002 are shown in Tables 4A, 4B, 4C, and 4F in the Addendum to this proposed rule. Hospitals that are redesignated should use the wage index values shown in Table 4C. Areas in Table 4C may have more than one wage index value because the wage index value for a redesignated urban or rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located. When the wage index value of the area to which a hospital is redesignated is lower than the wage index value for the rural areas of the State in which the hospital is located, the redesignated hospital receives the higher wage index value; that is, the wage index value for the rural areas of the State in which it is located, rather than the wage index value otherwise applicable to the redesignated hospitals.

As mentioned earlier, section 304(a) of Public Law 106-554 amended section 1886(d)(10)(D) of the Act by adding a new clause (v) to provide that a reclassification of a hospital by the MGCRB for purposes of the wage index is effective for 3 years (instead of 1 year) unless, under procedures established by the Secretary, the hospital elects to terminate the reclassification before the end of the 3-year period. Section 304(a) of Public Law 106-554 also amended section 1886(d)(10)(D) of the Act to specify that, for applications for reclassification for the wage index for FYs 2003 and later, the MGCRB must base any comparison of the average hourly wage of the hospital with the average hourly wage for hospitals in the area in which it is located and the area to which it seeks reclassification, using data from the most recently published hospital wage survey (as of the date of the hospital's application), as well as data from each of the two immediately preceding surveys. (Our policy proposals to incorporate the provisions of section 304(a) of Public Law 106-554 in the regulations are addressed in section IV.E. of this proposed rule).

Consistent with the section 304(a) amendment, Tables 3A and 3B list the 3-year average hourly wage for each labor market area before the redesignation of hospitals, based on FY 1996, 1997, and 1998 wage data. In addition, Table 2 in the Addendum to this proposed rule includes the adjusted average hourly wage for each hospital from the FY 1996 and FY 1997 cost reporting periods, as well as the FY 1998 period. Table 2 also shows the 3-year average (as well as hospitals' average hourly wages for each of the 3 years) that the MGCRB will use (as published in the final rule following

this proposed rule) to evaluate a hospital's application for reclassification for FY 2003 (unless that average hourly wage is later revised in accordance with § 412.63(w)(2)). The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously in this section) 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.

Applications for FY 2003 reclassifications are due to the MGCRB by September 1, 2001. (We note that the new location and mailing address of the MGCRB and the Provider Reimbursement Review Board (PRRB) is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244-2670. The MGCRB and PRRB will be functioning at this new location as of May 21, 2001. Also, please specify whether the mail is intended for the MGCRB or the PRRB.)

At the time this proposed wage index was constructed, the MGCRB had completed its review of FY 2002 reclassification requests. The proposed FY 2002 wage index values incorporate all 643 hospitals redesignated for purposes of the wage index (hospitals redesignated under section 1886(d)(8)(B) or section 1886(d)(10) of the Act for FY 2002. The final number of reclassifications may vary because some MGCRB decisions are still under review by the Administrator and because some hospitals may withdraw their requests for reclassification.

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

Under § 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of this proposed rule in the **Federal Register**. The request for withdrawal of an application for reclassification that would be effective

in FY 2002 must be received by the MGCRB by June 18, 2001. A hospital that requests to withdraw its application may not later request that the MGCRB decision be reinstated.

In addition, because the 3-year effect of the amendment made by section 304(a) of Public Law 106-554 is applicable to reclassifications for FY 2001 (which had already taken place prior to the date of enactment of Public Law 106-554) and because the application process for reclassification for FY 2002 had already been completed by the date of enactment, we are deeming hospitals that are reclassified for purposes of the wage index to one area for FY 2001 and are reclassified for purposes of the wage index or the standardized amount to another area for FY 2002 to be reclassified to the area for which they applied for FY 2002, unless they elect to receive the wage index reclassification they were granted for FY 2001. Consistent with our application withdrawal procedures under § 412.273, we are allowing hospitals that wish to receive, for FY 2002, the reclassification they were granted for FY 2001, to withdraw their applications within 45 days of the publication of this proposed rule (that is, by June 18, 2001. (These procedures are discussed in detail under section IV.E.1. of this preamble.)

3. Statewide Wage Index

As stated earlier, section 304(b) of Public Law 106-554 requires the Secretary to establish, by October 1, 2001, a process (based on the voluntary process utilized by the Secretary under section 1848 of the Act) under which an appropriate statewide entity may apply to have all the geographic areas in the State treated as a single geographic area for purposes of computing and applying a single wage index, for reclassification beginning in FY 2003. Section 304(b) further requires that, if the Secretary applies a statewide wage index to an area, an application by an individual hospital in that area would not be considered. We believe the reference to the voluntary process utilized by the Secretary under section 1848 of the Act refers to the process whereby we allow a State containing multiple physician fee schedule payment areas (and thus multiple geographic adjustment factors) to voluntarily convert to a single statewide payment area with a single geographic adjustment factor (see § 414.4(b), as discussed in the June 24, 1994 **Federal Register** (59 FR 32759).

Section IV.E. of this proposed rule contains our policy proposal for implementing the provisions of section 304(b) in regulations. We are proposing that hospitals that seek a statewide

geographic reclassification under the amendments made by section 304(b) of Public Law 106-554 apply to the MGCRB with the same deadlines as other hospitals. An approved application by the MGCRB would mean that the data of all the hospitals in the State would be used in computing and applying the wage index for that State. We are proposing that the statewide wage index would be applicable for 3 years from the date of approval or until all of the participating hospitals terminate their approved statewide wage index reclassification (effective with the next full fiscal year after their termination request), whichever occurs first.

4. Section 402 of Public Law 106-113

Beginning October 1, 1988, section 1886(d)(8)(B) of the Act required us to treat a hospital located in a rural county adjacent to one or more urban areas 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 areas) 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 data index.

During FY 1994, we incorporated the revised MSA definitions based on 1990 census population data. As a result, some counties that previously were treated as an adjacent county under section 1886(d)(8)(B) of the Act officially became part of certain MSAs. However, as specified in the Act, we continued to utilize the January 3, 1980 standards. For FY 2000, there were 27 hospitals in 22 counties affected by this provision.

On March 30, 1990, OMB issued revised 1990 standards (55 FR 12154). There has been an increasing amount of interest by the hospital industry in using the 1990 standards as opposed to the 1980 standards to determine which hospitals qualify under the provisions set forth in section 1886(d)(8)(B) of the Act. Section 402 of Public Law 106-113 provides that, with respect to FYs 2001

and 2002, a hospital may elect to have the 1990 standards applied to it for purposes of section 1886(d)(8)(B) and 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.

We worked with staff of the Population Distribution Branch within the Population Division of the United States Census Bureau to compile a list of hospitals that meet the March 30, 1990 standards using 1990 census population data and information prepared for the Metropolitan Area Standards Review Project. The conditions that must be met for a hospital located in a rural county adjacent to one or more urban areas to be treated as being located in the urban area to which the greatest number of workers in the rural county commute are as follows:

- The rural county would otherwise be considered part of an MSA but for the fact that the rural county does not meet the standard established by OMB relating to the commuting rate of workers between the county and the central county or counties of any adjacent MSA.
- The county would meet the commuting standard if commuting to (and where applicable, from) the central county or central counties of all adjacent MSAs or NECMAs (rather than to just one) were considered.

A county meeting the above commuting standards must also meet the other standards established by OMB for inclusion in an MSA as an outlying county. In order to meet these requirements, the rural county must have a degree of "metropolitan character." "Metropolitan character" is established by meeting one of the following OMB standards, which were published in the **Federal Register** on March 30, 1990:

a. At least 50 percent of the employed workers residing in the county commute to the central county/counties, and either—

- The population density of the county is at least 25 persons per square mile; or
 - At least 10 percent of the population, or at least 5,000 persons, lives in the qualifier urbanized area(s).
- b. From 40 to 50 percent of the employed workers commute to the central county/counties, and either—
- The population density is at least 35 persons per square mile; or
 - At least 10 percent of the population, or at least 5,000 persons, lives in the qualifier urbanized area(s).
- c. From 25 to 40 percent of the employed workers commute to the

central county/counties and either the population density of the county is at least 50 persons per square mile, or any two of the following conditions exist:

- Population density is at least 35 persons per square mile.
 - At least 35 percent of the population is urban.
 - At least 10 percent of the population, or at least 5,000 persons, lives in the qualifier urbanized area(s).
- d. From 15 to 25 percent of the employed workers commute to the central county/counties, the population density of the county is at least 50 persons per square mile, and any two of the following conditions also exist:
- Population density is at least 60 persons per square mile.
 - At least 35 percent of the population is urban.
 - Population growth between the last two decennial censuses is at least 20 percent.
 - At least 10 percent of the population, or at least 5,000 persons, lives in the qualifier urbanized area(s).
- Also accepted as meeting this commuting requirement under item d. are:
- The number of persons working in the county who live in the central county/counties is equal to at least 15 percent of the number of employed workers living in the county; or
 - The sum of the number of workers commuting to and from the central county/counties is equal to at least 20 percent of the number of employed workers living in the county.
- e. From 15 to 25 percent of the employed workers commute to the central county/counties, the population density of the county is less than 50 persons per square mile, and any two of the following conditions also exist:
- At least 35 percent of the population is urban.
 - Population growth between the last two decennial censuses is at least 20 percent.
 - At least 10 percent of the population, or at least 5,000 persons, lives in the qualifier urbanized area(s).
- f. At least 2,500 of the population lives in a central city of the MSA located in the qualifier urbanized area(s).

When we apply the 1990 standards as opposed to 1980 standards, the number of qualifying counties increases from 22 to 31. On the basis of the evaluation of these data, effective for discharges occurring on or after October 1, 2001, hospitals located in the first column of the following table are proposed to be considered, for purposes of assigning the inpatient standardized amount and the wage index, to be located in the corresponding urban area in the second column:

Rural County	MSA
Chilton, AL	Birmingham, AL.
Marshall, AL	Huntsville, AL.
Talladega, AL	Anniston, AL.
Bradford, FL	Jacksonville, FL.
Hendry, FL	West Palm Beach- Boca Raton, FL.
Putnam, FL	Gainesville, FL.
Jackson, GA	Athens, GA.
Christian, IL	Springfield, IL.
Macoupin, IL	St. Louis, MO-IL.
Piatt, IL	Champaign-Urbana, IL.
Brown, IN	Indianapolis, IN.
Carroll, IN	Lafayette, IN.
Henry, IN	Indianapolis, IN.
Jefferson, KS	Topeka, KS.
Barry, MI	Kalamazoo-Battle Creek, MI.
Cass, MI	Benton Harbor, MI.
Ionia, MI	Grand Rapids-Mus- kegon-Holland, MI.
Shiawassee, MI	Flint, MI.
Tuscola, MI	Saginaw-Bay City- Midland, MI
Caswell, NC	Greensboro-Winston Salem-High Point, NC.
Greene, NC	Greenville, NC.
Harnett, NC	Raleigh-Durham- Chapel Hill, NC.
Wilson, NC	Rocky Mount, NC.
Preble, OH	Dayton-Springfield, OH.
Van Wert, OH	Lima, OH.
Adams, PA	York, PA.
Lawrence, PA	Pittsburgh, PA.
Monroe, PA	Newark, NJ.
Schuylkill, PA	Reading, PA.
Jefferson, WI	Milwaukee- Waukesha, WI.
Walworth, WI	Milwaukee- Waukesha, WI.

There are 14 counties that meet the qualifying criteria using 1990 standards that did not meet the criteria using the 1980 standards. These 14 counties are:

- Chilton, AL
- Talladega, AL
- Bradford, FL
- Hendry, FL
- Putnam, FL
- Jackson, GA
- Piatt, IL
- Brown, IN
- Carroll, IN
- Greene, NC
- Wilson, NC
- Adams, PA
- Monroe, PA
- Schuylkill, PA

In addition, when we apply the 1980 standards for three of the counties, the MSA assigned is different from the MSA that would be assigned using the 1990 standards. These counties are as follows:

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

Section 402 of Public Law 106-113 states that hospitals may elect to use either the January 3, 1980 standards or the March 30, 1990 standards for payments during FY 2001 and FY 2002. We are assuming hospitals will elect to go to the MSA resulting in the highest payment amount accounting for the applicable wage indexes and standardized amounts. Based on our analysis, we believe all hospitals in the designated rural counties would benefit by being included in the respective MSAs shown above. Therefore, we are proposing to assign the FY 2002 standardized amount and wage index of each respective MSA to the affected hospitals. Hospitals electing not to use the 1990 standards would be required to notify their fiscal intermediary in writing of such election prior to September 1, 2001, in order to allow sufficient time to reflect this change in

our payment systems. (For FY 2001, we are providing further information related to this election, including recalculated wage indexes, through separate instruction.)

We note that five rural counties no longer meet the qualifying criteria when we apply the revised OMB standards. These rural counties are as follows: Indian River, FL; Mason, IL; Owen, IN; Morrow, OH; and Lincoln, WV. For FY 2002, we propose to continue to treat these hospitals as attached to an MSA on the basis of the 1980 standards. Beginning FY 2003, they must meet the 1990 standards to continue to be treated as such.

We stated in the August 1, 2000 final rule that implemented changes to the prospective payment system for FY 2001 that we were in the process of working with OMB to identify the hospitals that would be affected by section 402 of Public Law 106-113 (65

FR 47076). We further indicated we would revise payments to hospitals in the affected counties as soon as data were available. Now that the affected counties have been identified, hospitals in the 14 counties identified above will be offered the opportunity to elect this designation, as previously described. (For FY 2001, we are providing further information related to this election, including recalculated wage indexes, through separate instructions.)

Finally, three hospitals located in counties affected by the revised OMB standards also have been reclassified by the MGCRB. The affected hospitals are listed below. If the hospitals do not wish to be reclassified for FY 2002 based on their new designation as described above, they must follow the procedures described above for requesting that their reclassification be withdrawn.

Provider Number	1990 MSA designation	FY 2002 reclassification, MSA
34-0071	Raleigh-Durham-Chapel Hill, NC	Fayetteville, NC.
34-0124	Raleigh-Durham-Chapel Hill, NC	Fayetteville, NC.
34-0126	Rocky Mount, NC	Raleigh-Durham-Chapel Hill, NC (wage index only.)

G. Requests for Wage Data Corrections

As stated in section II.D. of this preamble, the data file used to construct the proposed wage index includes FY 1998 data submitted to HCFA as of mid-February 2001. In a memorandum dated February 5, 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 February 13, 2001 through the Internet at HCFA'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 HCFA. Additional details on ordering this data file are discussed in section IX.A of this preamble, "Requests for Data from the Public."

In addition, Table 2 in the Addendum to this proposed rule contains each hospital's adjusted average hourly wage used to construct the proposed wage index values for the past 3 years, including the FY 1998 data used to

construct the proposed FY 2002 wage index. It should be noted that the hospital average hourly wages shown in Table 2 do not reflect any changes made to a hospital's data after mid-February 2001. Changes approved by a hospital's fiscal intermediary and forwarded to HCFA by April 9, 2001, will be reflected on the final public use wage data file scheduled to be made available on or about May 4, 2001.

We believe hospitals have sufficient time to ensure the accuracy of their FY 1998 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. Additionally, they are notified of any changes to their data as a result of their intermediary's review. However, if a hospital believed that its FY 1998 wage data were incorrectly reported, the hospital was to submit corrections along with complete, detailed supporting documentation to its intermediary by March 9, 2001. Hospitals were notified of this deadline, and of all other

possible deadlines and requirements, through written communications from their fiscal intermediaries in early February 2001.

After reviewing requested changes submitted by hospitals, intermediaries transmitted any revised cost reports to HCFA and forwarded a copy of the revised Worksheet S-3, Parts II and III to the hospitals. In addition, fiscal intermediaries were to notify hospitals of the changes or the reasons that changes were not accepted. This procedure ensures that hospitals have every opportunity to verify the data that will be used to construct their wage index values. We believe that fiscal intermediaries are generally in the best position to make evaluations regarding the appropriateness of a particular cost and whether it should be included in the wage index data. However, if a hospital disagrees with the intermediary's resolution of a requested change, the hospital may contact HCFA in an effort to resolve policy disputes. We note that the April 9, 2001 deadline also applies to these requested changes. We will not consider factual determinations at this time, as these

should have been resolved earlier in the process.

Any wage data corrections to be reflected in the final wage index must have been reviewed and verified by the intermediary and transmitted to HCFA on or before April 9, 2001. (The deadline for hospitals to request changes from their fiscal intermediaries was March 9, 2001.) These deadlines are necessary to allow sufficient time to review and process the data so that the final wage index calculation can be completed for development of the final prospective payment rates to be published by August 1, 2001.

We have created the process described above to resolve all substantive wage data correction disputes before we finalize the wage data for the FY 2002 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage data corrections or to dispute the intermediary's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to later challenge, before the Provider Reimbursement Review Board, HCFA's failure to make a requested data revision (See *W. A. Foote Memorial Hospital v. Shalala*, No. 99-CV-75202-DT (E.D. Mich. 2001)).

The final wage data public use file will be released by May 4, 2001. Hospitals should examine both Table 2 of this proposed rule and the May 4 final public use wage data file (which reflects revisions to the data used to calculate the values in Table 2) to verify the data HCFA is using to calculate the wage index. Hospitals will have until June 4, 2001, to submit requests to correct errors in the final wage data due to data entry or tabulation errors by the intermediary or HCFA. The correction requests that will be considered at that time will be limited to errors in the entry or tabulation of the final wage data that the hospital could not have known about before the release of the final wage data public use file.

As with the file made available in February 2001, HCFA will make the final wage data file released in May 2001 available to hospital associations and the public on the Internet. However, the May 2001 file will be made available solely for the limited purpose of identifying any potential errors made by HCFA or the intermediary in the entry of the final wage data that result from the correction process described above (with the March 9 deadline). Hospitals are encouraged to review their hospital wage data promptly after the release of

the final file. Data presented at this time cannot be used by hospitals to initiate new wage data correction requests.

If, after reviewing the final file, a hospital believes that its wage data are incorrect due to a fiscal intermediary or HCFA error in the entry or tabulation of the final wage data, it should send a letter to both its fiscal intermediary and HCFA. The letters should outline why the hospital believes an error exists and provide all supporting information, including dates. These requests must be received by HCFA and the intermediaries no later than June 4, 2001. Requests mailed to HCFA should be sent to: Health Care Financing Administration; Center for Health Plans and Providers; Attention: Wage Index Team, Division of Acute Care; C4-07-07; 7500 Security Boulevard; Baltimore, MD 21244-1850. Each request must also be sent to the hospital's fiscal intermediary. The intermediary will review requests upon receipt and contact HCFA immediately to discuss its findings.

At this point in the process, that is, between release of the May 2001 wage index file and June 4, 2001, changes to the hospital wage data will only be made in those very limited situations involving an error by the intermediary or HCFA that the hospital could not have known about before its review of the final wage data file. Specifically, neither the intermediary nor HCFA will accept the following types of requests at this stage of the process:

- Requests for wage data corrections that were submitted too late to be included in the data transmitted to HCFA on or before April 9, 2001.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 2001 wage data file.
- Requests to revisit factual determinations or policy interpretations made by the intermediary or HCFA during the wage data correction process.

Verified corrections to the wage index received timely (that is, by June 4, 2001) will be incorporated into the final wage index to be published by August 1, 2001 and effective October 1, 2001.

Again, we believe the wage data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage data to the intermediary's attention. Moreover, because hospitals will have access to the final wage data by early May 2001, they will have the opportunity to detect any data entry or tabulation errors made by the intermediary or HCFA before the development and publication of the FY 2002 wage index by August 1, 2001 and

the implementation of the FY 2002 wage index on October 1, 2001. If hospitals avail themselves of this opportunity, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified after that date, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with § 412.63(w)(2), we may make midyear corrections to the wage index only in those limited circumstances in which a hospital can show (1) That the intermediary or HCFA 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 2002 (that is, by the June 4, 2001 deadline). As indicated earlier, since a hospital will have the opportunity to verify its data, and the intermediary will notify the hospital of any changes, we do not foresee any specific circumstances under which midyear corrections would be necessary. However, should a midyear correction be necessary, the wage index-change for the affected area will be effective prospectively from the date the correction is made.

H. Modification of the Process and Timetable for Updating the Wage Index

Although the wage data correction process described above has proven successful in the past for ensuring that the wage data used each year to calculate the wage indexes are generally reliable and accurate, we are concerned about the growing volume of wage data revisions initiated by hospitals during February and the first week of March. We first discussed this issue in the FY 1998 proposed rule (62 FR 29918). At that time, we noted that, in developing the FY 1997 wage index, the wage data were revised between the proposed and final rules for more than 13 percent of the hospitals (approximately 700 of 5,200). Last year, in developing the FY 2001 wage index, the wage data were revised between the proposed and final rules for more than 32 percent of the hospitals (1,605 of 4,950).

Since hospitals are expected to submit complete and accurate cost report data, and intermediaries review and request hospitals to correct problematic wage data before the data are submitted to HCFA in mid-November, we believe there should be limited revisions at this stage of the process. We remind the hospital community that the primary purpose of this file is to allow hospitals to verify that we have their correct data on file. However, according to information received from the

intermediaries, these late revisions are frequently due to hospitals' lack of responsiveness in providing sufficient information to the intermediaries during the desk reviews (that is, during the intermediary's review of the hospital's cost report).

We are proposing two changes to the wage index development process and timetable beginning with the FY 2003 wage index. We believe these changes will encourage earlier submissions of wage data revisions by hospitals and will allow intermediaries more time to address the heavy volume of revisions requested after the intermediaries have completed their desk reviews of these data. First, we are proposing to release the preliminary wage data file by early January rather than early February. As with the current preliminary file, the January file would include desk reviewed wage data that intermediaries submitted to HCFA by November of the previous year and any timely revisions HCFA received from intermediaries prior to release of the January file. Hospitals would be allowed until early February to submit requests for wage data revisions to their intermediaries. Second, intermediaries would be allowed approximately 8 weeks from the hospitals' deadline for submitting revision requests (that is, until early March) to review and transmit revised wage data to HCFA.

We believe this proposed revised schedule will improve the quality of the wage index by allowing intermediaries more time to sufficiently review wage data revisions before the data are submitted to HCFA. Further, we believe the proposed revised process will encourage hospitals to submit revisions earlier, so the proposed wage index, from which hospitals base geographic reclassification decisions, is more accurate.

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

A. Sole Community Hospitals (SCHs) (§§ 412.63, 412.71, 412.72, 412.73, 412.75, 412.77, and 412.92)

For the benefit of the reader, in this proposed rule, we are discussing and seeking to clarify many of the rules and policies governing SCHs because of the legislative changes that have occurred in recent years. It has been several years since the SCH criteria have been published in one location. Rather than continue to refer to various **Federal Register** documents and sections of the Code of Federal Regulations, we are publishing a detailed discussion of

these policies, proposing to make further changes to incorporate the provisions of sections 213, 302, 303, 304, and 311 of Public Law 106-554, and proposing to clarify other related policies.

Under the hospital inpatient prospective payment system, special payment protections are provided to an 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 (EACH), 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 at § 412.92. To be classified as an SCH, a hospital must either have been designated as an SCH prior to the beginning of the prospective payment system on October 1, 1983, and 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 more than 35 miles from other like hospitals.
- It is located between 25 and 35 miles from other like hospitals, and it—
 - Serves at least 75 percent of all inpatients, or 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 75 percent of its area's inpatients except that some patients seek specialized care unavailable at the hospital.
- It is located between 15 and 25 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:
 - The 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.

Effective with hospital cost reporting periods beginning on or after October 1, 2000, section 1886(b)(3)(I)(i) of the Act, as added by section 405 of Public Law 106-113 and amended by section 213 of Public Law 106-554, provides for other options, in addition to the three bulleted options in the above paragraph, for determining which rate would yield the greatest aggregate payment. For discharges for FY 2001 through FY 2003, these additional optional rates are—

- A phase-in blended rate of the updated hospital-specific rate based on FY 1982 costs per discharge and an FY 1996 hospital-specific rate; or
- A phase-in blended rate of the updated hospital-specific rate based on FY 1987 costs per discharge and an FY 1996 hospital-specific rate.

For discharges beginning in FY 2004, the additional optional rate would be 100 percent of the 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 update factor for the Federal rates, outlier payments, the amount of the DSH adjustment, or the 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.

In calculating a hospital-specific rate for an SCH based on its FY 1996 cost reporting period, we will, to the extent possible, use the same methodology that we used to calculate the hospital-specific rate based on either the FY 1982 or FY 1987 cost reporting period. That

methodology is set forth in §§ 412.71, 412.72, 412.73, 412.75 and 412.77.

- If a hospital has a cost reporting period ending in FY 1982, it will be paid a hospital-specific rate based on its FY 1982 costs; or a hospital-specific rate based on its FY 1987 costs; or a hospital-specific rate based on its FY 1996 costs (which, until FY 2004, would be a blend of the greater of the FY 1982 or FY 1987 costs and the FY 1996 costs); or it will be paid based on the Federal rate.

- If a hospital has no cost reporting period ending in FY 1982, it will be paid a hospital-specific rate based on its FY 1987 costs; or a hospital-specific rate based on its FY 1996 costs (which, until FY 2004, would be a blend of its FY 1987 costs and FY 1996 costs); or it will be paid based on the Federal rate.

- If a hospital has no cost reporting period ending in either FY 1982 or FY 1987, it will be paid based on its FY 1996 costs; or it will be paid based on the Federal rate.

- If a hospital has no cost reporting period ending in FY 1982, FY 1987, or FY 1996, it cannot be paid based on a hospital-specific rate; it will be paid based on the Federal rate.

- If a hospital was operating during any or all of FY 1982, FY 1987, or FY 1996, but, for some reason, the cost report records are no longer available, the hospital will be treated as if it had no cost report for the applicable period. The hospital will not be allowed to substitute any other base period for the FY 1982, FY 1987, or FY 1996 base period.

For each SCH, the fiscal intermediary will calculate a hospital-specific rate based on the hospital's FY 1982, FY 1987, or FY 1996 cost report as follows:

- Determine the hospital's total allowable Medicare inpatient operating cost, as stated on the cost report.

- Divide the total Medicare operating cost by the number of Medicare discharges (without adjusting for transfers) in the cost reporting period to determine the base period cost per case.

- In order to take into consideration the hospital's individual case-mix, the base year cost per case is divided by the hospital's case-mix index applicable to the cost reporting period. This step is necessary to adjust the hospital's base period cost for case mix. This is done to remove the effects of case mix from the base period costs per case. Payments using these base period costs are then adjusted to reflect the actual case mix during the payment year. A hospital's case mix is computed based on its Medicare patient discharges subject to DRG-based payment.

The fiscal intermediary will inform each SCH of its hospital-specific rate based on its applicable cost reporting period within 180 days after the start of its cost reporting period.

An SCH is also eligible for a payment adjustment if, for reasons beyond its control, it experiences a decline in volume of greater than 5 percent compared to its preceding cost reporting period. This adjustment is also available to hospitals that could qualify as SCHs but choose not to be paid as SCHs; that is, hospitals that qualify and successfully apply to be designated as SCHs but continue to receive payments based on the Federal rate. In addition, section 6003(c)(1) of Public Law 101-239 deleted the sunset date on the 5-percent volume decline adjustment, thus allowing SCHs to receive the adjustment indefinitely. The sunset provision was included under section 1886(d)(5)(C)(ii) of the Act. (Section 6003(c)(1) of Public Law 101-239 amended that provision and redesignated it as section 1886(d)(5)(D) of the Act.)

In the September 1, 1983, issue of the **Federal Register** (48 FR 39781), we stated that any hospital designated as an SCH would retain that status until it experienced a change in circumstances. Section 6003(e)(3) of Public Law 101-239 specifically stated that any hospital classified as an SCH as of the date of enactment of Public Law 101-239 (December 19, 1989), will retain its SCH status even if the hospital did not meet the criteria established under section 6003(e)(1) of that law. These hospitals are the "grandfathered" SCH hospitals. Therefore, we have continued to allow hospitals designated as SCHs prior to December 19, 1989, to be "grandfathered" under current criteria.

In the June 4, 1991, **Federal Register**, we stated that a hospital's special status as an SCH would not be retained in light of the hospital's geographic reclassification for purposes of the standardized amount. In the event the hospital's reclassification ceases, it must reapply for special status and must meet all of the applicable qualifying criteria in effect at the time it seeks requalification (56 FR 25482). However, in the event a "grandfathered" SCH was successfully reclassified, it would be reinstated as an SCH if its reclassification ceased.

Section 401(a) of Public Law 106-113 established that any subsection (d) hospital (section 1886(d) of the Act) located in an urban area may be redesignated as being located in a rural area if the hospital meets one of several criteria established by the legislation. One of these criteria is that the hospital

could qualify as an SCH if the hospital were located in a rural area. Under this provision, an urban hospital that may have been "grandfathered" as an SCH could now qualify and receive payment as an SCH if it met the criteria of a rural SCH. Given this extension of SCH eligibility, we no longer believe it is necessary to extend special protection to "grandfathered" SCHs that successfully apply for geographic reclassification through the MGCRB for the standardized amount after their MGCRB reclassification ends. This circumstance falls under the provisions of §§ 412.92(b)(3) and (b)(5), which state that an approved classification as an SCH remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved. We believe that a successful reclassification by the MGCRB fits the definition of a change in circumstances.

Because some hospitals may not have understood the effect reclassification would have on their special status, under existing § 412.273(a) we are permitting affected hospitals the option to withdraw their applications for reclassification for FY 2002, even if the MGCRB has issued a decision, by submitting a withdrawal request to the MGCRB within 45 days of publication of this proposed rule. Finally, just as a competing hospital that closes leaves an opportunity for an existing hospital to qualify as an SCH, a new hospital that opens in an area with an existing hospital designated as an SCH endangers the SCH status of the existing hospital.

As of October 1, 1997, no designations of hospitals as EACHs can be made. The EACHs designated by HCFA before October 1, 1997, will continue to be paid as SCHs for as long as they comply with the terms, conditions, and limitations under which they were designated as EACHs.

Under § 412.92(b)(2), we define the effective dates for several situations in which a hospital gains or gives up SCH status. First, SCH status and the associated payment adjustment is effective 30 days after HCFA's written notification to the SCH. Thus, 30 days after the issuance of HCFA's notice of approval, the hospital is considered to be an SCH and the payment adjustment is applied to discharges occurring on or after that date.

Second, § 412.92(b)(4)(ii) defines the effective date when a hospital chooses to give up its SCH status. Our policy has always been that an SCH can elect to give up its SCH status at any time by submitting a written request to the appropriate HCFA regional office

through its fiscal intermediary. The change to fully national rates becomes effective no later than 30 days after the hospital submits its request. We believe that the "no later than 30 days" policy for the effective date for cancelling SCH status is in keeping with the prospective nature of the prospective payment system. In addition, the 30-day timeframe to give up SCH status provides the fiscal intermediaries with enough time to alter their automated payment systems prospectively, thus avoiding expensive and time-consuming reprocessing of claims. The variable timeframe of "no later than 30 days from the date of the hospital's request" also permits the regional office, the fiscal intermediary, and the hospital to select a mutually agreeable date, for example, at the end of a month, to facilitate the change in SCH status. We expect that hospitals will anticipate when they wish to give up SCH status and to submit their requests in sufficient time to permit the 30-day period for making the change.

In addition, § 412.92(b)(2)(ii) defines the effective date of SCH status in the situation where a final and nonappealable administrative or judicial decision reverses HCFA's denial of SCH status to a hospital. In this situation, if the hospital's application was submitted on or after October 1, 1983, the effective date will be 30 days after the date of HCFA's original written notification of denial.

Under § 412.92(b)(2)(iii), we define retroactive approval of SCH status. If a hospital is granted retroactive approval of SCH status by a final and nonappealable court order or an administrative decision under subpart R of Part 405 of the regulations, and it wishes its SCH status terminated prior to the current date (that is, it wishes to be paid as an SCH for a time-limited period, all of which is in the past), it must submit written notice to the HCFA regional office through its fiscal intermediary within 90 days of the court order or the administrative decision. This written notice must clearly state that, although SCH status was granted retroactively by the court order or by the administrative decision, the hospital wants this status terminated as of a specific date. If written notice is not received within 90 days of the court order or the administrative decision, SCH status will continue. Written requests to terminate SCH status that are received subsequent to the 90-day period will be effective no later than 30 days after the request is submitted, as discussed above.

Under § 412.92(c)(1), we define mileage. We believe that mileage should

continue to be measured by the shortest route over improved roads maintained by any local, State, or Federal Government entity for public use. We consider improved roads to include the paved surface up to the front entrance of the hospital because this portion of the distance is utilized by the public to access the hospital. This definition provides consistency with the interpretation of the MGCRB when considering hospital reclassification applications. The MGCRB measures the distance between the hospital and the county line of the area to which it seeks reclassification beginning with the paved area outside the front entrance of the hospital. This provides a consistent, national definition that is easily recognizable for each hospital. Finally, rounding of mileage is not permissible. This is also consistent with the MGCRB definition of mileage (56 FR 25483). We are proposing to revise the definition of "miles" under § 412.92(c)(1) to state that an improved road includes the paved surface up to the front entrance of the hospital.

Under § 412.92(c)(2), we define "like" hospital. We consider like hospitals to be those hospitals furnishing short-term acute care. That is, a hospital may not qualify for an SCH classification on the grounds that neighboring hospitals offer specialty services, thereby seeking to exclude close-by competitors as like hospitals, in order to meet the mileage criteria by measuring to a like hospital that is located further away. For example, we believe that competing hospitals within a given area may each have their own specialty services, while all the facilities continue to be considered short-term acute care hospitals. We note that under § 412.92(a)(1)(ii), a hospital with fewer than 50 beds may qualify for SCH status under a special provision if patients that it would normally serve are seeking care elsewhere due to the unavailability of specialty services. This means that, if a hospital can prove that the patients from its service area are seeking specialty services elsewhere (such as, among others, heart surgery, transplants, and burn care), rather than routine care, and, because of that fact, that it otherwise would have met the criteria of section § 412.92(a)(1)(i), it can qualify as an SCH.

We note that § 412.92(b)(1)(iii)(A) retains an outdated reference to "hospitals located within a 50 mile radius of the hospital." With the issuance of the September 1, 1989 **Federal Register** (54 FR 36481, 36482), the 50 mile radius was determined to be unreasonable and all references should have been changed to 35 miles in

accordance with § 412.92(a)(1)(i). We are proposing to revise the reference to "a 50 mile radius" in § 412.92(b)(1)(iii)(A) to read "a 35 mile radius".

We note that the travel time and weather conditions criteria set forth in § 412.92(a)(3) were discussed in detail in the September 4, 1990 **Federal Register** (55 FR 36050 through 36055 and 36162 through 36163).

Under § 412.92(a)(1)(i) and (b)(1)(ii), we define the market area analysis criteria used to determine SCH status. There are several points concerning these requests for SCH status that we would like to clarify in this proposed rule. First, a hospital seeking an SCH designation based on these criteria must make its initial request to the fiscal intermediary with all the appropriate documents as will be discussed below (§ 412.92(b)(1)(i)). The fiscal intermediary will make a recommendation on the request, based on receipt of all the appropriate documentation and its own investigation and analysis, and that recommendation will be forwarded to the HCFA regional office for another level of review and final approval or disapproval. The fiscal intermediary would forward its recommendation to the HCFA regional office located in the hospital's area as opposed to the fiscal intermediary's area, if there is a difference in these areas. As discussed above, an approval of the request for SCH status will be effective 30 days after HCFA issues the approval letter. If a determination on the request requires the use of data that are available at HCFA central office only, upon receipt of the fiscal intermediary's recommendation, the HCFA regional office will forward the request and the fiscal intermediary's recommendation to the appropriate contact at HCFA central office where the determination will be made.

Second, a hospital must provide patient origin data (the number of patients from each zip code from which the hospital draws inpatients) for all inpatient discharges to document the boundaries of its service area (§ 412.92(b)(1)(ii)(A)). Or, the hospital can request that HCFA develop patient origin data to define its service area based on the number of patients from each zip code from which the hospital draws Medicare Part A inpatients (§ 412.92(b)(1)(iii)). Then, the lowest number of zip codes in descending percentage order of Medicare inpatients that meets the 75-percent threshold will be used to represent the hospital's service area. We note that hospitals cannot substitute zip codes elsewhere

on the list in order to manipulate the service area. See (*Howard Young Medical Center, Inc. v. Shalala*, 207 F.3d 437 (7th Cir. 2000).)

Third, the hospital must provide patient origin data from all other hospitals located within a 35-mile radius of it or, if larger, within its service area, to document that no more than 25 percent of either all of the population or the Medicare beneficiaries residing in the hospital's service area and hospitalized for inpatient care were admitted to other like hospitals for care (§ 412.92(b)(1)(ii)(B)). Again, HCFA central office can develop patient origin data for other hospitals within the requesting hospital's service area if the hospital is requesting SCH status based on an examination of Medicare Part A inpatient utilization. In either case, the requesting hospital is required to submit a comprehensive list of hospitals located within a 35-mile radius or, if larger, within its service area. This list will be checked by both the fiscal intermediary and HCFA. Again, a requesting hospital cannot argue that a competing hospital should be excluded from the service area based on the existence of specialty services at that hospital if both hospitals are short-term acute care facilities. Distances between all reported hospitals will be checked by both the fiscal intermediary and HCFA, through electronic geographic mapping services (such as Yahoo or Mapquest) or by physically driving the distance involved.

In addition, data will be analyzed based on the year for which the hospital requests SCH status. Subsequent hospital mergers or terminations will not be taken into consideration in processing the request. For example, if a hospital requests SCH status using data for FY 1999, and that data show that there is a competing hospital in existence that subsequently closed its doors in FY 2000, the data will be analyzed with the terminated hospital in existence, unless the hospital seeking SCH status applies using later data, such as FY 2001. This principle is consistent with how we analyze wage index data. If a terminated hospital has a viable cost report for the year of wage data that is being analyzed to produce the wage index, its data are included as part of the computation.

B. 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 a hospital must meet in order to receive special treatment 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 would continue to receive special treatment under both the disproportionate share hospital (DSH) payment adjustment and the criteria for geographic reclassification.

Section 401 of Public Law 106-113 amended section 1886(d)(8) of the Act by adding subparagraph (E), which creates a mechanism, separate and apart from the MGCRB, permitting an urban hospital to apply to the Secretary to be treated as being located in the rural area of the State in which the hospital is located. The statute directs the Secretary to treat a qualifying hospital as being located in the rural area for purposes of provisions under section 1886(d) of the Act. Congress clearly intended hospitals that become rural under section 1886(d)(8)(E) of the Act to receive some benefit as a result. In addition, one of the criteria under section 1886(d)(8)(E) of the Act is that the hospital would qualify as an SCH or a rural referral center if it were located in a rural area. An SCH would be eligible to be paid on the basis of the higher of its hospital-specific rate or the Federal rate. On the other hand, the only benefit under section 1886(d) of the Act for an urban hospital to become a rural referral center would be waiver of the proximity requirements that are otherwise applicable under the MGCRB process, as set forth in § 412.230(a)(3)(i).

When we implemented section 401 of Public Law 106-113 in the August 1, 2000 final rule (65 FR 47089), we stated that we believed Congress contemplated that hospitals might seek to be reclassified as rural under section 1886(d)(8)(E) of the Act in order to become rural referral centers so that the hospitals would be exempt from the MGCRB proximity requirement and could be reclassified by the MGCRB to another urban area. Therefore, in that final rule we sought a policy approach that would appropriately address our concern that these urban to rural redesignations not be utilized inappropriately, and that would benefit hospitals seeking to reclassify under the MGCRB process by achieving rural referral center status. (We became aware of several specific hospitals that were rural referral centers for FY 1991, but subsequently lost their status when the county in which they were located became urban, and had expressed their wish to be redesignated as a rural referral center in order to be eligible to

reclassify.) Accordingly, in light of section 1886(d)(8)(E) of the Act and the language in the accompanying Conference Report, effective as of October 1, 2000, hospitals located in what is now an urban area, if they were ever a rural referral center, were reinstated to rural referral center status.

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

- 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
- 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 HCFA 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 case-mix index value includes all urban hospitals nationwide, and the proposed regional values are the median values of urban hospitals within each census region, excluding those

with approved teaching programs (that is, those hospitals receiving indirect medical education payments as provided in § 412.105). These values are based on discharges occurring during FY 1999 (October 1, 1998 through September 30, 1999) and include bills posted to HCFA's records through December 1999.

We are proposing that, in addition to meeting other criteria, hospitals with fewer than 275 beds, if they are to qualify for initial rural referral center status for cost reporting periods beginning on or after October 1, 2001, must have a case-mix index value for FY 2000 that is at least—

- 1.3286; or

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

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

Region	Case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.2377
2. Middle Atlantic (PA, NJ, NY)	1.2305
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.3055
4. East North Central (IL, IN, MI, OH, WI)	1.2613
5. East South Central (AL, KY, MS, TN)	1.2537
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.1653
7. West South Central (AR, LA, OK, TX)	1.2484
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.3286
9. Pacific (AK, CA, HI, OR, WA)	1.2693

The preceding numbers will be revised in the final rule to the extent required to reflect the updated FY 2000 MedPAR file, which will contain data from additional bills received through March 31, 2001.

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 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 HCFA 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 1999 (that is, October 1, 1998 through

September 30, 1999). That is the latest year for which we have complete discharge data available.

Therefore, we are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial rural referral center status for cost reporting periods beginning on or after October 1, 2001, must have as the number of discharges for its cost reporting period that began during FY 1999 a figure that is at least—

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

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	7083
2. Middle Atlantic (PA, NJ, NY)	8371
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	8202
4. East North Central (IL, IN, MI, OH, WI)	7430
5. East South Central (AL, KY, MS, TN)	6505
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	4708
7. West South Central (AR, LA, OK, TX)	4911
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8287
9. Pacific (AK, CA, HI, OR, WA)	7001

These numbers will be revised in the final rule based on the latest FY 1999 cost report data.

We reiterate that an osteopathic hospital, if it is to qualify for rural referral center status for cost reporting periods beginning on or after October 1, 2001, must have at least 3,000 discharges for its cost reporting period that began during FY 2000.

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

1. IME Adjustment Factor Formula Multiplier (Section 302 of Public Law 106-554 and § 412.105(d)(3))

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 to reflect the higher indirect operating costs associated with GME. The 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 in part on the applicable 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 302 of Public Law 106-554 amended section 1886(d)(5)(B) of the Act to modify the transition for the IME formula multiplier, or c, that was first established by Public Law 105-33 and revised by Public Law 106-113.

Section 302(a) of Public Law 106-554 provides that, for discharges occurring during FY 2002, the formula multiplier is 1.6. For discharges occurring during FY 2003 and thereafter, the formula multiplier is 1.35. (Section 302(b) of Public Law 106-554 provides for a special payment rule which states that, for discharges occurring on or after April 1, 2001 and before October 1, 2001, IME payments are to be made if "c" equalled 1.66 rather than 1.54. We are issuing a separate interim final rule with comment period (HCFA-1178-IFC) to include this change for payments in FY 2001.) The multiplier of 1.6 for FY 2002 represents a 6.5-percent increase for every 10-percent increase in the resident-to-bed ratio. The multiplier for FY 2003 and thereafter (1.35) represents a 5.5-percent increase for every 10-percent increase in the resident-to-bed ratio.

We are proposing to revise § 412.105(d)(3)(vi) to reflect the change in the formula multiplier for FY 2002 to 1.6 as made by section 302(a) of Public Law 106-554 for discharges occurring during FY 2002. We also are proposing to add § 412.105(d)(3)(vii) to incorporate the formula multiplier of 1.35 for discharges occurring on or after October 1, 2002.

2. Resident-to-Bed Ratio Cap (§ 412.105(a)(1))

It has come to our attention that there is some misunderstanding about § 412.105(a)(1) regarding the determination of the resident-to-bed ratio that is used in calculating the IME adjustment. Section 4621(b)(1) of Public Law 105-33 amended section 1886(d)(5)(B) of the Act by adding a new clause (vi) to provide that, effective for cost reporting periods beginning on or after October 1, 1997, the resident-to-bed ratio may not exceed the ratio calculated during the prior cost reporting period (after accounting for the cap on the hospital's number of full-time equivalent (FTE) residents). We implemented this policy in the August 29, 1997 final rule (62 FR 46003) and the May 12, 1998 final rule (63 FR 26323) under regulations at § 412.105(a)(1). Existing § 412.105(a)(1) specifies that "[e]xcept for the special circumstances for affiliated groups and new programs described in paragraphs (f)(1)(vi) and (f)(1)(vii) of this section,

for a hospital's cost reporting periods beginning on or after October 1, 1997, this ratio may not exceed the ratio for the hospital's most recent prior cost reporting period." We are proposing to clarify § 412.105(a)(1) to add a provision that 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 FTE residents*.

In general, the resident-to-bed ratio from the prior cost reporting period, which is to be used as the cap on the resident-to-bed ratio for the current payment cost reporting period, should only include an FTE count that is subject to the FTE cap on the number of allopathic and osteopathic residents, but is *not* subject to the rolling average. (An explanation of rolling average appears in section IV.G.3. of this preamble.)

The following illustrates the steps for determining the resident-to-bed ratio for the current payment year cost reporting period and the cap on the resident-to-bed ratio:

Current payment year cost reporting period resident-to-bed ratio:

Step 1. Determine the hospital's number of FTE residents in the current payment year cost reporting period.

Step 2. Compare the number of FTEs from step 1 to the hospital's FTE cap (§ 412.105(f)(1)(iv)). If the number of FTEs from step 1 exceeds the FTE cap, replace it with the number of FTEs in the FTE cap.

Step 3. Determine the 3-year rolling average of the FTE residents using the FTEs from the current payment year cost reporting period and the prior two cost reporting periods (subject to the FTE cap in each cost reporting period). (Include podiatry and dental residents, and exclude residents in new programs in accordance with § 412.105(f)(1)(iv) and proposed revised (f)(1)(v). Residents in new programs are added to the quotient of the rolling average.)

Step 4. Determine the hospital's number of beds (see § 412.105(b)) in the current payment year cost reporting period.

Step 5. Determine the ratio of the number of FTEs from step 3 to the number of beds from step 4. The lower of this resident-to-bed ratio or the resident-to-bed ratio cap (calculated below) from the immediately preceding cost reporting period is used to calculate the hospital's IME adjustment factor for the current payment year cost reporting period.

Resident-to-bed ratio cap:

Step 1. Determine the hospital's number of FTE residents in its cost reporting period that immediately

precedes the current payment year cost reporting period.

Step 2. Compare the number of FTEs from step 1 to the hospital's FTE cap. If the number of FTEs from step 1 exceeds the FTE cap, replace it with the number of FTEs in the FTE cap. (If there is an increase in the number of FTEs in the current payment year cost reporting period due to a new program or an affiliation agreement, these FTEs are added to FTEs in the preceding cost reporting period after comparison to the FTE cap.)

Step 3. Determine the hospital's number of beds (§ 412.105(b)) in its cost reporting period that immediately precedes the current payment year cost reporting period.

Step 4. Determine the ratio of the number of FTEs in step 2 to the number of beds in step 3. This ratio is the resident-to-bed ratio cap for the current payment year cost reporting period.

Step 5. Compare the resident-to-bed ratio cap in step 4 to the resident-to-bed ratio in the current payment year cost reporting period. The lower of the resident-to-bed ratio from the current payment year cost reporting period or the resident-to-bed ratio cap from the immediately preceding cost reporting period is used to calculate the hospital's IME adjustment factor for the current payment year cost reporting period.

We note that the resident-to-bed ratio cap is a cap on the resident-to-bed ratio calculated for all residents, including allopathic, osteopathic, dental, and podiatry residents (63 FR 26324, May 12, 1998). However, as described in existing § 412.105(a)(1), the resident-to-bed ratio cap may be adjusted to reflect an increase in the current cost reporting period's resident-to-bed ratio due to residents in a new GME program or an affiliation agreement. While this exception does not apply if the resident-to-bed ratio increases because of an increase in the number of podiatry or dentistry residents or because of a change in the number of beds, the ratio could increase after a one-year delay. An increase in the current cost reporting period's ratio (while subject to the cap on the overall number of allopathic and osteopathic residents) thereby establishes a higher cap for the following cost reporting period.

The following is an example of the application of the cap on the resident-to-bed ratio:

Example—Part 1:

- Assume Hospital A has 50 FTEs in its cost reporting period ending September 30, 1996, thereby establishing an IME FTE resident cap of 50 FTEs.

- In its cost reporting period of October 1, 1996 to September 30, 1997 (the prior year), it has 50 FTEs and 200 beds, so that its resident-to-bed ratio for this period is $50/200 = .25$.

- In the (current year) cost reporting period of October 1, 1997 to September 30, 1998 (the first cost reporting period in which the FTE resident cap, the resident-to-bed ratio cap, and the rolling average apply), Hospital A has 50 FTEs and 200 beds.

- Hospital A's FTEs do not exceed its FTE cap, so its current number of FTEs (50) is used to calculate the 2-year rolling average: $(50 + 50)/2 = 50$.

- The result of the rolling average is used as the numerator of the resident-to-bed ratio. Thus, the resident-to-bed ratio is $50/200 = .25$.

- .25 is compared to the resident-to-bed ratio from the prior period of October 1, 1996 to September 30, 1997. Because the FTE resident cap and the rolling average were not yet effective in the period of October 1, 1996 to September 30, 1997, that period's resident-to-bed ratio does not have to be recalculated to account for the FTE resident cap. Accordingly, the resident-to-bed ratio cap for October 1, 1997 to September 30, 1998 is .25.

- Because the resident-to-bed ratio does not exceed the prior year ratio, Hospital A would use the resident-to-bed ratio of .25 to determine the IME adjustment in its cost reporting period of October 1, 1997 to September 30, 1998.

Example—Part 2:

- In the (current year) cost reporting period of October 1, 1998 to September 30, 1999, Hospital A adds 1 podiatric and 1 dental resident, so that it has a total of 52 FTEs and 200 beds. Since the FTE resident cap only includes allopathic and osteopathic residents, Hospital A has not exceeded its FTE resident cap with the addition of a podiatric and a dental resident.

- Accordingly, the (now) 3-year rolling average would be $(52 + 50 + 50)/3 = 50.67$.

- 50.67 is used in the numerator of the current payment year's resident-to-bed ratio, so that the resident-to-bed ratio is $50.67/200 = .253$.

- .253 is compared to the resident-to-bed ratio from the prior year's cost reporting period of October 1, 1997 to September 30, 1998 that is recalculated to account for the FTE resident cap. Because Hospital A did not exceed its FTE resident cap of 50 FTEs in this period of October 1, 1997 to September 30, 1998, the recalculated resident-to-bed ratio would be $50/200 = .25$.

- Compare the current year resident-to-bed ratio (.253) to the resident-to-bed ratio cap (.25); .253 *does exceed* .25.

- Therefore, the resident-to-bed ratio in the period of October 1, 1998 to September 30, 1999 is capped at .25, which is to be used in calculating Hospital A's IME adjustment for October 1, 1998 to September 30, 1999.

Example—Part 3:

- In the cost reporting period of October 1, 1999 to September 30, 2000, Hospital A adds 2 internal medicine residents so that it has a total of 54 FTEs and 200 beds. While podiatric and dental residents are not included in the FTE resident cap, internal medicine residents are included. Hospital A has exceeded its IME FTE resident cap of 50 by 2 FTEs. Thus, 2 FTEs are excluded from the FTE count.

- Accordingly, the rolling average would be $(52 + 52 + 50)/3 = 51.33$.

- 51.33 is used in the numerator of the resident-to-bed ratio, so that the resident-to-bed ratio is $51.33/200 = .257$.

- .257 is compared to the resident-to-bed ratio from October 1, 1998 to September 30, 1999 that is recalculated to only account for the FTE resident cap. The recalculated resident-to-bed ratio would be 50 allopathic or osteopathic FTEs plus 1 podiatric and 1 dental resident, which is $52/200 = .26$.

- .26 is the resident-to-bed ratio cap for October 1, 1999 to September 30, 2000. .257 *does not exceed* .26.

- Therefore, the resident-to-bed ratio in the period of October 1, 1998 to September 30, 1999 is .257, which is to be used in calculating this period's IME adjustment.

If a hospital starts a new GME program, the adjustment to the resident-to-bed ratio cap applies for the period of years equal to the minimum accredited length for that type of program. (For example, for a new internal medicine program, the period of years equals 3; for a new surgery program, the period of years equals 5.) Within these program years, the number of new FTE residents in the current cost reporting period is added to the FTE resident count used in the numerator of the resident-to-bed ratio from the previous cost reporting period. The lower of the resident-to-bed ratio from the current cost reporting period or the adjusted resident-to-bed ratio from the preceding cost reporting period is used to calculate the hospital's IME adjustment for the current cost reporting period. If a hospital continues to expand its program after the period of years, the numerator of the resident-to-bed ratio from the preceding cost reporting period would not be adjusted to reflect these additional residents. However, an increase in the ratio of the

current cost reporting period would establish a higher cap for the following cost reporting period. We also are proposing to add a provision that the exception for new programs described in § 412.105(f)(1)(vii) applies for the period of years equal to the minimum accredited length for that type of program.

Similarly, if a hospital increases the number of FTE residents in the current cost reporting period because of an affiliation agreement, the number of additional FTEs is added to the FTE resident count used in the numerator of the resident-to-bed ratio from the previous cost reporting period. The lower of the resident-to-bed ratio from the current cost reporting period or the adjusted resident-to-bed ratio from the preceding cost reporting period is used to calculate the hospital's IME adjustment for the current cost reporting period.

3. Conforming Changes

(§ 412.105(f)(1)(ii)(C) and (f)(1)(v))

In the August 29, 1997 final rule with comment period (62 FR 46003), the May 12, 1998 final rule (63 FR 26323), and the July 31, 1998 final rule (63 FR 40986), to implement the provisions of Public Law 105-33, we set forth certain policies that affected payment for both direct and indirect GME. Some of these policies related to the FTE cap on allopathic and osteopathic residents, the rolling average, and payment for residents training in nonhospital settings. When we amended the regulations under § 413.86 for direct GME, we inadvertently did not make certain conforming changes in § 412.105 for IME. We are proposing to make the following conforming changes:

- To revise § 412.105(f)(1)(ii)(C) to specify that, effective for discharges occurring on or after October 1, 1997, the time residents spend training in a nonhospital setting in patient care activities under an approved medical residency training program may be counted towards the determination of full-time equivalency if the criteria set forth at § 413.86(f)(3) or § 413.86(f)(4), as applicable, are met.

- To revise § 412.105(f)(1)(v) to specify that residents in new residency programs are not included in the rolling average for a period of years equal to the minimum accredited length for the type of program.

In addition, we are proposing to revise § 412.105(f)(1)(ix) to specify, for IME purposes, a temporary adjustment to a hospital's FTE cap to reflect residents added because of another hospital's closure of its medical residency program (to conform to the

proposed change for GME discussed in section IV.G.5. of this preamble).

D. Payments to Disproportionate Share Hospitals (§ 412.106)

Effective for discharges beginning on or after May 1, 1986, hospitals that serve a significantly disproportionate number of low-income patients (as defined in section 1886(d)(5)(F) of the Act) receive additional payments through the DSH adjustment.

Section 1886(d)(5)(F)(ix) of the Act, as amended by section 112 of Public Law 106-113, specifies a percentage reduction in the payments a hospital would otherwise receive under the disproportionate share formula. Prior to enactment of section 303 of Public Law 106-554, the reduction percentages were as follows: 3 percent for FY 2001, 4 percent for FY 2002, and 0 percent for FY 2003 and each subsequent fiscal year.

Section 303 of Public Law 106-554 revised the amount of the percent reductions to 2 percent for discharges occurring in FY 2001, and to 3 percent for discharges occurring in FY 2002. The reduction continues to be 0 percent for FY 2003 and each subsequent fiscal year. Section 303 of Public Law 106-554 contains a special rule for FY 2001: For discharges occurring on or after October 1, 2000 and before April 1, 2001, the reduction is to be 3 percent, and for discharges occurring on or after April 1, 2001 and before October 1, 2001, the reduction is to be 1 percent. Changes made by section 303 with respect to FY 2001 discharges are being implemented in a separate interim final rule with comment period (HCFA-1178-IFC).

We are proposing to revise § 412.106(e) to reflect the change in the percentage for FY 2002 made by section 303 of Public Law 106-554. We also are proposing to make a technical change in the heading of paragraph (e).

E. Medicare Geographic Classification Review Board (Proposed New § 412.235 and Existing §§ 412.256, 412.273, 412.274(b), and 412.276)

With the creation of the Medicare Geographic Classification Review Board (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 RRCs.

Section 304 of Public Law 106-554 contained several provisions related to the wage index and reclassification decisions made by the MGCRB. In summary, section 304 first establishes that hospital reclassification decisions by the MGCRB for wage index purposes are effective for 3 years, beginning with reclassifications for FY 2001. Second, it provides that the MGCRB must use the 3 most recent years of average hourly wage data in evaluating a hospital's reclassification application for FY 2003 and subsequent years. Third, it provides that an appropriate statewide entity may apply to have all of the geographic areas in a State treated as a single geographic area for purposes of computing and applying the wage index, for reclassifications beginning in FY 2003. A discussion of how we are proposing to implement these three provisions follows. (Section III.F. of this preamble discusses the application of these proposed policy changes to the development of the proposed FY 2002 and later wage indexes based on hospital reclassification under the provisions of section 304 of Public Law 106-554.)

1. Three-Year Reclassifications for Wage Index Purposes

Section 304(a) of Public Law 106-554 amended section 1886(d)(10)(D) of the Act by adding clause (v), which provides that, if a hospital is approved for reclassification by the MGCRB for purposes of the wage index, the reclassification is effective for 3 years. The amendment made by section 304(a) is effective for reclassifications for FY 2001 and subsequent years. In addition, the legislation specifies that the Secretary must establish a mechanism under which a hospital may elect to terminate such reclassification during the 3-year period.

Consistent with new section 1886(d)(10)(D)(v) of the Act, we are proposing to revise § 412.274(b) to provide under new paragraph (b)(2) that any hospital that is reclassified for a particular fiscal year for purposes of receiving the wage index value of another area would receive that reclassification for 3 years beginning with discharges occurring on the first day (October 1) of the second Federal fiscal year in which a hospital files a complete application. This 3-year reclassification would remain in effect unless the hospital terminates the

reclassification under proposed revised procedures that we are establishing under new proposed § 412.273(b). The proposed provision would apply to hospitals that are reclassified for purposes of the wage index only, as well as those that are reclassified for both the wage index and the standardized amount. However, in the latter case, only the wage index reclassification would be extended for 2 additional years beyond the 1 year provided for in the existing regulations (3 years total). Hospitals seeking reclassification for purposes of the standardized amount must continue to reapply to the MGCRB on an annual basis.

a. Special Rule for a Hospital That Was Reclassified for FY 2001 and FY 2002 to Different Areas

Because the 3-year effect of the amendment made by section 304(a) of Public Law 106-554 is applicable to reclassifications for FY 2001 (which had already taken place prior to the date of enactment of section 304(a) (December 21, 2000)), and because the application process for reclassifications for FY 2002 had already been completed by the date of enactment, we are establishing special procedures for hospitals that are reclassified for purposes of the wage index to one area for FY 2001, and are reclassified for purposes of the wage index or the standardized amount to another area for FY 2002. We are deeming such a hospital to be reclassified to the area for which it applied for FY 2002, unless the hospital elects to receive the wage index reclassification it was granted for FY 2001. Consistent with our procedures for withdrawing an application for reclassification (§ 412.273), we are allowing a hospital that wishes to receive the reclassification it was granted for FY 2001 to withdraw its FY 2002 application by making a written request to the MGCRB within 45 days of the publication date of this proposed rule (that is, by June 18, 2001). Again, only the wage index reclassification is extended for 2 additional years (3 years total). Hospitals seeking reclassification for purposes of the standardized amount must continue to reapply to the MGCRB on an annual basis.

(We note that the new location and mailing address of the MGCRB and the Provider Reimbursement Review Board (PRRB) is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244-2670. The MGCRB and PRRB will be functioning at this new location as of May 21, 2001. Also, please specify whether the mail is intended for the MGCRB or the PRRB.)

b. Overlapping Reclassifications Are Not Permitted

Under the broad authority delegated to the Secretary by section 1886(d)(10) of the Act, we are proposing that a hospital that is reclassified to an area for purposes of the wage index may not extend the 3-year effect of the reclassification under section 304(a) of Public Law 106-554 by subsequently applying for reclassification to the same area for purposes of the wage index for a fiscal year that would be within the 3-year period. For example, if a hospital is reclassified for purposes of the wage index to Area A for FY 2002, is approved to receive Area A's wage index for 3 years (FYs 2002, 2003, and 2004), and reapplies to be reclassified to Area A for FYs 2003, 2004, and 2005 (3 years) for purposes of the wage index, the hospital would not be permitted to receive Area A's wage index for FY 2005 as a result of the reapplication. Instead, we are proposing that if the hospital wishes to extend the FY 2002 3-year reclassification for fiscal years beyond FY 2004, it would have to apply for reclassification for FY 2005.

We believe new section 1886(d)(10)(D)(v) of the Act replaces the current annual reclassification cycle with a 3-year reclassification cycle. We believe this policy was intended to provide consistency and predictability in hospital reclassification and wage index data, as well as to alleviate the year-to-year fluctuations in the ability of some hospitals to qualify for reclassification. We do not believe it was intended to be used to extend reclassifications for which hospitals otherwise would not be eligible (by reapplying during the second year of a 3-year reclassification because a hospital fears it may not be eligible for reclassification after its current 3-year reclassification expires).

c. Withdrawals of Applications and Terminations of Approved Reclassifications

(1) General

Under § 412.273(a), a hospital, or group of hospitals, may withdraw its application for reclassification at any time before the MGCRB issues its decision or, if after the MGCRB issues its decision, within 45 days of publication of our annual notice of proposed rulemaking concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application was filed. We are proposing that the withdrawal procedures and the applicable timeframes in the existing regulations

would apply to hospitals that would receive 3-year reclassification for wage index purposes. For example, if a hospital applied for reclassification to Area A for purposes of the wage index for FY 2002, but wished or wishes to withdraw its application, it must have done so prior to the MGCRB issuing a decision on its application or, if the MGCRB issued such a decision, within 45 days of the publication date of this proposed rule. Such a withdrawal, if effective, means that the hospital would not be reclassified to Area A for purposes of the wage index for FY 2002 (and would not receive continued reclassification for FYs 2003 and 2004). In other words, a withdrawal, if accepted, prevents a reclassification from ever becoming effective.

On the other hand, a reclassification decision that is terminated upon the request of the hospital has partial effect. Section 1886(d)(10)(D)(v) of the Act, as added by section 304(a) of Public Law 106-554, provides that a reclassification for purposes of the wage index is effective for 3 years "except that the Secretary shall establish procedures under which a * * * hospital may elect to terminate such reclassification before the end of such period." Consistent with section 1886(d)(10)(D)(v) of the Act, we are proposing to allow a hospital to terminate its approved 3-year reclassification for 1 or 2 years of the 3-year effective period (proposed § 412.273(b)). For example, a hospital that has been reclassified for purposes of the wage index for FY 2001 is also reclassified for FYs 2002 and 2003 (3 years). Such a hospital could terminate its approved reclassification so that the reclassification is effective only for FY 2001, or only for FYs 2001 and 2002. Consistent with the prospective nature of reclassifications, we would not permit a hospital to terminate its approved 3-year reclassification for part of a fiscal year. A termination would be effective for the next fiscal year. In order to terminate an approved 3-year reclassification, we would require the hospital to notify the MGCRB in writing within 45 days of the publication date of the annual proposed rule for changes to the inpatient hospital prospective payment system. A termination request, once accepted, is effective for the balance of the 3-year period (as discussed below under reapplying within original 3-year period, following a termination).

We are establishing a special procedural rule for handling FY 2001 reclassifications. As noted above, the amendments made by section 304(a) of Public Law 106-554 are effective for reclassifications for FYs 2001 and

beyond, and reclassification applications for FY 2001 had already been submitted prior to the date of enactment of section 304(a). We are deeming those hospitals that were reclassified for FY 2001 to be reclassified for FYs 2002 and 2003. Therefore, if a deemed hospital that was reclassified for purposes of the wage index for FY 2001 does not wish to continue its reclassification for FY 2002 and FY 2003, the hospital must notify the MGCRB in writing within 45 days after the publication of this proposed rule (that is, by June 18, 2001).

(2) Reinstatement After a Withdrawal of Application or a Termination of an Approved Reclassification

We are proposing that if a hospital elects to withdraw its 3-year reclassification application after the MGCRB has issued its decision, it may cancel its withdrawal in a subsequent fiscal year and request the MGCRB to reinstate its reclassification for the remaining fiscal years of the 3-year reclassification period. (This proposal is consistent with our proposal that 3-year reclassification periods may not overlap, as discussed in section IV.E.1.b. of this preamble.) Alternatively, a hospital may apply for reclassification to a different area (that is, an area different from the one to which it was originally reclassified), and if successful, the reclassification effect would be for 3 years.

Example 1: Hospital A files an application and the MGCRB issues a decision to reclassify it to Area A for purposes of wage index for FY 2002 through FY 2004 (3 years). Within 45 days after the publication of this proposed rule, Hospital A withdraws its application. Within the time for applying for a FY 2003 reclassification, Hospital A cancels its withdrawal for classification to Area A. Its reclassification to Area A is reinstated, but only for FYs 2003 and 2004.

Example 2: Hospital B files an application for reclassification for wage index purposes for FY 2002 through FY 2004 and the MGCRB issues a decision for reclassification to Area B. Within 45 days after publication of this proposed rule, Hospital B withdraws its application. Hospital B does not cancel its withdrawal of the application. Hospital B timely applies and is reclassified to Area B for 3 years, beginning with FY 2003. In this case, the reclassification to Area B would be for FYs 2003 through 2005.

Similarly, and for the same reasons, we are proposing that if a hospital elects to terminate its accepted 3-year reclassification, it may cancel that termination and have its original reclassification reinstated for the duration of the original 3-year period. Alternatively, a hospital could apply for reclassification to a different area and receive a new 3-year period of reclassification.

Example 3: Hospital C is reclassified to Area A for purposes of the wage index for FY

2002, and terminates its 3-year reclassification effective for FYs 2003 and 2004. Within the timeframe for applying for FY 2004 reclassification, Hospital C cancels its termination. Its reclassification to Area A would be reinstated for FY 2004 only.

Example 4: Hospital D has the same circumstances as Hospital C in Example 3, except that instead of canceling its termination, Hospital D applies and is reclassified to Area B for FY 2004. In this case, the reclassification would be for FYs 2004 through 2006.

d. Special Rules for Group Reclassifications

Section 412.232 discusses situations where all hospitals in a rural county are seeking urban redesignation, and § 412.234 discusses criteria where all hospitals in an urban county are seeking redesignation to another urban county. In these cases, hospitals submit an application as a group, and all hospitals in the county must be a party to the application. The reclassification is effective both for purposes of the wage index and the standardized amount of the area to which the hospitals are reclassified.

Section 304(a) of Public Law 106-554 does not specifically address the group reclassification situations under §§ 412.232 and 412.234. However, we believe that, in the case of hospitals reclassified under these group reclassification procedures, it would be appropriate to extend the 3-year reclassification provision to these situations for the wage index only. In order to be reclassified for the standardized amount during the second and third years of a 3-year reclassification for the wage index, the hospitals located in these counties would have to reapply on an annual basis to the MGCRB either as a group or as individual hospitals and meet the criteria outlined in §§ 412.232(a) and 412.234(a).

Hospitals that are part of a group reclassification would be able to withdraw or terminate their 3-year wage index reclassifications in the same manner as described above. If one hospital within the group elects to withdraw or terminate its reclassification, the reclassification of other hospitals in the group would be unaffected.

Under section 152(b) of Public Law 106-113, hospitals in certain counties were deemed to be located in specified areas for purposes of payment under the hospital inpatient prospective payment system, for discharges occurring on or after October 1, 2000. For payment purposes, these hospitals are to be treated as though they were reclassified for purposes of both the standardized

amount and the wage index. Section 152(b) also requires that these reclassifications be treated for FY 2001 as though they are reclassification decisions by the MGCRB. For purposes of applying the 3-year extension of wage index reclassifications, we are proposing to extend section 1886(d)(10)(D)(v) to hospitals reclassified under section 152(b) of Public Law 106-113. These hospitals also would have to apply for the standardized amount on an annual basis to the MGCRB.

e. Administrator Authority To Cancel Inappropriate Reclassification Decisions

Under the provisions of § 412.278(g), the Administrator has the authority to review an inappropriate reclassification decision made by the MGCRB, as discovered by either the hospital or HCFA, including 3-year reclassifications in the second and third year, and to determine whether or not to cancel that decision as a result of the review of the facts. Hospitals that are concerned that they have been inappropriately reclassified should follow the procedures outlined in § 412.278.

2. Three-Year Average Hourly Wages

Section 304(a) of Public Law 106-554 amended section 1886(d)(10)(D) of the Act by adding clause (vi) which 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. Specifically, the MGCRB must base its evaluation on an average of the average hourly wage for the most recent years for the hospital seeking reclassification and the area to which the hospital seeks to reclassify. This provision is effective for reclassifications for FY 2003 and subsequent years. (Section III.F. of this preamble discusses the development and application of the proposed 3-year average hourly wage data (Table 2 in the Addendum to this proposed rule) that the MGCRB would use to evaluate hospitals' applications for reclassifications for FY 2003; and the 3-year average hourly wage data (Tables 3A and 3B in the Addendum to this proposed rule) for hospital reclassification applications for FY 2001.)

We are proposing to revise §§ 412.230(e)(2) and 412.232(d)(2) to incorporate the provisions of section 1886(d)(10)(D)(vi) of the Act as added by section 304(a) of Public Law 106-554. Specifically, we are providing that, for redesignations effective beginning FY 2003, for hospital-specific data, the hospital must provide a 3-year average

of its average hourly wages using data from the HCFA hospital wage survey used to construct the wage index in effect for prospective payment purposes. For data for other hospitals, we are proposing to require hospitals to provide a 3-year average of the average hourly wage in the area in which the hospital is located and a 3-year average of the average hourly wage in the area to which the hospital seeks reclassification. The wage data would be taken from the HCFA hospital wage survey used to construct the wage index for prospective payment purposes. The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described in section III. of the proposed rule) across all 3 years, by the sum of the hours.

3. Statewide Wage Index

As stated earlier, section 304(b) of Public Law 106-554 provides for a process under which an appropriate statewide entity may apply to have all the geographic areas in the State treated as a single geographic area for purposes of computing and applying the area wage index for reclassifications beginning in FY 2003.

Section 304 does not indicate the duration of the application of these statewide wage indexes. However, it should be noted that the statutory language does refer to these applications as reclassifications. We are proposing that these statewide wage index applications be processed similar to MGCRB applications, with the same effective dates of the decisions and the withdrawal process. Therefore, similar to wage index reclassification decisions under section 1886(d)(10)(D)(v) of the Act as added by section 304(a) of Public Law 106-554, the statewide wage index reclassification would be effective for a total of 3 years. The same deadlines and timetable applicable to MGCRB reclassification applications would apply for statewide wage index applications.

We are proposing to establish a new § 412.235 to include the requirements for statewide wage indexes. We are proposing to apply the following criteria to determine whether hospitals would be approved for a statewide geographic wage index reclassification (proposed § 412.235(a)):

- There must be unanimous support for a statewide wage index among hospitals in the State in which the statewide wage index would be applied. We would require a signed affidavit on behalf of all the hospitals in the State of this support as part of the application for reclassification.

- All hospitals in the State must apply through a signed single application for the statewide wage index in order for the application to be considered by the MGCRB. We believe this is necessary to ensure that every hospital in the State is included in the application, since the payment of every hospital would be affected by the statewide wage index.

- There must be unanimous support for the termination or withdrawal of a statewide wage index among hospitals in the State in which the statewide index would be applied. We would require a signed affidavit for this agreement.

- All hospitals in the State waive their rights to any wage index that they would otherwise receive absent the statewide wage index, including a wage index that any of the hospitals might have received through individual or group geographic reclassification under § 412.273(a).

An individual hospital within the State may receive a wage index that could be higher or lower under the statewide wage index reclassification in comparison to its wage index otherwise (proposed § 412.235(b)). Specifically, hospitals must be aware that there may be a reduction in the wage index as a result of participation on a statewide basis.

We are proposing to consider statewide wage index applications under the same process we use for hospital reclassification applications, including the effective dates of the MGCRB decision and the withdrawal process (proposed § 412.235(c)). We are proposing that applications for the statewide wage index would be effective for 3 years beginning with discharges occurring on the first day (October 1) of the second Federal fiscal year following the Federal fiscal year in which the hospitals file a complete application unless all of the participating hospitals terminate their approved statewide wage index classification earlier, as discussed below. Once approved by the MGCRB, an application for a statewide wage index can only be withdrawn or terminated as a result of a signed affidavit on behalf of all the hospitals in the State indicating their request that the statewide reclassification be withdrawn or terminated. A request for withdrawal or termination must be submitted within 45 days of the publication of the annual proposed rule for the inpatient hospital prospective payment system announcing the reclassification. New hospitals that open prior to the deadline for submitting an application for a statewide wage index, but after a group application has been

submitted, would be required to agree to the statewide wage index in order for the group application to remain viable. New hospitals that open after the deadline for submitting an application would receive the statewide wage index. The agreement of new hospitals would also be required in order to withdraw or terminate a statewide wage index reclassification. The proposed rules discussed under section IV.E.1.c. of this preamble for withdrawals of applications and terminations of approved 3-year wage index reclassification decisions would apply to decisions regarding statewide wage index reclassifications.

We also are proposing to allow hospitals outside a State in which hospitals have received approval of a statewide wage index classification to seek reclassification for the statewide wage index into that State. In that case, an outside hospital(s) that is reclassified into the statewide wage index area would receive a wage index calculated based on the statewide wage index reclassification. However, the support of such an outside hospital(s) would not be needed in the case of withdrawal or termination of a statewide wage index reclassification.

F. New Medical Services and Technology: Additional Payments Under the Inpatient Hospital Prospective Payment System (Proposed New §§ 412.87 and 412.88)

Section 533(b) of Public Law 106-554 amended section 1886(d)(5) of the Act to add new subparagraphs (K) and (L) to address a process of identifying and ensuring adequate payment for new medical services and technologies under Medicare. Under new section 1886(d)(5)(K)(i) of the Act, effective for discharges beginning on or after October 1, 2001, the Secretary is required to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new services and technologies under the inpatient hospital prospective payment system. New section 1886(d)(5)(K)(ii)(I) of the Act specifies that the mechanism 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." New 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).

New sections 1886(d)(5)(K)(ii) through (vi) of the Act further provide—

- For an additional payment for new medical services and technology in an amount beyond the DRG prospective payment system payment rate that adequately reflects the estimated average cost of the service or technology.

- That the requirement for an additional payment for a new service or technology may be satisfied by means of a new-technology group (described in new section 1886(d)(5)(L) of the Act), an add-on payment, a payment adjustment, or any other similar mechanism for increasing the amount otherwise payable with respect to a discharge.

- For the collection of data relating to the cost of new medical service, or technology for not less than 2 years and no more than 3 years after an appropriate inpatient hospital services code is issued. The statute further provides that discharges involving new services or technology that occur after the collection of these data will be classified within a new or existing DRG group with a weighting factor derived from cost data collected for discharges occurring during such period.

A discussion of how we are proposing to implement the provisions of section 533(b) of Public Law 106-554 follows. Section II.D. of this preamble discusses the Report to Congress required by section 533(a) of Public Law 106-553 relating to methods of expeditiously incorporating new medical services and technologies into the clinical coding system used for payments for inpatient hospital services and our preferred method of achieving this purpose.

1. Criteria for Identifying New Medical Services and Technology

New 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). (For convenience, hereafter we refer to "new medical services and technology" as "new technology.") We are proposing that a new technology would be an appropriate candidate for an additional payment when, in the judgment of the Secretary, it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries (proposed § 412.87(b)(1)). This criterion is to ensure that new technology can be demonstrated to provide a substantial clinical improvement based on verifiable evidence. Because any additional payments made under this

provision will be financed by reducing the payments made for all other services (in order to maintain budget neutrality as discussed under section IV.F.4. of this preamble), we believe that these payments should be focused on those technologies that afford clear improvements over use of previously available technologies. As explained below, we are proposing that new technologies meeting this clinical definition also must be demonstrated to be inadequately paid otherwise under the DRG system to receive special payment treatment (proposed § 412.87(b)(3)). Hospitals adopting other new technologies that do not meet these standards would be paid for these technologies through other applicable DRG payments. These payments would be recalibrated over time to reflect actual use of the new technology.

We expect to implement this criterion by considering the clinical benefits for beneficiaries. We are aware that some technologies may offer substantial clinical improvements for small subsets of beneficiaries, such as those who have not responded to other treatments, and we expect to recognize such substantial advantages in these instances.

In addition to the clinical and cost criteria, we are proposing that, in order to qualify for the special payment treatment provided under new section 1886(d)(5)(K)(ii)(I) of the Act, a specific technology must be new (proposed § 412.87(b)(2)). We believe the new provision contemplates 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 (generally 2 years). Specifically, new section 1886(d)(5)(K)(ii)(II) of the Act states that the Secretary must "provide for the collection of data with respect to the costs of a new medical service or technology * * * for a period of not less than two years and not more than three years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology." In addition, new section 1886(d)(5)(K)(ii)(III) states that the Secretary must "provide for additional payment to be made * * * with respect to discharges involving a new medical service or technology described in subclause (I) that occur during the period described in subclause (II) in an amount that adequately reflects the estimated average costs of such service or technology."

We are proposing to make determinations regarding which technologies meet this criterion using a panel of Federal clinical and other experts, supplemented as appropriate

with outside expertise. The results of all such determinations would be announced in the **Federal Register** as part of the annual updates and changes to the inpatient hospital prospective payment system (proposed § 412.87(b)(1)). We note that this determination is separate and distinct from the coverage decision process. In the case of new technologies that have gone through the national coverage determination process, we would expect that the evidence reviewed in that process would, in general, be sufficient for making these determinations as well.

Requests to recognize new technology for special payment treatment under new section 1886(d)(5)(K)(ii)(I) of the Act would be evaluated against this proposed criterion based on evidence submitted by the requestor. These requests should be submitted in conjunction with the initial submission of data on the costs of the new technology. In general, we encourage interested parties to initiate this process by August of the year preceding the year in which a new code identifying the new technology would become effective. This will allow maximum time to review the requestor's data and clinical material. In particular, it affords an opportunity to work with the requestor to resolve any problems or questions that may arise. At a minimum, requests should be submitted by early October of that year. It should be noted that submitting requests as late as October may not afford the opportunity for HCFA to work with the requestor to resolve problems or questions. Requests must be submitted by early October to allow adequate time to consider all aspects of a request prior to making a determination to be included in the proposed rule. Work begins on preparing the DRG changes for the following fiscal year by the middle of December, and any decisions to recognize particular new technologies should be taken into account at that time.

We are soliciting comments on these proposals. In particular, given that this process is the result of new legislation with possibly major implications for the hospital inpatient prospective payment system, we invite public comment on: our definition of new medical services and technologies; the use of Federal clinical and other experts to make determinations regarding which criteria meet our definition of a new service or technology; the information necessary to determine whether payment would be inadequate; and our payment mechanism (see following discussions for these latter two issues).

2. Determining Adequacy of Current Payments for New Services and Technology

Because the inpatient hospital prospective payment system includes costs associated with all aspects of a patient's stay in the hospital, it is not enough to simply identify a technology as "new" and pay an additional amount. A single DRG may encompass many different treatment approaches for a particular illness, with an array of costs associated with those approaches. Clinicians are expected to select the appropriate approach based on the needs of the patient, with the payments averaging out over time to approximate the level of resources needed to treat the average patient in the DRG.

Section 1886(d)(b)(K)(ii) of the Act, as added by section 533(b) of Public Law 106-554, requires that the Secretary make a determination whether the payment otherwise applicable under the existing DRG is inadequate compared to the estimated costs incurred with respect to new technology (as defined previously). We believe that, in order to evaluate whether the DRG payment inadequately reflects the costs of new technology, we must be able to assess the costs of cases involving the new technology against other cases in the DRG. In other words, the criteria for identifying new technology that will receive special payment treatment should reflect whether the new technology is so expensive that hospitals are unlikely to offset the higher costs with other less costly cases within the DRG. We are proposing that this threshold be set at one standard deviation beyond the mean standardized charge for all cases in the DRG 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) (proposed § 412.87(b)(3)). (Standardization adjusts the actual charges of a case by the payment factors such as the wage index, the indirect medical education adjustment factor, and the disproportionate share adjustment factor.)

This comparison would preferably be done using Medicare cases identifiable in our MedPAR database, although data from a clinical trial (including Food and Drug Administration clinical trials) where no bills were submitted for payment may be considered. To the extent possible, HCFA intends to rely on existing information in making these determinations. In most instances, the information would include the Medicare provider number of the hospital where each case was treated,